

Calibration reference materials supplier 【Abbreviation menu】

Abbreviation	Official Name
CDC	Centers for Disease Control and Prevention
ICSH	International Committee for Standardization in Haematology
NIBSC	National Institute for Biological Standards and Control
NIST	National Institute of Standards and Technology (USA)
IRMM	Institute for Reference Materials and Measurements
IFCC	International Federation of Clinical Chemistry
GSCC	German Society for Clinical Chemistry
ATCC	Type Strain deposited at the American Type Culture Collection
ICSH2	International Council for Standardization in Haematology
CLSI	Clinical and Laboratory Standards Institute
USP	The United States Pharmacopia
CERI	Chemicals Examination and Research Institute, Japan
JDS	The Japan Diabetes Society
ReCCS	Reference Material Institute for Clinical Chemistry Standards
NMIJ	National Institute of Advanced Industrial Science and Technology
JP	Chemical Reference Substances in the Japanese Pharmacopoeia
JPC	The Japanese Pharmaceutical Codex
JCCLS	Japanese Committee for Clinical Laboratory Standards

English edition of Japanese Medical Device Nomenclature (JMDN) and the definitions is arranged. These are provided for the convenience of users unfamiliar with the Japanese language. These contents are the latest and information except here will be aligned with these contents shortly. When and if any discrepancy arises between the Japanese original and its English translation, the former shall prevail.

As of May, 2022

Large classification	Middle classification	Test item	Japanese Medical Device Nomenclature (JMDN)	JMDN Code	Classification	Regulation	Definition	Calibration reference materials supplier
General-purpose test reagents	General-purpose test reagents	Leukocyte	Leukocyte kit	44611000	Ⅱ	Certification	A kit for measurement or detection of leucocytes, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		pH	pH kit	31369000	Ⅱ	Certification	A kit for measurement of pH, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Protein	Total protein kit	30181002	Ⅱ	Certification	A kit for measurement or detection of total protein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Glucose	Glucose kit	30167002	Ⅱ	Certification	A kit for measurement or detection of glucose, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		ketone body, ketone body fraction, Acetoacetic acid	Ketone body kit	33256002	Ⅱ	Certification	A kit for measurement or detection of ketone body, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Occult blood	Occult blood kit	33257002	Ⅱ	Certification	A kit for measurement or detection of occult blood, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Bilirubin	Bilirubin kit	30157002	Ⅱ	Certification	A kit for measurement or detection of bilirubin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Urobilinogen	Urobilinogen kit	31355000	Ⅱ	Certification	A kit for measurement or detection of urobilinogen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Nitrite	Nitrite kit	33300000	Ⅱ	Certification	A kit for measurement or detection of nitrite, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Specific gravity	Specific gravity kit	43117000	Ⅱ	Certification	A kit for measurement of specific gravity, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Ascorbic acid	Ascorbic acid kit	33292000	Ⅱ	Certification	A kit for measurement or detection of ascorbic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Sodium chloride	Sodium chloride kit	43078000	Ⅱ	Certification	A kit for measurement or detection of sodium chloride, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Amylase	Amylase kit	38502002	Ⅱ	Certification	A kit for measurement or detection of amylase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Albumin (including microalbumin)	Albumin kit	30155002	Ⅱ	Certification	A kit for measurement or detection of albumin (including microalbumin), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Catalase	Catalase kit	43109000	Ⅱ	Certification	A kit for measurement or detection of catalase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

Ammonia	Ammonia kit	43101002	II	Certification	A kit for measurement or detection of ammonia, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Delta-aminolaevulinic acid	Delta-aminolaevulinic acid kit	43085000	II	Certification	A kit for measurement or detection of delta-aminolaevulinic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Porphobilinogen	Porphobilinogen kit	43393000	II	Certification	A kit for measurement or detection of porphobilinogen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Creatinine (CRE)	Creatinine kit	30161002	II	Certification	A kit for measurement or detection of creatinine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Uropepsin	Uropepsin kit	43103000	II	Certification	A kit for measurement or detection of uropepsin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Human chorionic gonadotropin (HCG), Total human chorionic gonadotropin (HCG)	Human chorionic gonadotropin kit	30332002	II	Certification	A kit for measurement or detection of human chorionic gonadotropin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Luteinizing hormone (LH), Human luteinizing hormone (LH)	Luteinizing hormone kit	38246002	II	Certification	A kit for measurement or detection of luteinizing hormone, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Vanillylmandelic acid (VMA)	Vanillylmandelic acid kit	30453002	II	Certification	A kit for measurement or detection of vanillylmandelic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Human growth hormone (HGH), Growth hormone (GH)	Human growth hormone kit	30358002	II	Certification	A kit for measurement or detection of human growth hormone, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
β 2-microglobulin (β 2-m, BMG, β 2-MG)	Beta2-microglobulin kit	30296002	II	Certification	A kit for measurement or detection of β 2-microglobulin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Alkaline phosphatase (ALP)	Alkaline phosphatase kit	33165002	II	Certification	A kit for measurement or detection of alkaline phosphatase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Calcium (Ca)	Calcium kit	30187002	II	Certification	A kit for measurement or detection of calcium, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Magnesium (Mg)	Magnesium kit	30190002	II	Certification	A kit for measurement or detection of magnesium, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
γ -glutamyl transpeptidase (γ -GTP)	Gamma-glutamyl transpeptidase kit	38507002	II	Certification	A kit for measurement or detection of γ -glutamyl transpeptidase, using specimens of biological origin. It is mainly used to assist in the diagnosis of clinical diseases to provide information for the diagnosis of clinical diseases and for other purposes.	
Inorganic phosphate (IP)	Phosphorous/inorganic phosphate kit	30191002	II	Certification	A kit for measurement or detection of phosphorus or inorganic phosphate, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Testosterone	Testosterone kit	30327012	II	Certification	A kit for measurement or detection of testosterone, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

Cortisol	Cortisol kit	44399000	II	Certification	A kit for measurement or detection of cortisol, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Immunoglobulin G (IgG)	Immunoglobulin G kit	30232002	II	Certification	A kit for measurement or detection of immunoglobulin G, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Immunoglobulin A (IgA)	Immunoglobulin A kit	30228002	II	Certification	A kit for measurement or detection of immunoglobulin A, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Immunoglobulin M (IgM)	Immunoglobulin M kit	30234002	II	Certification	A kit for measurement or detection of immunoglobulin M, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Transferrin	Transferrin kit	30253002	II	Certification	A kit for measurement or detection of transferrin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Uric acid (UA)	Uric acid kit	30183002	II	Certification	A kit for measurement or detection of uric acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Urea nitrogen (UN)	Urea nitrogen kit	42849002	II	Certification	A kit for measurement or detection of urea nitrogen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
C-peptide (CPR)	C-peptide kit	30336002	II	Certification	A kit for measurement or detection of C-peptide, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Creatine	Creatine kit	43378002	II	Certification	A kit for measurement or detection of creatine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Amylase isoenzyme	Amylase isoenzyme kit	38541012	II	Certification	A kit for measurement or detection of amylase isoenzyme, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Haemoglobin	Haemoglobin kit	30535002	II	Certification	A kit for measurement or detection of haemoglobin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Tau protein	Tau protein kit	43049000	II	Certification	A kit for measurement or detection of tau protein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Human chorionic gonadotropin β -subunit (β -HCG), Beta-human chorionic gonadotropin (β -HCG)	Beta-human chorionic gonadotropin kit	30333002	II	Certification	A kit for measurement or detection of beta-human chorionic gonadotropin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Follicle stimulating hormone (FSH)	Follicle stimulating hormone kit	30322002	II	Certification	A kit for measurement or detection of follicle stimulating hormone, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Oestriol (E_3)	Oestriol kit	30329002	II	Certification	A kit for measurement or detection of oestriol, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
α_1 -antitrypsin	Alpha1-antitrypsin kit	30268002	II	Certification	A kit for measurement or detection of α_1 -antitrypsin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Haemoglobin/transferrin	Haemoglobin/transferrin kit	81001000	II	Certification	A kit for measurement or detection of haemoglobin or transferrin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

		Amino acid	Amino acid kit	81002002	II	Certification	A kit for measurement or detection of amino acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Urine test strip, multiple-constituent	Multiple-constituent test strip kit	30226000	II	Certification	A test strip kit for measurement or detection of multiple constituents for general-purpose test, using urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Zinc (Zn)	Zinc kit for general-purpose test	30184002	II	Certification	A kit for measurement or detection of zinc, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Chloride (Cl)	Chloride kit for general-purpose test	30188002	II	Certification	A kit for measurement or detection of chloride, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Total iodine	Total iodine kit for general-purpose test	81005000	II	Certification	A kit for measurement or detection of iodine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Immunoglobulin E (IgE), Non-specific immunoglobulin E (IgE)	Immunoglobulin E kit for general-purpose test	81004000	II	Certification	A kit for measurement or detection of immunoglobulin E or non-specific immunoglobulin E, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Myo-inositol	Myo-inositol kit	81003000	II	Certification	A kit for measurement or detection of myo-inositol, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

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Large classification	Middle classification	Test item	Japanese Medical Device Nomenclature (JMDN)	JMDN Code	Classification	Regulation	Definition	Calibration reference materials supplier
hematological test reagents	General blood/morphology test reagents	Haemoglobin (Hb)	Haemoglobin kit for blood test	30535001	I	Self-declaration	A kit for measurement or detection of haemoglobin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ICSH, NIBSC, ICSH2, CLSI
		Platelet (PLT)	Platelet count kit	41755000	II	Certification	A kit for measurement of platelet count, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Hemocyte and differential leukocyte count (Reticulocyte)	Reticulocyte kit	30526000	II	Certification	A kit for measurement of hemocyte and differential leukocyte count (reticulocyte), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Hemocyte and differential leukocyte count (Haematocrit set)	Haematocrit set	32411000	II	Certification	A kit for measurement of hemocyte and differential leukocyte count (haematocrit set), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Hemocyte and differential leukocyte count (Leukocyte count)	Leukocyte count kit	43091000	II	Certification	A kit for measurement of hemocyte and differential leukocyte count (leukocyte count), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Hemocyte and differential leukocyte count (Erythrocyte count)	Erythrocyte count kit	43095000	II	Certification	A kit for measurement of hemocyte and differential leukocyte count (erythrocyte count), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Hemocyte and differential leukocyte count (Mean corpuscular volume)	Mean corpuscular volume kit	43321000	II	Certification	A kit for measurement of hemocyte and differential leukocyte count (mean corpuscular volume), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Hemocyte and differential leukocyte count (Mean corpuscular haemoglobin)	Mean corpuscular haemoglobin kit	43097000	II	Certification	A kit for measurement of hemocyte and differential leukocyte count (mean corpuscular haemoglobin), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Hemocyte and differential leukocyte count (Mean corpuscular haemoglobin concentration)	Mean corpuscular haemoglobin concentration kit	42817000	II	Certification	A kit for measurement of hemocyte and differential leukocyte count (mean corpuscular haemoglobin concentration), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Hemocyte and differential leukocyte count (Eosinophil count)	Eosinophil count kit	43080000	II	Certification	A kit for measurement of hemocyte and differential leukocyte count (eosinophil count), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

Reagents for coagulation/fibrinolysis related substance	Hemocyte and differential leukocyte count (Basophilic erythrocyte) (Basophilic stippling in the erythrocyte)	Basophil count kit	43065000	II	Certification	A kit for measurement of hemocyte and differential leukocyte count (basophilic erythrocyte; basophilic stippling in the erythrocyte), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Hemocyte and differential leukocyte count (Erythrocyte diameter)	Erythrocyte diameter kit	44257000	II	Certification	A kit for measurement of hemocyte and differential leukocyte count (erythrocyte diameter), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Hemocyte and differential leukocyte count (Hemogram/differential leukocyte count)	Differential leukocyte count kit	44309000	II	Certification	A kit for measurement of hemocyte and differential leukocyte count (differential leukocyte count), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Activated partial thromboplastin time (APTT)	Activated partial thromboplastin time kit	38553000	II	Certification	A kit for measurement or detection of activated partial thromboplastin time, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Prothrombin time (PT)	Prothrombin time kit	30539000	III	Approval	A kit for measurement of prothrombin time, using specimens of biological origin. It is mainly used to provide information for the diagnosis of various diseases caused by extrinsic coagulation disorder. In some cases, it is also used for monitoring oral anticoagulant therapy. It also includes a kit for measurement of prothrombin time by patients themselves.	
	Complex coagulation factor (II, VII, X) activity	Coagulation factor II, VII, X kit	30550000	II	Certification	A kit for measurement of complex coagulation factor (II, VII, X) activity, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Total activity of all intrinsic coagulation factors (II, V, VIII, X, XI, XII) and fibrinogen, and detection of coagulation factors (II, VII, X) and PIVKA	Intrinsic coagulation factor kit	42889000	II	Certification	A kit for measurement or detection of total activity of all intrinsic coagulation factors (II, V, VIII, X, XI, XII) and fibrinogen, coagulation factors (II, VII, IX, X) and PIVKA, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Thrombin time	Thrombin time kit	30540000	II	Certification	A kit for measurement or detection of thrombin time, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Fibrinogen	Fibrinogen kit	30541000	I	Self-declaration	A kit for measurement or detection of fibrinogen, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
	Soluble fibrin monomer complex	Soluble fibrin monomer complex kit	43421000	II	Certification	A kit for measurement or detection of soluble fibrin monomer complex, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	FDP (Fibrin/fibrinogen degradation product)	Fibrin/fibrinogen degradation product kit	30575000	II	Certification	A kit for measurement or detection of FDP (fibrin/fibrinogen degradation product), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

FDP/fraction E (Fibrin/fibrinogen degradation product/fraction E)	Fibrin/fibrinogen degradation product/fraction E kit	43361000	II	Certification	A kit for measurement or detection of fibrin/fibrinogen degradation product/fraction E, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
D-dimer (FDP/D-dimer, FDP/D-D dimer, fibrin degradation product, stabilized fibrin degradation products, fraction D)	Fibrin degradation product kit	30576000	II	Certification	A kit for measurement or detection of fibrin degradation product (D-dimer), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Fibrinopeptide A (FPA)	Fibrinopeptide A kit	30563000	II	Certification	A kit for measurement or detection of fibrinopeptide A (FPA), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Prothrombin fragment 1+2	Prothrombin fragment 1+2 kit	30567000	II	Certification	A kit for measurement or detection of prothrombin fragment 1+2, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Antithrombin III (AT III) (Antithrombin III activity)	Antithrombin III kit	30583000	II	Certification	A kit for measurement or detection of antithrombin III, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Thrombin-antithrombin III-complex (TAT)	Thrombin-antithrombin III-complex kit	30568000	II	Certification	A kit for measurement or detection of thrombin-antithrombin III-complex, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Plasminogen (Plasminogen, plasminogen activity)	Plasminogen kit	30578000	II	Certification	A kit for measurement or detection of plasminogen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-plasmin (α 2-plasmin inhibitor, α 2PI activity)	Alpha2-anti-plasmin kit	30574000	II	Certification	A kit for measurement or detection of α 2-anti-plasmin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
α 2-plasmin inhibitor/plasmin complex (PIC, PPI, PAP)	Plasmin-alpha2-anti-plasmin complex kit	30566000	II	Certification	A kit for measurement or detection of plasmin- α 2-anti-plasmin complex, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Plasminogen activator inhibitor-1 (PAI-1)	Plasminogen activator inhibitor-1 kit	30579000	II	Certification	A kit for measurement or detection of plasminogen activator inhibitor-1 (PAI-1), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Tissue plasminogen activator/inhibitor-1 complex (t-PA/PAI-1 complex)	Tissue plasminogen activator inhibitor-1 complex kit	43073000	II	Certification	A kit for measurement or detection of tissue plasminogen activator/inhibitor-1 complex (t-PA/PAI-1 complex), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Coagulation factor II (Prothrombin, prothrombin activity)	Coagulation factor II kit	30542000	I	Self-declaration	A kit for measurement or detection of coagulation factor II, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
Coagulation factor V	Coagulation factor V kit	30544000	II	Certification	A kit for measurement or detection of coagulation factor V, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Coagulation factor VII	Coagulation factor VII kit	30545000	I	Self-declaration	A kit for measurement or detection of coagulation factor VII, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
Coagulation factor VIII	Coagulation factor VIII kit	30547000	I	Self-declaration	A kit for measurement or detection of coagulation factor VIII, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC

Coagulation factor IX (Factor IX antigen)	Coagulation factor IX kit	30548000	I	Self-declaration	A kit for measurement or detection of coagulation factor IX, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
Coagulation factor X (Factor X antigen)	Coagulation factor X kit	30549000	I	Self-declaration	A kit for measurement or detection of coagulation factor X, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
Coagulation factor XI	Coagulation factor XI kit	30551000	II	Certification	A kit for measurement or detection of coagulation factor XI, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Coagulation factor XII	Coagulation factor XII kit	30552000	II	Certification	A kit for measurement or detection of coagulation factor XII, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Coagulation factor XIIIa	Coagulation factor XIIIa kit	30555000	II	Certification	A kit for measurement or detection of coagulation factor XIIIa, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Coagulation factor XIII (Fibrin stabilizing factor, FSF)	Coagulation factor XIII kit	30554000	II	Certification	A kit for measurement or detection of coagulation factor XIII, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Factor Xa inhibitor	Factor Xa inhibitor kit	43046000	II	Certification	A kit for measurement or detection of factor Xa inhibitor, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Von Willebrand factor	Von Willebrand factor kit	30558000	I	Self-declaration	A kit for measurement or detection of Von Willebrand factor, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
Factor VIII-associated antigen (F. VIII R:Ag)	Factor VIII-associated antigen kit	43305000	II	Certification	A kit for measurement or detection of factor VIII-associated antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Factor VIII ristocetin cofactor activity	Factor VIII ristocetin cofactor kit	44416000	II	Certification	A kit for measurement or detection of factor VIII ristocetin cofactor activity, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
PIVKA-II (Prothrombin deficiency)	PIVKA-II kit for blood coagulation factor test	44379002	II	Certification	A kit for measurement or detection of PIVKA-II (blood coagulation factor II), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
β -thromboglobulin (β -TG)	Beta-thromboglobulin kit	30573000	I	Self-declaration	A kit for measurement or detection of β -thromboglobulin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
Platelet factor 4 (PF4)	Platelet factor 4 kit	30570000	I	Self-declaration	A kit for measurement or detection of platelet factor 4, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
Protein C (Protein C activity, Protein C antigen)	Protein C kit	30588000	II	Certification	A kit for measurement or detection of protein C, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Protein S (Protein S activity)	Protein S kit	30589000	II	Certification	A kit for measurement or detection of protein S, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Thrombomodulin (TM)	Thrombomodulin kit	44439000	II	Certification	A kit for measurement or detection of thrombomodulin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Activated protein C-resistant factor V	Activated protein C-resistant factor V kit	44418000	II	Certification	A kit for measurement or detection of activated protein C-resistant factor V, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

		Platelet aggregation	Platelet aggregation kit	44419000	II	Certification	A kit for measurement of platelet aggregation, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Antithrombin III (AT III) (Antithrombin III activity)	Antithrombin III kit for blood test	30583001	I	Self-declaration	A kit for measurement or detection of antithrombin III, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
		Protein S (Protein S activity)	Protein S kit for blood test	30589001	I	Self-declaration	A kit for measurement or detection of protein S, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
		Protein C (Protein C activity, Protein C antigen)	Protein C kit for blood test	30588001	I	Self-declaration	A kit for measurement or detection of protein C, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
		ADAMTS13	ADAMTS13 kit	82002000	II		A kit for measurement or detection of ADAMTS13, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Blood chemistry test reagents	TDT (Terminal deoxynucleotidyl transferase)	Terminal deoxynucleotidyl transferase kit	43412000	II	Certification	A kit for measurement or detection of terminal deoxynucleotidyl transferase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Erythropoietin (EPO)	Erythropoietin kit	30376000	II	Certification	A kit for measurement or detection of erythropoietin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Deoxythymidine kinase (Deoxythymidine kinase activity)	Deoxythymidine kinase kit for blood chemistry test	44254002	II	Certification	A kit for measurement or detection of deoxythymidine kinase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Other hematologic al test reagents	ESR (prevention of coagulation during measurement of erythrocyte sedimentation rate)	ESR kit	82001000	II	Certification	A kit for measurement of ESR, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Blood specific gravity	Blood specific gravity kit	44250000	II	Certification	A kit for measurement of blood specific gravity, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Prekallikrein Kallikrein	Prekallikrein/kallikrein kit	30559000	II	Certification	A kit for measurement or detection of prekallikrein or kallikrein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

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As of May, 2022

Large classification	Middle classification	Test item	Japanese Medical Device Nomenclature (JMDN)	JMDN Code	Classification	Regulation	Definition	Calibration reference materials supplier
Biochemical test reagents	Reagents for protein/colloidal reaction measurement	Total protein (TP)	Total protein kit for blood test	30181001	I	Self-declaration	A kit for measurement or detection of total protein, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, ReCCS
		Albumin (Alb)	Albumin kit for blood test	30155001	I	Self-declaration	A kit for measurement or detection of albumin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM, NIST
		A/G (Albumin/globulin) ratio	A/G ratio kit	43394000	I	Self-declaration	A kit for measurement of A/G (albumin/globulin) ratio, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM(Limited to ALB), NIST
		Protein fraction	Protein fraction kit	43264000	II	Certification	A kit for measurement or detection of protein fraction, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Thymol turbidity test (TTT)	Thymol turbidity test kit	43203000	II	Certification	A kit for thymol turbidity test, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Zinc sulfate turbidity test (ZTT)	Zinc sulfate turbidity test kit	43204000	II	Certification	A kit for zinc sulfate turbidity test, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Cephalin-cholesterol (CCLF)	Cephalin-cholesterol kit	43202000	II	Certification	A kit for measurement or detection of cephalin-cholesterol, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Cobalt reaction	Cobalt reaction kit	43347000	II	Certification	A kit for measurement or detection of cobalt reaction, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Phosphorylated tau protein	Phosphorylated tau protein kit	83014000	II	Certification	A kit for measurement of phosphorylated tau protein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		β -amyloid 1-40, β -amyloid 1-42	Beta-amyloid kit	83032000	II		A kit for measurement or detection of beta-amyloid, using specimens of biological origin. It is mainly used to provide information for understanding the state of beta-amyloid accumulation in the brain.	
	Reagents for enzyme and related substance measurement	Creatine kinase (CPK, CK)	Creatine kinase kit	38503000	I	Self-declaration	A kit for measurement or detection of creatine kinase, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, NIST, IRMM
		CK isoenzyme (including CK-MB)	Creatine kinase isoenzyme kit	38512002	II	Certification	A kit for measurement or detection of CK isoenzyme (including CK-MB), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		CK isoform (including CK-MM isoform)	Creatine kinase isoform kit	38512012	II	Certification	A kit for measurement or detection of creatine kinase isoforms (including CK-MM isoforms), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

GOT (AST)	Aspartate aminotransferase kit	38499000	I	Self-declaration	A kit for measurement or detection of aspartate aminotransferase, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, NIST
AST isoenzyme (including m-GOT)	Aspartate aminotransferase isoenzyme kit	42901000	II	Certification	A kit for measurement or detection of aspartate aminotransferase isoenzyme (including m-GOT), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
GPT (ALT)	Alanine aminotransferase kit	38556000	I	Self-declaration	A kit for measurement or detection of alanine aminotransferase, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, NIST, IRMM
Lactate dehydrogenase (LDH, LD)	Lactate dehydrogenase kit	38504000	I	Self-declaration	A kit for measurement or detection of lactate dehydrogenase, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, NIST, IRMM
Lactate dehydrogenase (LD) isoenzyme	Lactate dehydrogenase isoenzyme kit	42907002	II	Certification	A kit for measurement or detection of lactate dehydrogenase isoenzyme, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Lactate dehydrogenase isoenzyme LD1	Lactate dehydrogenase isoenzyme/LD1 kit	42907011	I	Self-declaration	A kit for measurement or detection of lactate dehydrogenase isoenzyme LD1, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
Alkaline phosphatase (ALP)	Alkaline phosphatase kit for blood test	33165001	I	Self-declaration	A kit for measurement or detection of alkaline phosphatase, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, NIST, IRMM
ALP isoenzymes (including bone-specific ALP)	Alkaline phosphatase isoenzyme kit	38511000	II	Certification	A kit for measurement or detection of alkaline phosphatase isoenzyme (including bone-specific ALP), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
γ-glutamyl transpeptidase (γ-GTP)	Gamma-glutamyl transpeptidase kit for blood test	38507001	I	Self-declaration	A kit for measurement or detection of γ-glutamyl transpeptidase, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, IRMM
Aldolase (ALD)	Aldolase kit	38538000	II	Certification	A kit for measurement or detection of aldolase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Monoamine oxidase (MAO)	Monoamine oxidase kit	42870000	II	Certification	A kit for measurement or detection of monoamine oxidase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Cholinesterase (ChE)	Cholinesterase kit	38506000	II	Certification	A kit for measurement or detection of cholinesterase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Cholinesterase (ChE)	Cholinesterase kit for blood test	38506001	I	Self-declaration	A kit for measurement or detection of cholinesterase, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, JCCLS, GSCC
Guanase (GUA)	Guanase kit	44171000	II	Certification	A kit for measurement or detection of guanase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Adenosine deaminase	Adenosine deaminase kit	43201000	II	Certification	A kit for measurement or detection of adenosine deaminase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Leucine aminopeptidase (LAP)	Leucine aminopeptidase kit	38546000	II	Certification	A kit for measurement or detection of leucine aminopeptidase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Cystine aminopeptidase (CAP)	Cystine aminopeptidase kit	43475000	II	Certification	A kit for measurement or detection of cystine aminopeptidase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

Amylase (AMY)	Amylase kit for blood test	38502001	I	Self-declaration	A kit for measurement or detection of amylase, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS
Amylase (AMY) isoenzyme (including P-AMY)	Amylase isoenzyme kit for blood test	38541001	I	Self-declaration	A kit for measurement or detection of amylase isoenzyme (including P-AMY), using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS
γ-glutamyl transpeptidase isoenzyme	Gamma-glutamyl transpeptidase isoenzyme kit	83001000	II	Certification	A kit for measurement or detection of γ-glutamyl transpeptidase isoenzyme, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Lipase	Lipase kit	38505000	I	Self-declaration	A kit for measurement or detection of lipase, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS
Trypsin	Trypsin kit	30272000	II	Certification	A kit for measurement or detection of trypsin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Trypsin-like enzyme	Periodontopathic peptidase kit	43349000	II	Certification	A kit for measurement or detection of periodontopathic peptidase (trypsin-like enzyme), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Chymotrypsin	Chymotrypsin kit	38543000	II	Certification	A kit for measurement or detection of chymotrypsin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Trypsin inhibitor (PSTI)	Trypsin inhibitor kit	43350000	II	Certification	A kit for measurement or detection of trypsin inhibitor, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Phospholipase A2 (PLA2)	Phospholipase A2 kit	43200000	II	Certification	A kit for measurement or detection of phospholipase A2, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
5'-nucleotidase	5'-nucleotidase kit	38540000	II	Certification	A kit for measurement or detection of 5'-nucleotidase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Acid phosphatase (ACP)	Acid phosphatase kit	38498000	II	Certification	A kit for measurement or detection of acid phosphatase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Acid phosphatase (ACP) isoenzyme (including prostatic or tartrate-resistant ACP)	Acid phosphatase isoenzyme kit	42864000	II	Certification	A kit for measurement or detection of acid phosphatase isoenzyme (including prostatic or tartrate-resistant ACP), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Glutamate dehydrogenase (GLDH)	Glutamate dehydrogenase kit	38544000	II	Certification	A kit for measurement or detection of glutamate dehydrogenase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Isocitric dehydrogenase (ICDH)	Isocitric dehydrogenase kit	33269000	II	Certification	A kit for measurement or detection of isocitric dehydrogenase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Ornithine carbamoyl transferase (OCT)	Ornithine carbamoyl transferase kit	44317000	II	Certification	A kit for measurement or detection of ornithine carbamoyl transferase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
α-hydroxybutyrate dehydrogenase (HBD) Oxybutyric dehydrogenase	Alpha-hydroxybutyrate dehydrogenase kit	38545000	II	Certification	A kit for measurement or detection of alpha-hydroxybutyrate dehydrogenase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

Lysozyme	Lysozyme kit	38547000	II	Certification	A kit for measurement or detection of lysozyme, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Pyruvate kinase (PK)	Pyruvate kinase kit	44421000	II	Certification	A kit for measurement or detection of pyruvate kinase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Glucose-6-phosphate dehydrogenase (G-6-PDH)	Glucose-6-phosphate dehydrogenase kit	33638000	II	Certification	A kit for measurement or detection of glucose-6-phosphate dehydrogenase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Phospho-hexose isomerase (PHI)	Phospho-hexose isomerase kit	38539000	II	Certification	A kit for measurement or detection of phospho-hexose isomerase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
2-5A synthetase	2-5A synthetase kit	42890000	II	Certification	A kit for measurement or detection of 2-5A synthetase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Prolyl hydroxylase (PH)	Prolyl hydroxylase kit	44229000	II	Certification	A kit for measurement or detection of prolyl hydroxylase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Super oxide dismutase (SOD)	Super oxide dismutase kit	43379000	II	Certification	A kit for measurement or detection of super oxide dismutase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Angiotensin I converting enzyme (ACE)	Angiotensin converting enzyme kit	38542000	II	Certification	A kit for measurement or detection of angiotensin I converting enzyme, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
N-acetyl-β-D-glucosaminidase (NAG)	N-acetyl-beta-D-glucosaminidase kit	38549000	II	Certification	A kit for measurement or detection of N-acetyl-β-D-glucosaminidase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Galactose-1-phosphate uridyl transferase	Galactose-1-phosphate kit	33647000	II	Certification	A kit for measurement or detection of galactose-1-phosphate uridyl transferase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Cystatin C	Cystatin C kit	83002000	II	Certification	A kit for measurement or detection of cystatin C, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Trypsinogen-2	Trypsinogen-2 kit	83017000	II	Certification	A kit for measurement or detection of trypsinogen-2, using specimens of biological origin. It is mainly used to provide information for the diagnosis of acute pancreatitis.	
Bone-specific tartrate-resistant acid phosphatase (TRACP-5b)	Bone-specific tartrate-resistant acid phosphatase kit	83020000	III	Approval	A kit for measurement or detection of bone-specific tartrate-resistant acid phosphatase (TRACP-5b), using specimens of biological origin. It is mainly used to select drug treatment policies and to provide information for the determination of drug effects for osteoporosis. In some cases, it is also used as an indicator of bone resorption and to provide information for the determination of therapeutic effects in primary and secondary hyperparathyroidism. In addition, it may be used to provide information for the diagnosis of bone metastasis from cancer.	

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As of May, 2022

Large classification	Middle classification	Test item	Japanese Medical Device Nomenclature (JMDN)	JMDN Code	Classification	Regulation	Definition	Calibration reference materials supplier
Biochemical test reagents	Reagents for low-molecular-weight nitrogen compound measurement	Creatine (CR)	Creatine kit for blood test	43378001	I	Self-declaration	A kit for measurement or detection of creatine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
		Creatinine (CRE)	Creatinine kit for blood test	30161001	I	Self-declaration	A kit for measurement or detection of creatinine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, IRMM, ReCCS
		Uric acid (UA)	Uric acid kit for blood test	30183001	I	Self-declaration	A kit for measurement or detection of uric acid, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, ReCCS
		Urea nitrogen (UN)	Urea nitrogen kit for blood test	30158001	I	Self-declaration	A kit for measurement or detection of urea nitrogen, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, ReCCS
		Ammonia (NH ₃)	Ammonia kit for blood test	30185001	I	Self-declaration	A kit for measurement or detection of ammonia, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	CERI
		Restnitrogen (NPN: Nonprotein nitrogen)	Restnitrogen kit	44178000	II	Certification	A kit for measurement or detection of restnitrogen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Amino acid fractionation	Amino acid fractionation kit	44174000	II	Certification	A kit for measurement or detection of amino acid fractionation, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Polyamine	Polyamine kit	44179000	II	Certification	A kit for measurement or detection of polyamine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Methionine	Methionine kit	44180000	I	Self-declaration	A kit for measurement or detection of methionine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	USP
		Branched-chain amino acid	Branched-chain amino acid kit	44176000	II	Certification	A kit for measurement or detection of branched-chain amino acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Phenylalanine	Phenylalanine kit	44181000	I	Self-declaration	A kit for measurement or detection of phenylalanine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	USP
		p-Aminohippuric acid (PRF)	p-Aminohippuric acid kit	44177000	II	Certification	A kit for measurement or detection of p-aminohippuric acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		p-Aminobenzoic acid (PABA)	p-Aminobenzoic acid kit	43199000	II	Certification	A kit for measurement or detection of p-aminobenzoic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

		Amino acid	Amino acid kit for blood test	83003001	I	Self-declaration	A kit for measurement or detection of amino acid, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	USP
		Leucine	Leucine kit	83004000	I	Self-declaration	A kit for measurement or detection of leucine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST
		Histidine	Histidine kit	83005000	I	Self-declaration	A kit for measurement or detection of histidine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST
		Tyrosine	Tyrosine kit	83006000	I	Self-declaration	A kit for measurement or detection of tyrosine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST
		Branched-chain amino acid/tyrosine molar ratio	Branched-chain amino acid/tyrosine kit	83007000	II	Certification	A kit for measurement or detection of branched-chain amino acid/tyrosine ratio, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Creatinine (CRE)	Creatinine kit for blood/urine test	30161021	I	Self-declaration	A kit for measurement or detection of creatinine, using blood (serum, plasma, or whole blood) specimens or urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, NIST, IRMM
		Uric acid (UA)	Uric acid kit for blood/urine test	30183021	I	Self-declaration	A kit for measurement or detection of uric acid, using blood (serum, plasma, or whole blood) specimens or urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, NIST
		Urea nitrogen (UN)	Urea nitrogen kit for blood/urine test	30158021	I	Self-declaration	A kit for measurement or detection of urea nitrogen, using blood (serum, plasma, or whole blood) specimens or urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, NIST
		Creatinine (CRE)	Creatinine kit for urine test	30161011	I	Self-declaration	A kit for measurement or detection of creatinine, using urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS
		Uric acid (UA)	Uric acid kit for urine test	30183011	I	Self-declaration	A kit for measurement or detection of uric acid, using urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS
		Urea nitrogen (UN)	Urea nitrogen kit for urine test	30158011	I	Self-declaration	A kit for measurement or detection of urea nitrogen, using urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS
		Total carnitine	Total carnitine kit	83024000	II		A kit for measurement or detection of total carnitine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. In some cases, it is also used to calculate acylcarnitine value in addition to measurement of free carnitine.	
		Free carnitine	Free carnitine kit	83025000	II		A kit for measurement or detection of free carnitine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. In some cases, it is also used to calculate acylcarnitine value in addition to measurement of total carnitine.	
	Reagents for sugar and relating substance measurement	Glucose (GLU)	Glucose kit for blood test	30167001	I	Self-declaration	A kit for measurement or detection of glucose, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, ReCCS
		Glucose (GLU)	Glucose self-test kit	30221003	III	Approval	A kit for measurement or detection of glucose by patients themselves, using specimens of biological origin. It is mainly used for follow-up of various diseases (diabetes mellitus, etc.) associated with glucose metabolism dysfunction or disorder.	
		Galactose	Galactose kit	30166000	II	Certification	A kit for measurement or detection of galactose, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Glycated haemoglobin A ₁ (HbA _{1c})	Glycated haemoglobin A ₁ kit	43198000	II	Certification	A kit for measurement or detection of glycated haemoglobin A ₁ , using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

		Glycated haemoglobin A _{1c} (HbA _{1c})	Glycated haemoglobin A _{1c} kit	30168000	I	Self-declaration	A kit for measurement or detection of glycated haemoglobin A1c, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, JDS, IRMM, IFCC
		Fructosamine	Fructosamine kit	30164000	II	Certification	A kit for measurement or detection of fructosamine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Glycated albumin	Glycated albumin kit	44153000	II	Certification	A kit for measurement or detection of glycated albumin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Mucoprotein	Mucoprotein kit	44154000	II	Certification	A kit for measurement or detection of mucoprotein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Hyaluronic acid	Hyaluronic acid kit	43294000	II	Certification	A kit for measurement or detection of hyaluronic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		1,5-anhydroglucitol (1,5AG)	1,5-anhydroglucitol kit	43010000	II	Certification	A kit for measurement or detection of 1,5-anhydroglucitol, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Sialic acid	Sialic acid kit	34225000	II	Certification	A kit for measurement or detection of sialic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		D-arabinitol	D-arabinitol kit	44342000	III	Approval	A kit for measurement or detection of D-arabinitol, using specimens of biological origin. It is mainly used to provide information for the diagnosis of deep-seated candida infection.	
		Sorbitol	Sorbitol kit	44343000	II	Certification	A kit for measurement or detection of sorbitol, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Pentosidine	Pentosidine kit	83008000	II	Certification	A kit for measurement or detection of pentosidine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Glucose (GLU)	Glucose kit for blood/urine test	30167021	I	Self-declaration	A kit for measurement or detection of glucose, using blood (serum, plasma, or whole blood) specimens or urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, NIST
		Glucose (GLU)	Glucose kit for urine test	30167011	I	Self-declaration	A kit for measurement or detection of glucose, using urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS
		Inulin	Inulin kit	83015000	II	Certification	A kit for measurement or detection of inulin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
	Reagents for organic acid measurement	Lactate	Lactate kit	30171000	I	Self-declaration	A kit for measurement or detection of lactate, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	USP, NIST
		Pyruvate	Pyruvate kit	30178000	II	Certification	A kit for measurement or detection of pyruvate, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		3-hydroxybutyric acid (β-hydroxybutyric acid)	3-hydroxybutyric acid kit	33256012	II	Certification	A kit for measurement or detection of 3-hydroxybutyric acid (β-hydroxybutyric acid), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		3-hydroxybutyric acid (β-hydroxybutyric acid)	3-hydroxybutyric acid self-test kit	44562003	III	Approval	A kit for measurement or detection of 3-hydroxybutyric acid (β-hydroxybutyric acid) by patients themselves, using specimens of biological origin. It is mainly used for follow-up of various diseases (diabetes mellitus, etc.) associated with glucose metabolism dysfunction or disorder.	

Reagents for lipid and relating substance measurement	2,3-diphosphoglycerate	2,3-diphosphoglycerate kit	44228000	II	Certification	A kit for measurement or detection of 2,3-diphosphoglycerate, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Total lipids	Total lipids kit	30179000	II	Certification	A kit for measurement or detection of total lipids, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Triglyceride (TG)	Triglyceride kit	30182000	I	Self-declaration	A kit for measurement or detection of triglyceride, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, ReCCS
	Triglyceride fraction	Triglyceride fraction kit	83009000	II	Certification	A kit for measurement or detection of triglyceride fraction, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Phospholipid (PL)	Phospholipid kit	30176000	II	Certification	A kit for measurement or detection of phospholipid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Free fatty acid (NEFA)	Non-esterified fatty acid kit	30174000	II	Certification	A kit for measurement or detection of free fatty acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Cholesterol (T-CHO)	Cholesterol kit	30159000	I	Self-declaration	A kit for measurement or detection of cholesterol, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, NIST, NMIJ
	Cholesterol fraction	Cholesterol fraction kit	83010000	II	Certification	A kit for measurement or detection of cholesterol fraction, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Free cholesterol (F-CHO)	Free cholesterol kit	44653000	I	Self-declaration	A kit for measurement or detection of free cholesterol, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST
	HDL-cholesterol (HDL-C)	HDL-cholesterol kit	30169000	I	Self-declaration	A kit for measurement or detection of HDL-cholesterol, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, CDC
	LDL-cholesterol (LDL-C)	LDL-cholesterol kit	30173000	I	Self-declaration	A kit for measurement or detection of LDL-cholesterol, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, CDC
	Remnant like lipoprotein particle cholesterol	Remnant like lipoprotein particle cholesterol kit	44169000	II	Certification	A kit for measurement or detection of remnant-like lipoprotein particle cholesterol, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Lipid peroxide	Lipid peroxide kit	42998000	II	Certification	A kit for measurement or detection of lipid peroxide, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Bile acid (TBA)	Bile acid kit	30156000	II	Certification	A kit for measurement or detection of bile acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	β -Lipoprotein (β -LP)	Beta-Lipoprotein kit	44378000	II	Certification	A kit for measurement or detection of β -lipoprotein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Lipoprotein fraction	Lipoprotein fraction kit	44170000	II	Certification	A kit for measurement or detection of lipoprotein fraction, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Lipoprotein X	Lipoprotein X kit	44375000	II	Certification	A kit for measurement or detection of lipoprotein X, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

		Lipoprotein-a (LP(a))	Lipoprotein (a) kit	41419000	II	Certification	A kit for measurement or detection of lipoprotein-a, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Lipoprotein lipase (LPL)	Lipoprotein lipase kit	44352000	II	Certification	A kit for measurement or detection of lipoprotein lipase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Lecithin-cholesterol acyltransferase (LCAT)	Lecithin-cholesterol acyltransferase kit	43296000	II	Certification	A kit for measurement or detection of lecithin-cholesterol acyltransferase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Apoprotein A-I	Apolipoprotein A-I kit	30256000	I	Self-declaration	A kit for measurement or detection of apoprotein A-I, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
		Apoprotein A-II	Apolipoprotein A-II kit	30257000	I	Self-declaration	A kit for measurement or detection of apoprotein A-II, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
		Apoprotein B	Apolipoprotein B kit	30258000	II	Certification	A kit for measurement or detection of apoprotein B, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Apoprotein C-II	Apolipoprotein C-II kit	44392000	II	Certification	A kit for measurement or detection of apoprotein C-II, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Apoprotein C-III	Apolipoprotein C-III kit	44391000	II	Certification	A kit for measurement or detection of apoprotein C-III, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Apoprotein E	Apolipoprotein E kit	42978000	II	Certification	A kit for measurement or detection of apoprotein E, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Cholesteryl ester transfer protein (CETP)	Cholesteryl ester transfer protein kit	42993000	II	Certification	A kit for measurement or detection of cholesteryl ester transfer protein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		MDA-LDL (Oxidized LDL)	MDA-LDL (Oxidized LDL) kit	83018000	II	Certification	A kit for measurement of MDA-LDL, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis in predicting the risk of coronary artery disease in diabetic patients with a history of coronary artery disease.	
		sdLDL-cholesterol (sdLDL-C)	sdLDL-cholesterol kit	83033000	II		A kit for measurement or detection of sdLDL-cholesterol, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

English edition of Japanese Medical Device Nomenclature (JMDN) and the definitions is arranged. These are provided for the convenience of users unfamiliar with the Japanese language. These contents are the latest and information except here will be aligned with these contents shortly. When and if any discrepancy arises between the Japanese original and its English translation, the former shall prevail.

As of May, 2022

Large classification	Middle classification	Test item	Japanese Medical Device Nomenclature (JMDN)	JMDN Code	Classification	Regulation	Definition	Calibration reference materials supplier
Biochemical test reagents	Reagents for Vitamin and relating substance measurement	Vitamin B12	Vitamin B12 kit	30384000	II	Certification	A kit for measurement or detection of vitamin B12, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Folate	Folate kit	30378000	II	Certification	A kit for measurement or detection of folate, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Vitamin D, 1-25-dihydroxyvitamin D3	Vitamin D kit, 1-25-dihydroxyvitamin D3	30349000	II	Certification	A kit for measurement or detection of vitamin D and 1,25-dihydroxyvitamin D3, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		25-hydroxyvitamin D	Vitamin D kit, 25-hydroxyvitamin D	83026000	II	Certification	A kit for measurement or detection of 25-hydroxyvitamin D, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Vitamin B12	Vitamin B12 kit for blood test	83034000	I	Self-declaration	A kit for measurement or detection of vitamin B12, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC, JP, USP
		Folate	Folate kit for blood test	83035000	I	Self-declaration	A kit for measurement or detection of folate, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC, JP, USP
		25-hydroxyvitamin D	25-hydroxyvitamin D kit for blood test	83036000	I	Self-declaration	A kit for measurement or detection of 25-hydroxyvitamin D, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST
	Reagents for electrolyte and inorganic matter measurement	Sodium (Na)	Sodium kit	30193000	I	Self-declaration	A kit for measurement or detection of sodium, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, ReCCS
		Potassium (K)	Potassium kit	30192000	I	Self-declaration	A kit for measurement or detection of potassium, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, ReCCS
		Chloride (Cl)	Chloride kit	30188000	I	Self-declaration	A kit for measurement or detection of chloride, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, ReCCS
		Magnesium (Mg)	Magnesium kit for blood test	30190001	I	Self-declaration	A kit for measurement or detection of magnesium, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, IRMM, ReCCS, CERI
		Calcium (Ca)	Calcium kit for blood test	30187001	I	Self-declaration	A kit for measurement or detection of calcium, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, IRMM, ReCCS, CERI
		Inorganic phosphate (IP)	Phosphorous/inorganic phosphate kit for blood test	30191001	I	Self-declaration	A kit for measurement or detection of phosphorus or inorganic phosphate, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, CERI, ReCCS

	Carbonate (CO ₂)	Bicarbonate kit	30186000	I	Self-declaration	A kit for measurement or detection of carbonate, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST
	Aluminium (Al)	Aluminium kit	42818000	I	Self-declaration	A kit for measurement or detection of aluminum, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, IRMM, CERI
	Cadmium (Cd)	Cadmium kit	43273000	I	Self-declaration	A kit for measurement or detection of cadmium, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, IRMM
	Chromium (Cr)	Chromium kit	44558000	I	Self-declaration	A kit for measurement or detection of chromium, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST
	Molybdenum (Mo)	Molybdenum kit	43263000	I	Self-declaration	A kit for measurement or detection of molybdenum, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST
	Lead (Pb)	Lead kit	31636000	I	Self-declaration	A kit for measurement or detection of lead, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST
	Selenium (Se)	Selenium kit	42876000	I	Self-declaration	A kit for measurement or detection of selenium, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST
	Cobalt (Co)	Cobalt kit	42930000	I	Self-declaration	A kit for measurement or detection of cobalt, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST
	Manganese (Mn)	Manganese kit	43275000	I	Self-declaration	A kit for measurement or detection of manganese, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST
	Lithium (Li)	Lithium kit	30189000	I	Self-declaration	A kit for measurement or detection of lithium, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, ReCCS
	Calcium (Ca)	Calcium kit for blood/urine test	30187021	I	Self-declaration	A kit for measurement or detection of calcium, using blood (serum, plasma, or whole blood) specimens or urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, NIST, IRMM, CERI
	Magnesium (Mg)	Magnesium kit for blood/urine test	30190021	I	Self-declaration	A kit for measurement or detection of magnesium, using blood (serum, plasma, or whole blood) specimens or urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, NIST, IRMM, CERI
	Inorganic phosphate (IP)	Phosphorous/inorganic phosphate kit for blood/urine test	30191021	I	Self-declaration	A kit for measurement or detection of phosphorus or inorganic phosphate, using blood (serum, plasma, or whole blood) specimens or urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS, NIST, CERI
	Calcium (Ca)	Calcium kit for urine test	30187011	I	Self-declaration	A kit for measurement or detection of calcium, using urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS
	Magnesium (Mg)	Magnesium kit for urine test	30190011	I	Self-declaration	A kit for measurement or detection of magnesium, using urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS
	Inorganic phosphate (IP)	Phosphorous/inorganic phosphate kit for urine test	30191011	I	Self-declaration	A kit for measurement or detection of phosphorus or inorganic phosphate, using urine specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	ReCCS
Reagents for trace element measurement	Iron (Fe)	Iron kit	30379000	I	Self-declaration	A kit for measurement or detection of iron, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, ReCCS, CERI
	Total iron binding capacity (TIBC)	Iron binding capacity kit	30380000	I	Self-declaration	A kit for measurement or detection of iron-binding capacity, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, CERI

		Unsaturated iron binding capacity (UIBC)	Unsaturated iron binding capacity kit	44236000	I	Self-declaration	A kit for measurement or detection of unsaturated iron-binding capacity, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, CERI
		Copper (Cu)	Copper kit	30160000	I	Self-declaration	A kit for measurement or detection of copper, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	CERI, NIST, IRMM
		Zinc (Zn)	Zinc kit	30184000	I	Self-declaration	A kit for measurement or detection of zinc, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, IRMM, CERI
	Reagents for vital pigment and relating substance measurement	Bilirubin (Total bilirubin)	Total bilirubin kit for blood test	30157001	I	Self-declaration	A kit for measurement or detection of bilirubin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST, ReCCS
		Direct bilirubin	Direct bilirubin kit	30157012	II	Certification	A kit for measurement or detection of direct bilirubin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Unbound bilirubin	Unbound bilirubin kit	83019000	II	Certification	A kit for measurement or detection of unbound bilirubin (albumin-unbound bilirubin), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Indirect bilirubin	Indirect bilirubin kit	43274000	II	Certification	A kit for measurement or detection of indirect bilirubin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Reagents for drug measurement	Acetaminophen	Acetaminophen kit	30437000	I	Self-declaration	A kit for measurement or detection of acetaminophen, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	JP, USP
		Free carbamazepine	Free carbamazepine kit	30397000	II	Certification	A kit for measurement or detection of free carbamazepine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
		Carbamazepine	Carbamazepine kit	30395000	I	Self-declaration	A kit for measurement or detection of carbamazepine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP
		Ethosuximide	Ethosuximide kit	30396000	I	Self-declaration	A kit for measurement or detection of ethosuximide, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP
		Phenobarbital	Phenobarbital kit	30401000	I	Self-declaration	A kit for measurement or detection of phenobarbital, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP
		Primidone	Primidone kit	30403000	I	Self-declaration	A kit for measurement or detection of primidone, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP, JP
		Free phenytoin	Free phenytoin kit	30398000	I	Self-declaration	A kit for measurement or detection of free phenytoin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP
		Phenytoin	Phenytoin kit	30402000	I	Self-declaration	A kit for measurement or detection of phenytoin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP
		Free valproic acid	Free valproic acid kit	30400000	II	Certification	A kit for measurement or detection of free valproic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	

Valproic acid	Valproic acid kit	30404000	I	Self-declaration	A kit for measurement or detection of valproic acid, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP
Digitoxin	Digitoxin kit	30387000	I	Self-declaration	A kit for measurement or detection of digitoxin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	JP, USP
Digoxin	Digoxin kit	30386000	I	Self-declaration	A kit for measurement or detection of digoxin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	JP, USP
Disopyramide	Disopyramide kit	30388000	I	Self-declaration	A kit for measurement or detection of disopyramide, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP
Lidocaine	Lidocaine kit	30390000	I	Self-declaration	A kit for measurement or detection of lidocaine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP
N-acetylprocainamide	N-acetylprocainamide kit	30391000	II	Certification	A kit for measurement or detection of N-acetylprocainamide, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Procainamide	Procainamide kit	30392000	I	Self-declaration	A kit for measurement or detection of procainamide, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP
Quinidine	Quinidine kit	30394000	II	Certification	A kit for measurement or detection of quinidine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Theophylline	Theophylline kit	30417000	I	Self-declaration	A kit for measurement or detection of theophylline, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP
Salicylate	Salicylate kit	30449000	II	Certification	A kit for measurement or detection of salicylate, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Heparin	Heparin kit	30564000	I	Self-declaration	A kit for measurement or detection of heparin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	NIBSC
Amikacin	Amikacin kit	30405000	I	Self-declaration	A kit for measurement or detection of amikacin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP, JP
Tobramycin	Tobramycin kit	30413000	I	Self-declaration	A kit for measurement or detection of tobramycin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP, JP
Gentamicin	Gentamicin kit	30408000	I	Self-declaration	A kit for measurement or detection of gentamicin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP, JP
Dibekacin	Dibekacin kit	30407000	II	Certification	A kit for measurement or detection of dibekacin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Netilmicin	Netilmicin kit	30410000	II	Certification	A kit for measurement or detection of netilmicin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Methotrexate	Methotrexate kit for blood test	30418001	I	Self-declaration	A kit for measurement or detection of methotrexate, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	JP, USP

Methotrexate	Methotrexate kit	30418002	II	Certification	A kit for measurement or detection of methotrexate, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Ethanol	Ethanol kit	38524000	II	Certification	A kit for measurement or detection of ethanol, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Bromperidol	Bromperidol kit	42931000	II	Certification	A kit for measurement or detection of bromperidol, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Zonisamide	Zonisamide kit	42928000	II	Certification	A kit for measurement or detection of zonisamide, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Haloperidol	Haloperidol kit	42921000	I	Self-declaration	A kit for measurement or detection of haloperidol, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP
Aprindine	Aprindine kit	42925000	II	Certification	A kit for measurement or detection of aprindine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Arbekacin	Arbekacin kit	42929000	II	Certification	A kit for measurement or detection of arbekacin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Isepamicin	Isepamicin kit	42920000	II	Certification	A kit for measurement or detection of isepamicin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Cyclosporine	Cyclosporine kit	30419000	I	Self-declaration	A kit for measurement or detection of cyclosporine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP, JP
Tacrolimus	Tacrolimus kit	30421000	II	Certification	A kit for measurement or detection of tacrolimus, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Vancomycin	Vancomycin kit	30414000	I	Self-declaration	A kit for measurement or detection of vancomycin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP
Tricyclic antidepressant (TCA)	Tricyclic antidepressant kit	30451000	II	Certification	A kit for measurement or detection of tricyclic antidepressant, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Teicoplanin	Teicoplanin kit	30415000	II	Certification	A kit for measurement or detection of teicoplanin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Morphine	Morphine kit	83011000	II	Certification	A kit for measurement or detection of morphine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Mexiletine	Mexiletine kit	83012000	II	Certification	A kit for measurement or detection of mexiletine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
Abusable drugs (phencyclidines, benzodiazepines, cocaine, stimulants, narcotics, hypnotics, psychotropics, etc.)	Kit for drug addiction detection	83013000	III	Approval	A kit for detection of abusable drugs using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases, such as drug addiction	

		Ethanol kit	Ethanol kit for blood test	38524001	I	Self-declaration	A kit for measurement or detection of ethanol, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	NIST
		Quinidine kit	Quinidine kit for blood test	30394001	I	Self-declaration	A kit for measurement or detection of quinidine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	USP
		Phenolsulfonphthalein (PSP)	Phenolsulfonphthalein kit	83016000	II	Certification	A kit for measurement of phenolsulfonphthalein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Everolimus	Everolimus kit	83022000	II	Certification	A kit for measurement or detection of everolimus, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
		Topiramate	Topiramate kit	83023000	II	Certification	A kit for measurement or detection of topiramate concentrations, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
		Mycophenolate	Mycophenolate kit	83029000	II		A kit for measurement or detection of mycophenolate, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
		Infliximab (genetical recombination)	Infliximab kit	83030000	II		A kit for measurement or detection of infliximab (genetical recombination), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	
		Salicylate	Salicylate kit for blood test	83037000	I	Self-declaration	A kit for measurement or detection of salicylate, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes. It is also used for therapeutic drug monitoring.	JP、USP
	Reagent for genetic polymorphism test	UDP Glucuronosyltransferase (UGT1A1) polymorphism	UDP Glucuronosyltransferase (UGT1A1) polymorphism kit	83021000	III		A kit for determination of UDP glucuronosyltransferase (UGT1A1) polymorphism, a drug-metabolizing enzyme, using specimens of biological origin. It is mainly used to provide information for recognizing the possibility of decreased activity of UDP glucuronosyltransferase.	
		Interleukin 28B (IL28B) polymorphism (rs8099917)	Interleukin 28B polymorphism kit	83027000	III		A kit for detection of interleukin 28B (IL28B) polymorphism, using specimens of biological origin. It is mainly used to provide information for the determination of interleukin 28B (IL28B) polymorphism.	
		Nudix hydrolase 15 (NUDT15) polymorphism	Nudix hydrolase 15 (NUDT15) polymorphism kit	83031000	III		A kit for detection of Nudix hydrolase 15 (NUDT15) polymorphisms using specimens of biological origin. It is mainly used to provide information for the selection of treatment for patients with decreased activity of NUDT15.	

English edition of Japanese Medical Device Nomenclature (JMDN) and the definitions is arranged. These are provided for the convenience of users unfamiliar with the Japanese language. These contents are the latest and information except here will be aligned with these contents shortly. When and if any discrepancy arises between the Japanese original and its English translation, the former shall prevail.

As of May, 2022

Large classification	Middle classification	Test item	Japanese Medical Device Nomenclature (JMDN)	JMDN Code	Classification	Regulation	Definition	Calibration reference materials supplier
Immunological test reagents	Reagents for immunoglobulin measurement	Immunoglobulin G (IgG)	Immunoglobulin G kit for blood test	30232001	I	Self-declaration	A kit for measurement or detection of immunoglobulin G, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
		Specific immunoglobulin G	Immunoglobulin G monotest/monoresult multiantigen kit	84001000	II	Certification	A kit for measurement or detection of specific immunoglobulin G, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Immunoglobulin A (IgA)	Immunoglobulin A kit for blood test	30228001	I	Self-declaration	A kit for measurement or detection of immunoglobulin A, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
		Secretory immunoglobulin A (IgA)	Secretory immunoglobulin A kit	30228012	II	Certification	A kit for measurement or detection of secretory immunoglobulin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Immunoglobulin M (IgM)	Immunoglobulin M kit for blood test	30234001	I	Self-declaration	A kit for measurement or detection of immunoglobulin M, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
		Immunoglobulin D (IgD)	Immunoglobulin D kit	30230000	I	Self-declaration	A kit for measurement or detection of immunoglobulin D, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
		Immunoglobulin E (IgE) Nonspecific Immunoglobulin E (IgE)	Immunoglobulin E kit	30275000	I	Self-declaration	A kit for measurement or detection of immunoglobulin E or nonspecific immunoglobulin E, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
		Allergen-specific IgE Specific Immunoglobulin E (IgE) Antigen-specific IgE antibody Anti-inhalant allergen IgE antibody	Immunoglobulin E monotest/monoresult multiantigen kit	30277000	II	Certification	A kit for measurement or detection of multiantigens in monotest/monoresult for immunoglobulin E, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Allergen-specific IgE Specific Immunoglobulin E (IgE) Antigen-specific IgE antibody Anti-inhalant allergen IgE antibody	Immunoglobulin E monotest/pluriresult multiantigen kit	30278000	II	Certification	A kit for measurement or detection of multiantigens in monotest/pluriresult for immunoglobulin E, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

	Immunoglobulin light chain kappa Immunoglobulin light chain λ (light chain λ)	Immunoglobulin kappa/lambda chain kit	30236000	II	Certification	A kit for measurement or detection of immunoglobulin kappa/lambda (κ and λ) chains, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	IgG subclass	Immunoglobulin G subclass kit	84002000	II	Certification	A kit for measurement or detection of immunoglobulin G subclasses, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Multiple isotypes of immunoglobulins (IgG, IgA, IgM, light chain kappa, light chain lambda)	Multi-isotype immunoglobulin kit	84021000	II	Certification	A kit for measurement or detection of multiple isotypes of immunoglobulins (IgG, IgA, IgM, light chain kappa, light chain lambda, etc.), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Allergen component-specific immunoglobulin E	Allergen component-specific immunoglobulin E kit	84072000	II		A kit for measurement or detection of allergen component (a single protein with allergenicity)-specific immunoglobulin E, using specimens of biological origin. It is mainly used to provide information for the diagnosis of allergic diseases.	
Reagents for complement and related substance measurement	50% Haemolytic complement (CH ₅₀)	Complement CH ₅₀ kit	43254000	II	Certification	A kit for measurement or detection of 50% haemolytic complement (CH ₅₀), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Complement component 3 (C ₃) Complement protein (C3) Complement C3	Complement component C3 kit	30241001	I	Self-declaration	A kit for measurement or detection of complement component C ₃ , using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
	Complement component C3c	Complement component C3c kit	30241002	II	Certification	A kit for measurement or detection of complement component C3c, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Complement component 4 (C ₄) Complement protein (C4) Complement C4	Complement component C4 kit	30243000	I	Self-declaration	A kit for measurement or detection of complement component C4, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
	C1-inactivator C1-inactivator activity	Complement component C1 inactivator kit	30240000	II	Certification	A kit for measurement or detection of complement component C1 inactivator, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	C3 proactivator	C3 proactivator kit	43815000	II	Certification	A kit for measurement or detection of C3 proactivator, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Complement control factor (Sperm motility)	Complement control factor kit	84003000	II	Certification	A kit for measurement or detection of complement control factor (sperm motility), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Reagents for plasma protein measurement	Prealbumin	Prealbumin/transthyretin kit	30251000	I	Self-declaration	A kit for measurement or detection of prealbumin/transthyretin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
	α ₁ -microglobulin (α ₁ -m)	Alpha1-microglobulin kit	30270000	II	Certification	A kit for measurement or detection of alpha1-microglobulin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

α_1 -antitrypsin	Alpha1-antitrypsin kit for blood test	30268001	I	Self-declaration	A kit for measurement or detection of alpha1-antitrypsin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
α_1 -acid glycoprotein (α_1 -AGP)	Alpha1-acid glycoprotein kit	36010000	II	Certification	A kit for measurement or detection of alpha1-acid glycoprotein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Retinol binding protein (RBP)	Retinol binding protein kit	30252000	II	Certification	A kit for measurement or detection of retinol- binding protein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
α_2 -macroglobulin	Alpha2-macroglobulin kit	30269000	I	Self-declaration	A kit for measurement or detection of alpha2-macroglobulin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
Haptoglobin (Hp)	Haptoglobin kit	30248000	I	Self-declaration	A kit for measurement or detection of haptoglobin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
Ceruloplasmin (Cp)	Ceruloplasmin kit	30247000	I	Self-declaration	A kit for measurement or detection of ceruloplasmin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
Haemopexin (Hx)	Haemopexin kit	30249000	II	Certification	A kit for measurement or detection of haemopexin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Transferrin (Tf)	Transferrin kit for blood test	30253001	I	Self-declaration	A kit for measurement or detection of transferrin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
β_2 -microglobulin (β_2 -m, BMG, β_2 -MG)	Beta2-microglobulin kit for blood test	30296001	I	Self-declaration	A kit for measurement or detection of beta2-microglobulin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
C-reactive protein (CRP)	C-reactive protein kit	30499000	I	Self-declaration	A kit for measurement or detection of C-reactive protein, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
APR score	APR score kit	42986000	II	Certification	A kit for measurement of APR score, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Human heart fatty acid binding protein (H-FABP)	Human heart fatty acid binding protein kit	42860000	II	Certification	A kit for measurement or detection of human heart fatty acid- binding protein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Myoglobin (Mb)	Myoglobin kit	30264000	II	Certification	A kit for measurement or detection of myoglobin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Cardiac troponin I (cTnI) Troponin T (TnT) Cardiac troponin T	Troponin kit	30266000	II	Certification	A kit for measurement or detection of troponin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Cardiac myosin light chain I	Myosin light chain kit	30265000	II	Certification	A kit for measurement or detection of cardiac myosin light chain I, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Ferritin (FRN)	Ferritin kit	30377000	I	Self-declaration	A kit for measurement or detection of ferritin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
Fibronectin Carcinoembryonic fibronectin	Fibronectin kit	30271000	II	Certification	A kit for measurement or detection of fibronectin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Chondrocalcin	Chondrocalcin kit	43224000	II	Certification	A kit for measurement or detection of chondrocalcin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

Procollagen III peptide (PIIP)	Procollagen III peptide kit	44444000	II	Certification	A kit for measurement or detection of procollagen III peptide, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Serum amyloid A protein (SAA)	Amyloid A protein kit	44442000	I	Self-declaration	A kit for measurement or detection of amyloid A protein, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
Type IV collagen	Type IV collagen kit	43373000	II	Certification	A kit for measurement or detection of type IV collagen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Type IV collagen 7S	Type IV collagen 7S kit	44293000	II	Certification	A kit for measurement or detection of type IV collagen 7S, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Matrix metalloproteinase-3 (MMP-3)	Matrix metalloproteinase-3 kit	44647000	II	Certification	A kit for measurement or detection of matrix metalloproteinase-3, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Histamine release test Histamine released from blood cells with allergen stimulation	Histamine release test kit	44211000	II	Certification	A kit for histamine release test (histamine released from blood cells with allergen stimulation), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Pulmonary surfactant apoprotein A (SP-A)	Pulmonary surfactant apoprotein A kit	44441000	II	Certification	A kit for measurement or detection of pulmonary surfactant apoprotein-A, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Surfactant protein D (SP-D)	Surfactant protein D kit	43194000	II	Certification	A kit for measurement or detection of surfactant protein-D, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Sialylated carbohydrate antigen KL-6	Sialylated carbohydrate antigen KL-6 kit	43462000	II	Certification	A kit for measurement or detection of sialylated carbohydrate antigen KL-6, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Granulocyte elastase	Granulocyte elastase kit	44398000	II	Certification	A kit for measurement or detection of granulocyte elastase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
βclosslap	Beta-closslap kit	44155000	II	Certification	A kit for measurement or detection of β-crosslaps, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Trypsinogen activation peptide	Trypsinogen activation peptide kit	84026000	III	Approval	A kit for measurement or detection of trypsinogen activation peptide, using specimens of biological origin. It is used for diagnosis of diseases (pancreatitis, etc.) by measurement or detection of trypsinogen activation peptide.	
α1-acid glycoprotein (α1-AGP)	Alpha1-acid glycoprotein kit for blood test	36010001	I	Self-declaration	A kit for measurement or detection of alpha1-acid glycoprotein, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
Intact Type I procollagen-N-propeptide (Intact PINP) Type I procollagen-N-propeptide (PINP)	Type I procollagen-N-propeptide kit	84046000	II	Certification	A kit for measurement or detection of type I procollagen-N-propeptide (PINP), using specimens of biological origin. It is mainly used for determination and monitoring of therapeutic effects and to provide information for the diagnosis in osteoporosis treatment.	
Human liver-type fatty acid binding protein (L-FABP)	Human liver-type fatty acid binding protein (L-FABP) kit	84051000	II	Certification	A kit for measurement or detection of human liver-type fatty acid binding protein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Cytochrome c	Cytochrome c kit	84045000	II	Certification	A kit for measurement or detection of cytochrome c, using specimens of biological origin. It is mainly used to provide information for the diagnosis of acute encephalitis in children and for other purposes.	

		Mac-2 binding protein (M2BP) glycosylation isomer (Lectin-reactive M2BP)	Mac-2 binding protein (M2BP) glycosylation isomer kit	84073000	II		A kit for measurement or detection of Mac-2 binding protein (M2BP) glycosylation isomer (lectin-reactive M2BP), using specimens of biological origin. It is mainly used to provide information for the diagnosis of liver fibrosis progression.	
		Carbohydrate-deficient transferrin (CDT)	Carbohydrate-deficient transferrin kit	84087000	II		A kit for measurement or detection of carbohydrate-deficient transferrin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Autotaxin	Autotaxin kit	84093000	II		A kit for measurement or detection of autotaxin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of liver fibrosis progression.	
		Leucine-rich α2 glycoprotein (LRG)	Leucine-rich α2 glycoprotein kit	84097000	II		A kit for measurement or detection of leucine-rich α2 glycoprotein (LRG), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Cytokeratin fragment 18	Cytokeratin fragment 18 kit	84121000	II		A kit for measurement or detection of cytokeratin fragment 18, using specimens of biological origin. It is mainly used to provide information for the diagnosis of nonalcoholic steato-hepatitis.	
	Reagents for tumor associated antigen (antibody) measurement	Carcinoembryonic antigen (CEA)	Carcinoembryonic antigen kit	30288000	III	Approval	A kit for measurement or detection of carcinoembryonic antigen (CEA), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of carcinoembryonic antigen (CEA).	
		α-fetoprotein (AFP)	Alpha-fetoprotein kit	30295000	III	Approval	A kit for measurement or detection of α-fetoprotein (AFP), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of α-fetoprotein (AFP). In some cases, α-fetoprotein (AFP) in vaginal secretion is also used to provide information for the diagnosis of rupture of membranes.	
		Lectin-reactive AFP fraction (AFP-L3%)	Lectin-reactive alpha-fetoprotein fraction kit	43480000	III	Approval	A kit for measurement of lectin-reactive AFP fraction (AFP-L3%), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement of lectin-reactive AFP fraction (AFP-L3%).	
		Basic fetoprotein (BFP)	Basic fetoprotein kit	44440000	III	Approval	A kit for measurement or detection of basic fetoprotein (BFP), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of basic fetoprotein (BFP).	
		CA125 Ovarian cancer-associated antigen CA125 Ovarian cancer-derived antigen CA125 Cancer-associated antigen 125 (CA125)	Cancer antigen 125 kit	30283000	III	Approval	A kit for measurement or detection of cancer antigen 125 (CA-125), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of cancer antigen 125 (CA-125). It is also used to provide information for the diagnosis of endometriosis or others.	
		Cancer antigen 602	Cancer antigen 602 kit	43034000	III	Approval	A kit for measurement or detection of cancer antigen 602 (CA602), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of cancer antigen 602 (CA602). It is also used to provide information for the diagnosis of endometriosis or others.	
		Pulmonary adenocarcinoma antigen 130 (CA130)	Pulmonary adenocarcinoma antigen 130 kit	43150000	III	Approval	A kit for measurement or detection of pulmonary adenocarcinoma antigen 130 (CA130), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of pulmonary adenocarcinoma antigen 130 (CA130). It is also used to provide information for the diagnosis of endometriosis or others.	

CA15-3 Cancer associated antigen CA15-3 Human breast carcinoma antigen (CA15-3)	Cancer antigen 15-3 kit	30279000	Ⅲ	Approval	A kit for measurement or detection of cancer antigen 15-3 (CA15-3), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of cancer antigen 15-3 (CA15-3).	
Breast carcinoma antigen (BCA 225)	Breast carcinoma antigen/BCA 225 kit	43825000	Ⅲ	Approval	A kit for measurement or detection of breast carcinoma antigen (BCA 225), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of breast carcinoma antigen (BCA 225).	
CA19-9 Carbohydrate antigen CA19-9 Human colorectal cancer-derived carbohydrate antigen (CA19-9) Cancer-associated antigen CA19-9	Cancer antigen 19-9 kit	30280000	Ⅲ	Approval	A kit for measurement or detection of cancer antigen 19-9 (CA19-9), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of cancer antigen 19-9 (CA19-9).	
Human epididymis protein 4 (HE4)	Human epididymis protein 4 kit	84082000	Ⅲ	Approval	A kit for measurement or detection of human epididymis protein 4 (HE4), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of human epididymis protein 4 (HE4).	
Cancer antigen 50 (CA50)	Cancer antigen 50 kit	30281000	Ⅲ	Approval	A kit for measurement or detection of cancer antigen 50 (CA50), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of cancer antigen 50 (CA50).	
Cancer antigen CA72-4 (CA72-4)	Cancer antigen 72-4 kit	30282000	Ⅲ	Approval	A kit for measurement or detection of cancer antigen 72-4 (CA72-4), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of cancer antigen 72-4 (CA72-4).	
Sialyl Tn antigen (STN)	Sialyl Tn antigen kit	43306000	Ⅲ	Approval	A kit for measurement or detection of sialyl Tn antigen (STN), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of sialyl Tn antigen (STN).	
Human cancer associated carbohydrate antigen (KMO1)	Human cancer associated carbohydrate antigen/KMO1 kit	43309000	Ⅲ	Approval	A kit for measurement or detection of human cancer associated carbohydrate antigen (KMO1), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of human cancer associated carbohydrate antigen (KMO1).	
DUPAN-2 antigen	DUPAN-2 antigen kit	43308000	Ⅲ	Approval	A kit for measurement or detection of DUPAN-2 antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of DUPAN-2 antigen.	
Sialyl Le ^x -i antigen (SLX)	Sialyl Le ^x -i antigen kit	43824000	Ⅲ	Approval	A kit for measurement or detection of sialyl Le ^x -i antigen (SLX), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of sialyl Le ^x -i antigen (SLX).	
NCC-ST-439 antigen	NCC-ST-439 antigen kit	43307000	Ⅲ	Approval	A kit for measurement or detection of NCC-ST-439 antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of NCC-ST-439 antigen.	
SPan-1 antigen	SPan-1 antigen kit	43823000	Ⅲ	Approval	A kit for measurement or detection of SPan-1 antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of SPan-1 antigen.	
Squamous cell carcinoma antigen (SCC antigen)	Squamous cell carcinoma antigen/SCC kit	30291000	Ⅲ	Approval	A kit for measurement or detection of squamous cell carcinoma antigen (SCC antigen), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of squamous cell carcinoma antigen (SCC antigen).	
γ-seminoprotein (γ-Sm)	Gamma-seminoprotein kit	43428000	Ⅲ	Approval	A kit for measurement or detection of γ-seminoprotein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of γ-seminoprotein.	

Tissue polypeptide antigen (TPA)	Tissue polypeptide antigen kit	30292000	Ⅲ	Approval	A kit for measurement or detection of tissue polypeptide antigen (TPA), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of tissue polypeptide antigen (TPA).	
Immunosuppressive acidic protein (IAP)	Immunosuppressive acidic protein kit	36010010	Ⅲ	Approval	A kit for measurement or detection of immunosuppressive acidic protein (IAP), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of immunosuppressive acidic protein (IAP). It is also used to assist in the diagnosis of inflammatory diseases, autoimmune diseases, or others.	
Prostatic acid phosphatase (PAP)	Prostatic acid phosphatase kit	34226000	Ⅲ	Approval	A kit for measurement or detection of prostatic acid phosphatase (PAP), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of prostatic acid phosphatase (PAP).	
Prostate-specific antigen (PA) Prostate specific antigen (PSA)	Prostate specific antigen kit	37286000	Ⅲ	Approval	A kit for measurement or detection of prostate specific antigen (PSA), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of prostate specific antigen (PSA). In some cases, it is also used to measure F/T ratio (free PSA/total PSA) in addition to free prostate specific antigen (free PSA).	
Free prostate specific antigen (Free PSA)	Free prostate specific antigen kit	37287000	Ⅲ	Approval	A kit for measurement or detection of free prostate specific antigen (free PSA), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of free prostate specific antigen (free PSA). In some cases, it is also used to measure F/T ratio (free PSA/total PSA) in addition to prostate-specific antigen (PA) and prostate specific antigen (PSA).	
Prostate specific antigen/ α_1 -antichymotrypsin complex (PSA-ACT)	Prostate specific antigen/ α_1 -antichymotrypsin complex kit	43145000	Ⅲ	Approval	A kit for measurement or detection of prostate specific antigen/ α_1 -antichymotrypsin complex (PSA-ACT), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of prostate specific antigen/ α_1 -antichymotrypsin complex (PSA-ACT).	
Neuron specific enolase (NSE)	Neuron specific enolase kit	30301000	Ⅲ	Approval	A kit for measurement or detection of neuron specific enolase (NSE), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of neuron specific enolase (NSE).	
Galactosyltransferase associated with tumor (GAT)	Galactosyltransferase associated with tumor/GAT kit	43195000	Ⅲ	Approval	A kit for measurement or detection of galactosyltransferase associated with tumor (GAT), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of galactosyltransferase associated with tumor (GAT).	
Pregnancy specific protein-1 (SP1)	Pregnancy specific protein-1 kit	44325000	Ⅲ	Approval	A kit for measurement or detection of pregnancy specific protein-1 (SP1), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of pregnancy specific protein-1 (SP1). In some cases, it is also used for early diagnosis of pregnancy or for management of the prognosis of threatened miscarriage.	
PIVKA-II (Prothrombin deficiency)	PIVKA-II kit	44379003	Ⅲ	Approval	A kit for measurement or detection of PIVKA-II (prothrombin deficiency), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of PIVKA-II (prothrombin deficiency).	
Cytokeratin fragment 19 (Cyfra)	Cytokeratin fragment 19 kit	30287000	Ⅲ	Approval	A kit for measurement or detection of cytokeratin fragment 19 (Cyfra), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of cytokeratin fragment 19 (Cyfra).	
Gastrin releasing peptide precursor [ProGRP(31-98)]	Gastrin releasing peptide precursor kit	44438000	Ⅲ	Approval	A kit for measurement or detection of gastrin releasing peptide precursor [ProGRP (31-98)], using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of gastrin releasing peptide precursor [ProGRP (31-98)].	
CA54/61	Cancer antigen 54/61 kit	43196000	Ⅲ	Approval	A kit for measurement or detection of cancer antigen 54/61 (CA54/61), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of cancer antigen 54/61 (CA54/61).	
Elastase I	Elastase I kit	43237000	Ⅲ	Approval	A kit for measurement or detection of elastase I, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of elastase I.	

ErbB-2 (c-erbB gene product) HER2 protein (c-erb gene product)	ErbB-2 kit	43270000	III	Approval	A kit for measurement or detection of ErbB-2 (c-erbB gene product), etc., using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of ErbB-2 (c-erbB gene product).	
Sialyl Le ^x antigen (CSLEX)	Sialyl Le ^x antigen kit	42825000	III	Approval	A kit for measurement or detection of sialyl Lex antigen (CSLEX), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of sialyl Lex antigen (CSLEX).	
Nuclear matrix protein 22 (NMP22)	Nuclear matrix protein 22 kit	43197000	III	Approval	A kit for measurement or detection of nuclear matrix protein 22 (NMP22), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of nuclear matrix protein 22 (NMP22).	
Type I procollagen-C-propeptide (PICP)	Type I procollagen-C-propeptide kit	42822000	III	Approval	A kit for measurement or detection of type I procollagen-C-propeptide (PICP), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of type I procollagen-C-propeptide (PICP).	
Type I collagen-C-telopeptide (ICTP)	Type I collagen-C-telopeptide kit	42941000	III	Approval	A kit for measurement or detection of type I collagen-C-telopeptide (ICTP), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of type I collagen-C-telopeptide (ICTP).	
Type I collagen cross-linked N-telopeptide (NT _x)	Type I collagen cross-linked N-telopeptide kit	43299000	III	Approval	A kit for measurement or detection of type I collagen cross-linked N-telopeptide (NT _x), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of type I collagen cross-linked N-telopeptide (NT _x). In some cases, type I collagen cross-linked N-telopeptide (NT _x) is also used as an indicator of bone resorption and for determination of (surgery) effects in primary hyperparathyroidism. In addition, it may be used to select drug treatment policies for osteoporosis.	
Pancreatic oncofetal antigen (POA)	Pancreatic oncofetal antigen/POA kit	44433000	III	Approval	A kit for measurement or detection of pancreatic oncofetal antigen (POA), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of pancreatic oncofetal antigen (POA).	
Bladder tissue antigen (BTA)	Bladder tissue antigen/BTA kit	30510000	III	Approval	A kit for measurement or detection of bladder tissue antigen (BTA), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of bladder tissue antigen (BTA).	
Oestrogen receptor (ER)	Oestrogen receptor kit	30293000	III	Approval	A kit for measurement or detection of oestrogen receptors, using specimens of biological origins. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of oestrogen receptors.	
Progesterone receptor	Progesterone receptor kit	30294000	III	Approval	A kit for measurement or detection of progesterone receptors, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of progesterone receptors.	
Faecal occult blood	Faecal occult blood kit	38217000	III	Approval	A kit for measurement or detection of faecal occult blood, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of faecal occult blood.	
Urinary free fucose	Free fucose kit	44432000	III	Approval	A kit for measurement or detection of free fucose, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of free fucose.	
Deoxypyridinoline (DPD)	Deoxypyridinoline kit	30348000	III	Approval	A kit for measurement or detection of deoxypyridinoline, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of deoxypyridinoline. In some cases, deoxypyridinoline is also used as an indicator of bone resorption and for determination of (surgery) effects in primary hyperparathyroidism. In addition, it may be used to select drug treatment policies for osteoporosis.	

Major Bcr-Abl mRNA Major Bcr-Abl mRNA/ABL mRNA ratio	Major Bcr-Abl mRNA kit	44431000	III		A kit for measurement or detection of major BCR-ABL mRNA (major BCR-ABL nucleic acid), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors (chronic myeloid leukemia [CML] or acute lymphocytic leukemia [ALL]). In some cases, it may be also used to measure major BCR-ABL mRNA/ABL mRNA ratio, which is converted to the international standard value.	
LCAP (Lung cancer-associated protein)	Lung cancer-associated protein/LCAP kit	44430000	III	Approval	A kit for measurement or detection of lung cancer-associated protein (LCAP), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of lung cancer-associated protein (LCAP).	
Deoxythymidine kinase (TK) (Deoxythymidine (TK) activity)	Deoxythymidine kinase kit	44254013	III	Approval	A kit for measurement or detection of deoxythymidine kinase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of deoxythymidine kinase.	
HER-2 gene kit	HER-2 gene kit	84004000	III		A kit for measurement or detection of HER-2 gene (c-erb gene product), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of HER-2 gene (c-erb gene product).	
Glutathione S-transferase	Glutathione S-transferase kit	84027000	III	Approval	A kit for measurement or detection of glutathione S-transferase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of glutathione S-transferase.	
Gastric mucin	Gastric mucin kit	84041000	III	Approval	A kit for measurement or detection of gastric mucin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of cervical diseases (mainly malignant tumors) with gastric type traits by measurement or detection of gastric mucin in cervical mucus.	
Wilms' tumor-1 gene (WT1) mRNA	Wilms' tumor-1 gene (WT1) mRNA kit	84028000	III		A kit for measurement or detection of Wilms' tumor-1 gene nucleic acid (WT1 mRNA), using specimens of biological origin. It is mainly used to provide information for the diagnosis or to monitor therapeutic effects for malignant tumors (acute myeloid leukemia [AML] or myelodysplastic syndrome [MDS]).	
Soluble methotelin-related peptides (SMRP)	Soluble methotelin-related peptides kit	84058000	III	Approval	A kit for measurement or detection of soluble mesothelin-related peptides (SMRP), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of soluble mesothelin-related peptides (SMRP).	
Ferritin (FRN)	Ferritin kit for blood test	30377010	III	Approval	A kit for measurement or detection of ferritin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of malignant tumors, etc. by measurement or detection of ferritin.	
Anti-p53 antibody	Anti-p53 antibody kit	84039000	III	Approval	A kit for measurement or detection of autoantibody against p53 protein (anti-p53 antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of anti-p53 antibody.	
Cytokeratin 19 mRNA	Cytokeratin 19 mRNA kit	84042000	III		A kit for measurement or detection of cytokeratin 19 mRNA, using specimens of biological origin. It is mainly used to provide information for the diagnosis of metastasis of malignant tumors by measurement or detection of cytokeratin 19 mRNA.	
Total cytokeratin 8/cytokeratin 18	Total cytokeratin 8/cytokeratin 18 kit	84034000	III	Approval	A kit for measurement or detection of total cytokeratin 8 and/or total cytokeratin 18 (UBC), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of total cytokeratin 8 and/or total cytokeratin 18.	
C-C chemokine receptor type 4 (CCR4)	CCR4 kit	84068000	III		A kit for measurement or detection of C-C chemokine receptor type 4 (CCR4), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors.	
Free prostate-specific antigen (free PSA)/ Prostate-specific antigen (PSA) ratio	Free prostate-specific antigen/ Prostate-specific antigen ratio kit	84091000	III		A kit for measurement of prostate specific antigen (PSA) and free prostate specific antigen (free PSA) to measure F/T ratio (free PSA/total PSA ratio), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement of prostate specific antigen (PSA) and free prostate specific antigen (free PSA).	

		JAK2 gene mutation rate	JAK2 gene mutation kit	84094000	III		A kit for measurement of JAK2 gene mutation rate or for detection of JAK2 gene mutations, using specimens of biological origin. It is mainly used to provide information for the diagnosis of polycythemia vera, essential thrombocythemia, and primary myelofibrosis.	
		Prostate specific antigen precursor	Prostate specific antigen precursor kit	84104000	III		A kit for measurement of prostate specific antigen (PSA) precursor, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of prostate specific antigen (PSA) precursor. In some cases, it is also used with prostate specific antigen (PSA) and free prostate specific antigen (free PSA).	
		Tissue factor pathway inhibitor 2 (TFPI2)	Tissue factor pathway inhibitor 2 kit	84111000	III		A kit for measurement of tissue factor pathway inhibitor 2 (TFPI2), using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors by measurement or detection of tissue factor pathway inhibitor 2 (TFPI2).	
		Minor Bcr-Abl mRNA	Minor Bcr-Abl mRNA kit	84119000	III		A kit for measurement or detection of minor BCR-ABL mRNA, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors (acute lymphocytic leukemia [ALL]).	

English edition of Japanese Medical Device Nomenclature (JMDN) and the definitions is arranged. These are provided for the convenience of users unfamiliar with the Japanese language. These contents are the latest and information except here will be aligned with these contents shortly. When and if any discrepancy arises between the Japanese original and its English translation, the former shall prevail.

As of May, 2022

Large classification	Middle classification	Test item	Japanese Medical Device Nomenclature (JMDN)	JMDN Code	Classification	Regulation	Definition	Calibration reference materials supplier
Immunological test reagents	Infectious disease (non-viral) related test	Chlamydia antigen Chlamydia trachomatis antigen	Chlamydia antigen kit	30676000	Ⅲ	Approval	A kit for measurement or detection of Chlamydia antigen (Chlamydia trachomatis antigen), using specimens of biological origin. It is mainly used to provide information for the diagnosis of Chlamydia trachomatis infection.	
		Chlamydia trachomatis DNA Chlamydia trachomatis ribosome RNA Chlamydia pneumoniae DNA	Chlamydia nucleic acid kit	30677000	Ⅲ		A kit for measurement or detection of Chlamydia nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Chlamydia trachomatis infection.	
		Chlamydia trachomatis antibody Chlamydia psittaci CF antibody titre	Chlamydia antibody kit	30678000	Ⅲ	Approval	A kit for measurement or detection of Chlamydia antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Chlamydia trachomatis or Chlamydia psittaci infection.	
		Chlamydia trachomatis IgG antibody Chlamydia pneumoniae IgG antibody	Chlamydia immunoglobulin G kit	30680000	Ⅲ	Approval	A kit for measurement or detection of Chlamydia immunoglobulin G, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Chlamydia trachomatis or Chlamydia pneumoniae infection.	
		Chlamydia trachomatis IgA antibody Chlamydia pneumoniae IgA antibody	Chlamydia immunoglobulin A kit	30679000	Ⅲ	Approval	A kit for measurement or detection of Chlamydia immunoglobulin A, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Chlamydia trachomatis or Chlamydia pneumoniae infection.	
		Chlamydia trachomatis IgM antibody Chlamydia pneumoniae IgM antibody	Chlamydia immunoglobulin M kit	30681000	Ⅲ	Approval	A kit for measurement or detection of Chlamydia immunoglobulin M, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Chlamydia trachomatis or Chlamydia pneumoniae infection.	
		Antistreptolysin O (ASO) antibody titre	Antistreptolysin O antibody kit	37756000	Ⅲ	Approval	A kit for measurement or detection of antistreptolysin-O antibody titre, using specimens of biological origin. It is mainly used to provide information for the diagnosis of group A beta-hemolytic streptococcal (group A hemolytic streptococcal) infection.	
		Antistreptokinase (ASK) antibody titre	Antistreptokinase antibody kit	30493000	Ⅲ	Approval	A kit for measurement or detection of antistreptokinase antibody titre, using specimens of biological origin. It is mainly used to provide information for the diagnosis of infection with hemolytic streptococcus groups.	
		Group A streptococcus polysaccharide antibody (ASP) titre	Group A streptococcus polysaccharide antibody titre kit	44024000	Ⅲ	Approval	A kit for measurement or detection of group A streptococcus polysaccharide antibody titre, using specimens of biological origin. It is mainly used to provide information for the diagnosis of group A streptococcal infection.	

Antistreptococcal DNase-B antibody	Antistreptococcal DNase-B antibody kit	30491000	III	Approval	A kit for measurement or detection of antistreptococcal DNase-B antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of streptococcal infection.	
Antistreptococcal hyaluronidase antibody	Antistreptococcal hyaluronidase antibody kit	30492000	III	Approval	A kit for measurement or detection of antistreptococcal hyaluronidase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of streptococcal infection.	
Group A β-hemolytic streptococcus antigen Group A streptococcus	Group A beta-hemolytic streptococcus antigen kit	44031000	III	Approval	A kit for measurement or detection of group A beta-hemolytic streptococcus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of group A streptococcal infection.	
Gonococcus antigen	Gonococcus antigen kit	30682000	III	Approval	A kit for measurement or detection of gonococcus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of gonococcal infection.	
Gonococcus DNA Neisseria gonorrhoeae ribosome RNA	Gonococcus nucleic acid kit	30683000	III		A kit for measurement or detection of gonococcal nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of gonococcal infection.	
Endotoxin	Endotoxin kit	42947000	III	Approval	A kit for measurement or detection of endotoxin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of severe Gram-negative bacterial infection. In some cases, it is also used to provide information for the diagnosis of various diseases that indicate the condition of endotoxemia.	
Salmonella antibody titre Widal reaction	Salmonella antibody kit	44028000	III	Approval	A kit for measurement or detection of Salmonella antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Salmonella infection.	
Bordetella pertussis antigen Serotype of Bordetella pertussis phase I organism	Bordetella pertussis antigen kit	37723000	III	Approval	A kit for measurement or detection of Bordetella pertussis antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Bordetella pertussis infection.	
Bordetella pertussis antibody Bordetella pertussis agglutinin titre	Bordetella pertussis antibody kit	44021000	III	Approval	A kit for measurement or detection of Bordetella pertussis antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Bordetella pertussis infection.	
Helicobacter pylori	Helicobacter pylori antigen kit	30689000	III	Approval	A kit for measurement or detection of Helicobacter pylori antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Helicobacter pylori infection. In some case, it is also used for determination after bacterial eradication.	
Helicobacter pylori urease	Helicobacter pylori urease kit	44204000	III	Approval	A kit for measurement or detection of urease produced by Helicobacter pylori bacteria, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Helicobacter pylori infection. In some case, it is also used for determination of bacterial eradication after infection.	
Helicobacter pylori antibody Helicobacter pylori IgG antibody	Helicobacter pylori antibody kit	30691000	III	Approval	A kit for measurement or detection of Helicobacter pylori antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Helicobacter pylori infection. In some case, it is also used for determination of bacterial eradication after infection.	
Leptospira antibody Leptospira antigen Leptospira antibody titre	Leptospira kit	30716000	III	Approval	A kit for measurement or detection of Leptospira (antibody, antigen, and antibody titre), using specimens of biological origin. It is mainly used to provide information for the diagnosis of Leptospira infection.	
Treponema pallidum (TP) antibody	Treponemal antibody kit	30687000	III	Approval	A kit for measurement or detection of Treponema pallidum antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Treponema pallidum infection.	

Anti-TP IgM antibody	Treponemal immunoglobulin M antibody kit	44429000	III	Approval	A kit for measurement or detection of Treponemal immunoglobulin M antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Treponema pallidum infection.	
Syphilis lipid antibody Anticardiolipin antibody	Non-treponemal lipid antibody kit	32450000	III	Approval	A kit for measurement or detection of non-Treponemal lipid antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Treponema pallidum infection.	
Anti-Borrelia burgdorferi antibody	Borrelia antibody kit	30697000	III	Approval	A kit for measurement or detection of anti-Borrelia burgdorferi antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Borrelia infection.	
Mycoplasma antibody (antibody titre) Tract mycoplasma antibody (antibody titre)	Mycoplasma antibody kit	30704000	III	Approval	A kit for measurement or detection of Mycoplasma antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Mycoplasma infection.	
Clostridium difficile antigen Clostridium difficile toxin A Clostridium difficile toxin B Enterotoxin D-1 produced by Clostridium difficile	Clostridium difficile kit	30714000	III	Approval	A kit for measurement or detection of Clostridium difficile antigen, Clostridium difficile toxin A, Clostridium difficile toxin B, and enterotoxin D-1 produced by Clostridium difficile, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Clostridium difficile infection.	
Rickettsia antibody Rickettsia antigen Rickettsia antibody titre Weil-Felix test	Rickettsia kit	30717000	III	Approval	A kit for measurement or detection of Rickettsia (antibody, antigen, and antibody titre) or for Weil-Felix test, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Rickettsia infection.	
Rickettsia tsutsugamushi antigen	Rickettsia tsutsugamushi antigen kit	43250000	III	Approval	A kit for measurement or detection of Rickettsia tsutsugamushi antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Rickettsia tsutsugamushi infection.	
Rickettsia tsutsugamushi antibody Rickettsia tsutsugamushi antibody titre Rickettsia tsutsugamushi CF antibody titre	Rickettsia tsutsugamushi antibody kit	44428000	III	Approval	A kit for measurement or detection of Rickettsia tsutsugamushi antibody, Rickettsia tsutsugamushi antibody titre, and Rickettsia tsutsugamushi CF antibody titre, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Rickettsia tsutsugamushi infection.	
Cryptococcus neoformans antigen	Cryptococcus neoformans kit	37746000	III	Approval	A kit for measurement or detection of Cryptococcus neoformans antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Cryptococcus neoformans infection.	
Candida antigen	Candida kit	37748000	III	Approval	A kit for measurement or detection of Candida antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Candida infection.	
Aspergillus antigen	Aspergillus kit	37741000	III	Approval	A kit for measurement or detection of Aspergillus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Aspergillus infection.	
Toxoplasma antibody	Toxoplasma antibody kit	30816000	III	Approval	A kit for measurement or detection of Toxoplasma antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Toxoplasma infection.	
Toxoplasma antibody (IgM)	Toxoplasma immunoglobulin M kit	30818000	III	Approval	A kit for measurement or detection of Toxoplasma immunoglobulin M, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Toxoplasma infection.	

Toxoplasma antibody (IgG)	Toxoplasma immunoglobulin G kit	30817000	III	Approval	A kit for measurement or detection of Toxoplasma immunoglobulin G, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Toxoplasma infection.	
Entamoeba histolytica antibody	Entamoeba histolytica antibody kit	30819000	III	Approval	A kit for measurement or detection of Entamoeba histolytica antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Entamoeba histolytica infection.	
Mycobacterium tuberculosis complex (Mycobacterium tuberculosis) Mycobacterium avium Mycobacterium avium complex Mycobacterium intracellulare Mycobacterium tuberculosis complex (M. Tuberculosis, M. Bovis, M. BovisBCG, M. Africanum and M. Microti)	Mycobacterium nucleic acid kit	30699000	III		A kit for measurement or detection of Mycobacterium tuberculosis complex nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Mycobacterium infection due to Mycobacterium tuberculosis complex or others.	
Mycobacterium antibody Anti-TBGL antibody Anti-glicopeptidolipid (GPL) core antibody	Mycobacterium antibody kit	30700000	III	Approval	A kit for measurement or detection of Mycobacterium antibody, anti-TBGL antibody, or anti-GPL core antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Mycobacterium infection.	
Mycobacterium antigen	Mycobacterium antigen kit	84022000	III	Approval	A kit for measurement or detection of Mycobacterium antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Mycobacterium infection.	
Escherichia coli O157 antigen	Escherichia coli O157 antigen kit	44023000	III	Approval	A kit for measurement or detection of Escherichia coli O157 antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of enterohemorrhagic Escherichia coli O157 infection.	
Escherichia coli H7 antigen	Escherichia coli H7 antigen kit	44030000	III	Approval	A kit for measurement or detection of Escherichia coli H7 antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of enterohemorrhagic Escherichia coli O157 infection.	
Escherichia coli vero toxin	Escherichia coli vero toxin kit	42846000	III	Approval	A kit for measurement or detection of Escherichia coli vero toxin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of enterohemorrhagic Escherichia coli O157 infection.	
Escherichia coli O157 LPS antibody	Escherichia coli O157 LPS antibody kit	44025000	III	Approval	A kit for measurement or detection of Escherichia coli O157 LPS antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of enterohemorrhagic Escherichia coli O157 infection.	
(1→3)-β-D-glucan	(1→3)-β-D-glucan kit	43226000	III	Approval	A kit for measurement or detection of (1→3)-β-D-glucan, using specimens of biological origin. It is mainly used to provide information for the diagnosis of deep-seated fungal infection.	

Myelitis-causing bacteria Haemophilus influenzae type B, Streptococcus pneumoniae, Group A meningococcus, Group B meningococcus/E. coli K1, Group C meningococcus antigen, Haemophilus influenzae type B, Streptococcus pneumoniae, Group B Streptococcus (Streptococcus agalactiae), Neisseria meningitidis (C/W135), Neisseria meningitidis (A/Y), Neisseria meningitidis B antigen, Meningitis-causing bacteria capsular polysaccharide antigen	Meningitis-causing bacteria capsular polysaccharide antigen kit	44198000	III	Approval	A kit for measurement or detection of Meningitis-causing bacteria capsular polysaccharide antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Meningitis-causing bacterial infection.	
Streptococcus antigen (including each group)	Streptococcus antigen kit	44029000	III	Approval	A kit for measurement or detection of Streptococcus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of streptococcal infection.	
Vibrio parahaemolyticus thermostable direct hemolysin (TDH)	Vibrio parahaemolyticus thermostable direct hemolysin kit	44203000	III	Approval	A kit for measurement or detection of Vibrio parahaemolyticus thermostable direct hemolysin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Vibrio parahaemolyticus infection.	
Brucella agglutination reaction	Brucella kit	30713000	III	Approval	A kit for measurement or detection of Brucella agglutination reaction, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Brucella infection.	
Anti-Anisakis IgG/IgA antibody titre	Anti-Anisakis immunoglobulin G/immunoglobulin A antibody kit	44202000	III	Approval	A kit for measurement or detection of anti-Anisakis immunoglobulin G/immunoglobulin A antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of the parasitic Anisakis infection.	
Mycoplasma antigen (in the throat)	Mycoplasma antigen kit	30702000	III	Approval	A kit for measurement or detection of Mycoplasma antigen (in the throat), using specimens of biological origin. It is mainly used to provide information for the diagnosis of Mycoplasma infection.	
Mycobacterium leprae-specific antibody (anti-PGL antibody)	Mycobacterium leprae-specific antibody kit	44020000	III	Approval	A kit for measurement or detection of Mycobacterium leprae-specific antibody (anti-PGL antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of Mycobacterium leprae infection.	
Anti-acid fast bacteria antibody	Anti-acid fast bacteria antibody kit	44201000	III	Approval	A kit for measurement or detection of anti-acid fast bacteria antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of acid-fast bacterial infection.	
Falciparum malaria HRP-2 antigen	Falciparum malaria HRP-2 antigen kit	84005000	III	Approval	A kit for measurement or detection of Falciparum malaria HRP-2 antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Falciparum malaria infection.	

Legionella grouping Legionella antibody Legionella antigen	Legionella kit	30692000	III	Approval	A kit for measurement or detection of Legionella (group, antibody, and antigen), using specimens of biological origin. It is mainly used to provide information for the diagnosis of Legionella infection.	
Interferon-γ release assay Interferon-γ released with Mycobacterium tuberculosis-specific protein stimulation Number of T cells producing interferon-γ with Mycobacterium tuberculosis-specific protein stimulation	Interferon-γ release assay kit	84033000	III	Approval	A kit for measurement of interferon-γ released or number of T cells producing interferon-γ with Mycobacterium tuberculosis-specific protein stimulation, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Mycobacterium tuberculosis infection.	
Pneumococcus	Pneumococcus kit	84054000	III	Approval	A kit for measurement or detection of pneumococcal antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of pneumococcal infection.	
Streptococcus pneumoniae capsule antigen	Streptococcus pneumoniae capsule antigen kit	84030000	III	Approval	A kit for measurement or detection of streptococcus pneumoniae capsule antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of pneumococcal infection.	
Procalcitonin (PCT)	Procalcitonin kit	84040000	III	Approval	A kit for measurement or detection of procalcitonin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of sepsis (bacterial), and for other purposes.	
Mycoplasma DNA Mycoplasma RNA	Mycoplasma nucleic acid kit	84055000	III		A kit for measurement or detection of Mycoplasma nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Mycoplasma pneumoniae infection.	
Legionella DNA Legionella RNA	Legionella nucleic acid kit	84056000	III		A kit for measurement or detection of Legionella nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of genus Legionella bacterial infection.	
Haemophilus influenza antigen	Haemophilus influenza antigen kit	84062000	III	Approval	A kit for measurement or detection of Haemophilus influenzae antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Haemophilus influenzae infection.	
Presepsin	Presepsin kit	84070000	III	Approval	A kit for measurement or detection of presepsin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of sepsis (bacterial), and for other purposes.	
Bordetella pertussis DNA	Bordetella pertussis nucleic acid kit	84083000	III		A kit for measurement or detection of Bordetella pertussis nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Bordetella pertussis infection.	
Clostridium difficile toxin B DNA Clostridium difficile 027 strain DNA	Clostridium difficile nucleic acid kit	84085000	III		A kit for measurement or detection of Clostridium difficile nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Clostridium difficile infection.	
Trichophyton antigen	Trichophyton antigen kit	84086000	III		A kit for measurement or detection of Trichophyton antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Onychomycosis infection.	
Campylobacter antigen	Campylobacter antigen kit	84095000	III		A kit for measurement or detection of Campylobacter antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Campylobacter infection.	

		Entamoeba histolytica antigen	Entamoeba histolytica antigen kit	84114000	III		A kit for measurement or detection of Entamoeba histolytica antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Entamoeba histolytica infection.	
		Trichomonas vaginalis DNA	Trichomonas vaginalis nucleic acid kit	84122000	III		A kit for measurement or detection of trichomonas vaginalis nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of trichomonas vaginalis infection.	
		Mycoplasma genitalium DNA	Mycoplasma genitalium nucleic acid kit	84123000	III		A kit for measurement or detection of mycoplasma genitalium nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of mycoplasma genitalium infection.	

English edition of Japanese Medical Device Nomenclature (JMDN) and the definitions is arranged. These are provided for the convenience of users unfamiliar with the Japanese language. These contents are the latest and information except here will be aligned with these contents shortly. When and if any discrepancy arises between the Japanese original and its English translation, the former shall prevail.

As of May, 2022

Large classification	Middle classification	Test item	Japanese Medical Device Nomenclature (JMDN)	JMDN Code	Classification	Regulation	Definition	Calibration reference materials supplier
Immunological test reagents	Viral infectious disease test reagents	Hepatitis A virus (HAV) antibody HA antibody HAV IgG antibody	Hepatitis A virus antibody kit	30720000	Ⅲ	Approval	A kit for measurement or detection of hepatitis A virus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis A virus infection. It is also used for determination of hepatitis A virus vaccination and to monitor therapeutic effects.	
		HAV IgM antibody	Hepatitis A virus immunoglobulin M kit	30722000	Ⅲ	Approval	A kit for measurement or detection of hepatitis A virus immunoglobulin M, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis A virus infection.	
		HBc antibody	Hepatitis B virus core antibody kit	30731000	Ⅲ	Approval	A kit for measurement or detection of hepatitis B virus core antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis B virus infection.	
		HBc IgM antibody	Hepatitis B virus core immunoglobulin M kit	30733000	Ⅲ	Approval	A kit for measurement or detection of hepatitis B virus core immunoglobulin M, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis B virus infection.	
		HBe antigen	Hepatitis B virus e antigen kit	30734000	Ⅲ	Approval	A kit for measurement or detection of hepatitis B virus e antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis B virus infection.	
		HBe antibody	Hepatitis B virus e antibody kit	30737000	Ⅲ	Approval	A kit for measurement or detection of hepatitis B virus e antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis B virus infection.	
		HBe antigen and HBe antibody	Hepatitis B virus/e antigen/antibody kit	36017000	Ⅲ	Approval	A kit for measurement or detection of hepatitis B virus e antigen and hepatitis B virus e antibody, using specimens of biological origin. It is mainly to provide information for the diagnosis of hepatitis B virus infection.	
		HBs antigen	Hepatitis B virus surface antigen kit	30723000	Ⅲ	Approval	A kit for measurement or detection of hepatitis B virus surface antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis B virus infection.	
		HBs antibody	Hepatitis B virus surface antibody kit	30725000	Ⅲ	Approval	A kit for measurement or detection of hepatitis B virus surface antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis B virus infection. In some cases, it is also used for determination of hepatitis B virus vaccination and to monitor therapeutic effects.	
		Pre-S2 antigen	Hepatitis B virus pre-S2 antigen kit	44200000	Ⅲ	Approval	A kit for measurement or detection of hepatitis B virus pre-S2 antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis B virus infection.	
		Albumin receptor (HBs antigen-associated albumin receptor)	HBs antigen-associated albumin receptor kit	44199000	Ⅲ	Approval	A kit for measurement or detection of albumin receptor (HBs antigen-associated albumin receptor), using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis B virus infection.	
		Hepatitis B virus (HBV) DNA (HBV DNA precore mutation (nt1896), core promoter mutation (nt1762, 1764))	Hepatitis B virus core nucleic acid kit	30730000	Ⅲ		A kit for measurement or detection of hepatitis B virus core nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis B virus infection.	

Hepatitis C virus (HCV) nucleic acid Hepatitis C virus (HCV) RNA	Hepatitis C virus nucleic acid kit	30742000	III		A kit for measurement or detection of hepatitis C virus nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis C virus infection.	
Hepatitis C virus antigen	Hepatitis C virus antigen kit	30740000	III		A kit for measurement or detection of hepatitis C virus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis C virus infection.	
Hepatitis C virus (HCV) core protein	Hepatitis C virus core protein kit	44292000	III		A kit for measurement or detection of hepatitis C virus core protein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis C virus infection.	
Hepatitis C virus (HCV) antibody Hepatitis C virus (HCV)-related antibody	Hepatitis C virus antibody kit	30743000	III		A kit for measurement or detection of hepatitis C virus-related antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis C virus infection.	
Hepatitis C virus (HCV) antibody Hepatitis C virus (HCV)-related antibody (IgG)	Hepatitis C virus immunoglobulin G kit	30744000	III		A kit for measurement or detection of hepatitis C virus immunoglobulin G, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis C virus infection.	
Hepatitis C virus (HCV) core antibody	Hepatitis C virus core antibody kit	44324000	III		A kit for measurement or detection of hepatitis C virus core antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis C virus infection.	
Hepatitis C virus (HCV) grouping	Hepatitis C virus grouping kit	44426000	III		A kit for measurement of HCV antibody titre, using specimens of biological origin. It is mainly used for determination of hepatitis C virus grouping (group 1 or 2) and to provide information for the diagnosis of hepatitis C virus infection.	
GOR antibody	GOR antibody kit	44425000	III		A kit for measurement or detection of GOR antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis C virus infection.	
Hepatitis C virus (HCV) protein-specific antibody	Hepatitis C virus antibody confirmatory kit	30746000	III		A kit for measurement or detection of hepatitis C virus protein-specific antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis C virus infection.	
Hepatitis delta virus (HDV) antibody	Hepatitis D virus antibody kit	30750000	III		A kit for measurement or detection of hepatitis delta virus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis D virus (hepatitis delta virus) infection.	
Papillomavirus DNA	Papillomavirus nucleic acid kit	44017000	III		A kit for measurement or detection of papillomavirus nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of papillomavirus infection.	
Adenovirus Adenovirus antigen Adenovirus type 40/41 antigen Adenovirus CF antibody titre Adenovirus antibody	Adenovirus antibody kit	41274000	III	Approval	A kit for measurement or detection of adenovirus (antigen, type 40/41 antigen, CF antibody titre, and antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of adenovirus infection.	
Herpes simplex virus immunoglobulin G	Herpes simplex virus immunoglobulin G kit	30805000	III	Approval	A kit for measurement or detection of herpes simplex virus immunoglobulin G, using specimens of biological origin. It is mainly used to provide information for the diagnosis of herpes simplex virus infection.	
Herpes simplex virus immunoglobulin M	Herpes simplex virus immunoglobulin M kit	30806000	III	Approval	A kit for measurement or detection of herpes simplex virus immunoglobulin M, using specimens of biological origin. It is mainly used to provide information for the diagnosis of herpes simplex virus infection.	

Herpes simplex virus Herpes simplex virus CF antibody titre Herpes simplex virus antibody	Herpes simplex virus antibody kit	30804000	III	Approval	A kit for measurement or detection of herpes simplex virus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of herpes simplex virus infection.	
Herpes simplex virus type 1 Herpes simplex virus type 1 antibody	Herpes simplex virus type 1 kit	30802003	III	Approval	A kit for measurement or detection of herpes simplex virus type 1 antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of herpes simplex virus infection.	
Herpes simplex virus type 2 Herpes simplex virus type 2 antibody	Herpes simplex virus type 2 kit	30802013	III	Approval	A kit for measurement or detection of herpes simplex virus type 2 antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of herpes simplex virus infection.	
Varicella-zoster virus antibody	Varicella-zoster virus antibody kit	41759013	III	Approval	A kit for measurement or detection of varicella-zoster virus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of varicella-zoster virus infection.	
Varicella-zoster virus antigen	Varicella-zoster virus antigen kit	41759003	III	Approval	A kit for measurement or detection of varicella-zoster virus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of varicella-zoster virus infection.	
Varicella-zoster virus immunoglobulin G	Varicella-zoster virus immunoglobulin G kit	44016000	III	Approval	A kit for measurement or detection of varicella-zoster virus immunoglobulin G, using specimens of biological origin. It is mainly used to provide information for the diagnosis of varicella-zoster virus infection.	
Varicella-zoster virus immunoglobulin M	Varicella-zoster virus immunoglobulin M kit	44027000	III	Approval	A kit for measurement or detection of varicella-zoster virus immunoglobulin M, using specimens of biological origin. It is mainly used to provide information for the diagnosis of varicella-zoster virus infection.	
Cytomegalovirus	Cytomegalovirus antigen kit	30797000	III	Approval	A kit for measurement or detection of cytomegalovirus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of cytomegalovirus infection.	
Cytomegalovirus antibody	Cytomegalovirus antibody kit	30799000	III	Approval	A kit for measurement or detection of cytomegalovirus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of cytomegalovirus infection.	
Cytomegalovirus IgG antibody	Cytomegalovirus immunoglobulin G kit	30800000	III	Approval	A kit for measurement or detection of cytomegalovirus immunoglobulin G, using specimens of biological origin. It is mainly used to provide information for the diagnosis of cytomegalovirus infection.	
Cytomegalovirus IgM antibody	Cytomegalovirus immunoglobulin M kit	30801000	III	Approval	A kit for measurement or detection of cytomegalovirus immunoglobulin M, using specimens of biological origin. It is mainly used to provide information for the diagnosis of cytomegalovirus infection.	
EB virus antibody Antibody titre against EB virus nuclear antigen (EBNA)	Epstein-Barr virus antibody kit	30809000	III	Approval	A kit for measurement or detection of Epstein-Barr virus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Epstein-Barr virus infection.	
EB virus IgG antibody IgG antibody titre against EB virus early antigen (EA) IgG antibody titre against EB virus capsid antigen (VCA) EB virus capsid antigen (VCA) IgG antibody EB virus nuclear antigen (EBNA) IgG antibody	Epstein-Barr virus immunoglobulin G kit	84006000	III	Approval	A kit for measurement or detection of Epstein-Barr virus immunoglobulin G, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Epstein-Barr virus infection.	

EB virus IgA antibody IgA antibody titre against EB virus capsid antigen (VCA) EB virus capsid antigen (VCA) IgA antibody EB virus nuclear antigen (EBNA) IgA antibody	Epstein-Barr virus immunoglobulin A kit	84007000	III	Approval	A kit for measurement or detection of Epstein-Barr virus immunoglobulin A, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Epstein-Barr virus infection.	
EB virus IgM antibody EB virus nuclear antigen (EBNA) IgM antibody EB virus capsid antigen (VCA) IgM antibody IgM antibody titre against EB virus capsid antigen (VCA)	Epstein-Barr virus immunoglobulin M kit	33902000	III	Approval	A kit for measurement or detection of Epstein-Barr virus immunoglobulin M, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Epstein-Barr virus infection.	
Poliovirus Poliovirus antigen Poliovirus antibody	Poliovirus kit	37731000	III	Approval	A kit for measurement or detection of poliovirus (antigen and antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of poliovirus infection.	
Coxsackievirus Coxsackievirus antigen Coxsackie A virus Coxsackie B virus Coxsackie A virus antibody Coxsackie B virus antibody	Coxsackievirus kit	37729000	III	Approval	A kit for measurement or detection of coxsackievirus (antigen and antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of coxsackievirus infection.	
Echovirus Echovirus antigen	Echovirus kit	37728000	III	Approval	A kit for measurement or detection of echovirus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of echovirus infection.	
Japanese encephalitis virus antibody	Japanese encephalitis virus antibody kit	44321000	III	Approval	A kit for measurement or detection of Japanese encephalitis virus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Japanese encephalitis virus infection.	
Rubella virus antibody	Rubella virus antibody kit	30794000	III	Approval	A kit for measurement or detection of rubella virus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of rubella virus infection.	
Rubella virus IgG antibody	Rubella virus immunoglobulin G kit	30796000	III	Approval	A kit for measurement or detection of rubella virus immunoglobulin G, using specimens of biological origin. It is mainly used to provide information for the diagnosis of rubella virus infection.	
Rubella virus IgM antibody	Rubella virus immunoglobulin M kit	30795000	III	Approval	A kit for measurement or detection of rubella virus immunoglobulin M, using specimens of biological origin. It is mainly used to provide information for the diagnosis of rubella virus infection.	
Influenza A virus antigen Influenza B virus antigen Influenza virus antigen	Influenza virus kit	30813000	III	Approval	A kit for measurement or detection of influenza virus (antigen and antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of influenza virus infection.	

Influenza A virus- or influenza B virus-derived neuraminidase	Influenza A virus- or influenza B virus-derived neuraminidase kit	43228000	III	Approval	A kit for measurement or detection of influenza A virus- or influenza B virus-derived neuraminidase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of influenza virus infection.	
Parainfluenza virus antigen Parainfluenza virus antibody	Parainfluenza virus kit	32487000	III	Approval	A kit for measurement or detection of parainfluenza virus (antigen and antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of parainfluenza virus infection.	
RS (Respiratory syncytial) virus RS virus antigen RS virus antibody	RS virus kit	30814000	III	Approval	A kit for measurement or detection of RS virus (antigen and antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of RS virus infection.	
Rubeola virus Rubeola virus antigen	Rubeola virus kit	84008000	III	Approval	A kit for measurement or detection of rubeola virus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of rubeola virus infection.	
Rubeola virus antibody	Rubeola virus antibody kit	44019000	III	Approval	A kit for measurement or detection of rubeola virus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of rubeola virus infection.	
Rubeola virus IgG antibody	Rubeola virus immunoglobulin G antibody kit	84009000	III	Approval	A kit for measurement or detection of rubeola virus immunoglobulin G antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of rubeola virus infection.	
Rubeola virus IgM antibody	Rubeola virus immunoglobulin M antibody kit	84026010	III	Approval	A kit for measurement or detection of rubeola virus immunoglobulin M antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of rubeola virus infection.	
Mumps virus Mumps virus antigen Mumps virus antibody Mumps virus IgG antibody Mumps virus IgM antibody	Mumps virus kit	37740000	III	Approval	A kit for measurement or detection of mumps virus (antigen and antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of mumps virus infection.	
Human T-cell leukaemia virus I (HTLV-I) antibody	Human T-cell leukaemia virus I antibody kit	30783000	III		A kit for measurement or detection of human T-cell leukaemia virus I antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human T-cell leukaemia virus infection.	
HTLV-II antibody	Human T-cell leukaemia virus II antibody kit	30787000	III		A kit for measurement or detection of human T-cell leukaemia virus II antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human T-cell leukaemia virus infection.	
HTLV-I-specific antibody	Human T-cell leukaemia virus I antibody confirmatory kit	30784000	III		A kit for measurement or detection of human T-cell leukaemia virus I-specific antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human T-cell leukaemia virus infection.	
HTLV-II-specific antibody	Human T-cell leukaemia virus II antibody confirmatory kit	30788000	III		A kit for measurement or detection of human T-cell leukaemia virus II-specific antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human T-cell leukaemia virus infection.	
HTLV-I/II antibody	Human T-cell leukaemia virus I/II antibody kit	84010000	III		A kit for measurement or detection of human T-cell leukaemia virus I and II, and human T-cell leukaemia virus I or II antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human T-cell leukaemia virus infection.	
HIV-1 DNA HIV-1 RNA	Human immunodeficiency virus 1 nucleic acid kit	30768000	III		A kit for measurement or detection of human immunodeficiency virus 1 nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human immunodeficiency virus infection.	
HIV core antigen (p24) HIV-1 p24 antigen	Human immunodeficiency virus 1 p24 antigen kit	30775000	III		A kit for measurement or detection of human immunodeficiency virus 1 p24 antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human immunodeficiency virus infection.	

HIV-1 p24 antigen and HIV antibody	Human immunodeficiency virus 1 p24 antigen/HIV antibody kit	84011000	III		A kit for measurement or detection of human immunodeficiency virus 1 p24 antigen, and human immunodeficiency virus 1 or 2 antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human immunodeficiency virus infection.	
HIV-1 antibody	Human immunodeficiency virus 1 antibody kit	30765000	III		A kit for measurement or detection of human immunodeficiency virus 1 antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human immunodeficiency virus infection.	
HIV-2 antibody	Human immunodeficiency virus 2 antibody kit	30773000	III		A kit for measurement or detection of human immunodeficiency virus 2 antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human immunodeficiency virus infection.	
HIV-1-specific antibody	Human immunodeficiency virus 1 antibody confirmatory kit	40436000	III		A kit for measurement or detection of human immunodeficiency virus 1-specific antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human immunodeficiency virus infection.	
HIV-2-specific antibody	Human immunodeficiency virus 2 antibody confirmatory kit	84012000	III		A kit for measurement or detection of human immunodeficiency virus 2-specific antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human immunodeficiency virus infection.	
HIV antibody	Human immunodeficiency virus antibody kit	84013000	III		A kit for measurement or detection of human immunodeficiency virus 1 and 2, and human immunodeficiency virus 1 or 2 antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human immunodeficiency virus infection.	
AIDS-associated virus antibody HIV envelope antibody titre	AIDS-associated virus antibody kit	43477000	III		A kit for measurement or detection of AIDS-associated virus antibody (HIV envelope antibody titre), using specimens of biological origin. It is mainly used to provide information for the diagnosis of human immunodeficiency virus infection.	
HIV structural protein-specific antibody	HIV structural protein-specific antibody kit	43454000	III		A kit for measurement or detection of HIV structural protein-specific antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human immunodeficiency virus infection.	
Reovirus	Reovirus kit	37732000	III	Approval	A kit for measurement or detection of reovirus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of reovirus infection.	
Reovirus antibody	Reovirus antibody kit	44022000	III	Approval	A kit for measurement or detection of reovirus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of reovirus infection.	
Rotavirus antigen	Rotavirus kit	30815000	III	Approval	A kit for measurement or detection of rotavirus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of rotavirus infection.	
Rotavirus antibody	Rotavirus antibody kit	44026000	III	Approval	A kit for measurement or detection of rotavirus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of rotavirus infection.	
SV5 virus SV5 virus antigen	SV5 virus kit	43009000	III	Approval	A kit for measurement or detection of SV5 virus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of SV5 virus infection.	
SV5 virus antibody	SV5 virus antibody kit	42994000	III	Approval	A kit for measurement or detection of SV5 virus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of SV5 virus infection.	
SV41 virus SV41 antigen	SV41 virus kit	43955000	III	Approval	A kit for measurement or detection of SV41 virus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of SV41 virus infection.	
Enterovirus Enterovirus antigen	Enterovirus kit	30811000	III	Approval	A kit for measurement or detection of enterovirus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of enterovirus infection.	
Parvovirus	Parvovirus kit	38877003	III	Approval	A kit for measurement or detection of parvovirus, using specimens of biological origin. It is mainly used to provide information for the diagnosis of parvovirus infection.	
Human parvovirus B19 IgG antibody	Human parvovirus B19 immunoglobulin G antibody kit	38877013	III	Approval	A kit for measurement or detection of human parvovirus B19 immunoglobulin G antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human parvovirus infection.	
Human parvovirus IgM antibody	Human parvovirus immunoglobulin M antibody kit	38877023	III	Approval	A kit for measurement or detection of human parvovirus B19 immunoglobulin M antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human parvovirus B19 infection.	

Hepatitis virus-related test DNA polymerase	Hepatitis B virus DNA polymerase kit	43251000	III		A kit for measurement or detection of hepatitis B virus DNA polymerase, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis B virus infection.	
SARS-coronavirus RNA SARS-coronavirus-2 RNA	SARS-coronavirus nucleic acid kit	84014000	III		A kit for measurement or detection of SARS-coronavirus nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of SARS-coronavirus infection.	
Hepatitis E virus (HEV) antibody	Hepatitis E virus antibody kit	84057000	III	Approval	A kit for measurement or detection of hepatitis E virus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis E virus infection.	
Influenza A (H1N1) pdmRNA Influenza A virus RNA Influenza B virus RNA	Influenza virus nucleic acid kit	84052000	III		A kit for measurement or detection of influenza virus nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of influenza virus infection.	
Novel influenza (subtype H5) virus RNA	Novel influenza (subtype H5) virus nucleic acid kit	84044000	III		A kit for measurement or detection of novel influenza (subtype H5) virus nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of novel influenza (subtype H5) virus infection.	
Herpes simplex virus antigen	Herpes simplex virus kit	30802023	III	Approval	A kit for measurement or detection of herpes simplex virus antigen, using specimens of biological origin; typing is not available. It is mainly used to provide information for the diagnosis of herpes simplex virus infection.	
Norovirus antigen	Norovirus antigen kit	84029000	III	Approval	A kit for measurement or detection of norovirus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of norovirus infection.	
Hepatitis B virus DNA polymerase gene mutation detection	Hepatitis B virus DNA polymerase gene mutation detection kit	84032000	III		A kit for detection of gene mutations of viruses resistant to the antiviral therapeutic drug "lamivudine" against hepatitis B virus. It is mainly used to provide information for the diagnosis of hepatitis B virus (HBV) infection.	
Hepatitis B virus core-related antigen	Hepatitis B virus core-related antigen kit	84031000	III	Approval	A kit for detection or measurement of hepatitis B virus core-related antigen (HBcrAg), using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis B virus (HBV) infection to monitor therapeutic effects.	
Hepatitis B virus (HBV) DNA (surface nucleic acid, surface DNA)	Hepatitis B virus surface nucleic acid kit	84050000	III		A kit for measurement or detection of hepatitis B virus surface nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of hepatitis B virus infection.	
Hepatitis B virus (HBV) antigenic epitope	Hepatitis B virus antigenic epitope kit	84059000	III	Approval	A kit for detection or measurement of antigenic epitope, using specimens of biological origin of which hepatitis B virus antigen is positive. It is mainly used for determination of hepatitis B virus genotypes.	
Human papillomavirus nucleic acid typing	Human papillomavirus nucleic acid typing kit	84048000	III		A kit for detection and typing of human papillomavirus nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of high-risk human papillomavirus infection.	
Human metapneumovirus Human metapneumovirus antigen	Human metapneumovirus kit	84061000	III	Approval	A kit for measurement or detection of human metapneumovirus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of human metapneumovirus infection.	
Dengue virus NS1 antigen	Dengue virus NS1 antigen kit	84077000	III		A kit for measurement or detection of dengue virus NS1 antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of dengue virus infection.	
Anti-dengue virus IgG antibody Anti-dengue virus IgM antibody	Dengue virus antibody kit	84084000	III		A kit for measurement or detection of dengue virus antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of dengue virus infection.	

		Herpes simplex virus type 1 DNA, Herpes simplex virus type 2 DNA	Herpes simplex virus nucleic acid kit	84088000	III		A kit for measurement or detection of herpes simplex virus nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of herpes simplex virus infection.	
		Cytomegalovirus DNA	Cytomegalovirus nucleic acid kit	84092000	III		A kit for measurement or detection of cytomegalovirus nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of cytomegalovirus infection.	
		Zika virus RNA	Zika virus nucleic acid kit	84096000	III		A kit for measurement or detection of Zika virus nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Zika virus infection.	
		RS virus RNA	RS virus nucleic acid kit	84106000	III		A kit for measurement or detection of RS virus nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of RS virus infection.	
		Epstein-Barr virus DNA	Epstein-Barr virus nucleic acid kit	84109000	III		A kit for measurement or detection of Epstein-Barr virus nucleic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Epstein-Barr virus infection.	
		SARS-coronavirus-2 antigen	SARS-coronavirus antigen kit	84110000	III		A kit for measurement or detection of SARS-coronavirus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of SARS-coronavirus infection.	
		Ebola virus antigen	Ebola virus antigen kit	84116000	III		A kit for measurement or detection of Ebola virus antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Ebola virus infection.	

English edition of Japanese Medical Device Nomenclature (JMDN) and the definitions is arranged. These are provided for the convenience of users unfamiliar with the Japanese language. These contents are the latest and information except here will be aligned with these contents shortly. When and if any discrepancy arises between the Japanese original and its English translation, the former shall prevail.

As of May, 2022

Large classification	Middle classification	Test item	Japanese Medical Device Nomenclature (JMDN)	JMDN Code	Classification	Regulation	Definition	Calibration reference materials supplier
Immunological test reagents	Auto-immune related test reagents	Antinuclear antibody (ANA)	Antinuclear antibody kit	30454000	Ⅱ	Certification	A kit for measurement or detection of antinuclear antibody (ANA), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Anti-smooth muscle antibody	Anti-smooth muscle antibody kit	37725000	Ⅱ	Certification	A kit for measurement or detection of anti-smooth muscle antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Anti-gastric parietal cell antibody	Anti-gastric parietal cell antibody kit	37765000	Ⅱ	Certification	A kit for measurement or detection of anti-gastric parietal cell antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Antinuclear antibody (LE factor)	Antinuclear antibody/LE factor kit	84015000	Ⅱ	Certification	A kit for measurement or detection of antinuclear antibody (LE factor), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		ACA (anticentromere antibody) Antinuclear antibody (anticentromere antibody)	Antinuclear antibody/anticentromere antibody kit	44308000	Ⅱ	Certification	A kit for measurement or detection of antinuclear antibody (anticentromere antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Anti-DNA antibody Anti-deoxyribonucleic acid antibody Anti-nDNA antibody Anti-double-stranded DNA antibody, Anti-dsDNA antibody Anti-single-stranded DNA antibody, Anti-ssDNA antibody	Anti-deoxyribonucleic acid antibody kit	37724000	Ⅱ	Certification	A kit for measurement or detection of anti-deoxyribonucleic acid antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Anti-ENA antibody (anti-RNP antibody, anti-Sm antibody, anti-ss-A antibody, anti-ss-B antibody, anti-scl-70 antibody, and anti-Jo-1 antibody)	Anti-ENA antibody kit	44300000	Ⅱ	Certification	A kit for measurement or detection of anti-ENA antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Anti-Sm antibody	Anti-Sm antibody kit	84016000	Ⅱ	Certification	A kit for measurement or detection of anti-Sm antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Anti-RNP antibody	Anti-ribonucleoprotein antibody kit	33916000	Ⅱ	Certification	A kit for measurement or detection of anti-ribonucleoprotein antibody (anti-RNP antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Anti-SS-A/Ro antibody	Anti-SS-A/Ro antibody kit	43427000	Ⅱ	Certification	A kit for measurement or detection of anti-SS-A/Ro antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

Anti-SS-B antibody/La antibody	Anti-SS-B/La antibody kit	42899000	II	Certification	A kit for measurement or detection of anti-SS-B antibody/La antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anit-Scl-70 antibody Anti-scleroderma antibody	Anti-Scl-70 antibody kit	30463000	II	Certification	A kit for measurement or detection of anti-Scl-70 antibody (anti-scleroderma antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Rheumatoid factor (RF) Rheumatoid-like factor	Rheumatoid factor kit	30500000	II	Certification	A kit for measurement or detection of rheumatoid factor, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
IgG rheumatoid factor (IgG-RF)	Immunoglobulin G rheumatoid factor kit	44310000	II	Certification	A kit for measurement or detection of immunoglobulin G rheumatoid factor, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-agalactyl IgG antibody	Anti-agalactyl immunoglobulin G antibody kit	44385000	II	Certification	A kit for measurement or detection of anti-agalactosyl immunoglobulin G antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Antimitochondrial antibody	Antimitochondrial antibody kit	30476000	II	Certification	A kit for measurement or detection of antimitochondrial antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Antimitochondrial antibody M2	Antimitochondrial antibody M2 kit	43106000	II	Certification	A kit for measurement or detection of antimitochondrial antibody M2, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-thyroglobulin antibody (TgAb) Anti-thyroglobulin (ATG) antibody titre Thyroid autoantibody level	Thyroglobulin autoantibody kit	30490000	II	Certification	A kit for measurement or detection of thyroglobulin autoantibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-thyroid microsomal (AMC) antibody	Thyroid microsomal antibody kit	30488000	II	Certification	A kit for measurement or detection of anti-thyroid microsomal antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-thyroid peroxidase antibody (Anti-TPO antibody)	Thyroid peroxidase antibody kit	30317000	II	Certification	A kit for measurement or detection of anti-thyroid peroxidase antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
TSH receptor antibody	Thyroid stimulating hormone receptor antibody kit	30489000	II	Certification	A kit for measurement or detection of thyroid stimulating hormone receptor antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Thyroid-stimulating autoantibody Thyroid-stimulating autoantibody (TSAb) activity	Thyroid-stimulating autoantibody kit	84017000	II	Certification	A kit for measurement or detection of thyroid-stimulating autoantibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Acetylcholine receptor antibody	Acetylcholine receptor antibody kit	43074000	II	Certification	A kit for measurement or detection of acetylcholine receptor antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anticardiolipin antibody	Anticardiolipin antibody kit	30475000	II	Certification	A kit for measurement or detection of anticardiolipin antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anticardiolipin-β2-glycoprotein I complex antibody	Anticardiolipin-beta2-glycoprotein I complex antibody kit	43075000	II	Certification	A kit for measurement or detection of anticardiolipin-β2-glycoprotein I complex antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Platelet antibody (PLTAb)	Platelet antibody kit	43105000	II	Certification	A kit for measurement or detection of platelet antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

ANCA Cytoplasmic antineutrophil cytoplasmic antibody titer Antineutrophil cytoplasmic antibody (c-ANCA) Anti-PR-3 antibody (c-ANCA)	Proteinase 3-antineutrophil cytoplasmic autoantibody kit	30484000	II	Certification	A kit for measurement or detection of proteinase 3-antineutrophil cytoplasmic autoantibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
MPT-ANCA (myeloperoxidase antineutrophil cytoplasmic antibody)	Myeloperoxidase antineutrophil cytoplasmic autoantibody kit	30483000	II	Certification	A kit for measurement or detection of myeloperoxidase antineutrophil cytoplasmic autoantibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Immune complex (IC) C1q binding immune complex (IC) C3d binding immune complex	Circulating immune complex kit	30498000	II	Certification	A kit for measurement or detection of immune complex, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-Jo-1 antibody	Anti-Jo-1 antibody kit	30461000	II	Certification	A kit for measurement or detection of anti-Jo-1 antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-glutamic acid decarboxylase antibody (GAD) Anti-islet cell antibody	Anti-glutamic acid decarboxylase antibody/anti-islet cell antibody kit	30340000	II	Certification	A kit for measurement or detection of anti-glutamic acid decarboxylase antibody or anti-islet cell antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Lupus anticoagulant	Lupus anticoagulant kit	30587000	II	Certification	A kit for measurement or detection of lupus anticoagulant, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-GBM antibody (Anti-glomerular basement membrane antibody)	Anti-GBM antibody kit	43128000	II	Certification	A kit for measurement or detection of anti-GBM antibody (anti-glomerular basement membrane antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-liver-kidney microsome 1 antibody (liver-kidney microsome antibody, anti-LKM-1 antibody)	Anti-LKM-1 antibody kit	84018000	II	Certification	A kit for measurement or detection of anti-LKM-1 antibody (anti-liver-kidney microsome 1 antibody), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-desmoglein-1 antibody Anti-desmoglein-3 antibody	Anti-desmoglein antibody kit	84019000	II	Certification	A kit for measurement or detection of anti-desmoglein-1 antibody or anti-desmoglein-3 antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Insulin antibody	Insulin antibody kit	84023000	II	Certification	A kit for measurement or detection of insulin antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-IA-2 antibody	Anti-IA-2 antibody kit	84024000	II	Certification	A kit for measurement or detection of anti-IA-2 antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
TSH receptor antibody	Thyroid stimulating hormone receptor antibody kit for blood test	30489001	I	Self-declaration	A kit for measurement or detection of thyroid stimulating hormone receptor antibody, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC

Anti-thyroid peroxidase antibody (Anti-TPO antibody)	Thyroid peroxidase antibody kit for blood test	30317001	I	Self-declaration	A kit for measurement or detection of anti-thyroid peroxidase antibody, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
Anti-thyroglobulin antibody (TgAb) Anti-thyroglobulin (ATG) antibody titre Thyroid autoantibody level	Thyroglobulin autoantibody kit for blood kit	30490001	I	Self-declaration	A kit for measurement or detection of thyroglobulin autoantibody, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
Anti-GM1 IgG antibody	IgG anti-GM1 antibody kit	84037000	II	Certification	A kit for detection of anti-GM1 IgG antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Guillain-Barre syndrome.	
Anti-GQ1b IgG antibody	IgG anti-GQ1b antibody kit	84038000	II	Certification	A kit for detection of anti-GQ1b IgG antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Fisher syndrome.	
Anti-BP180NC16a antibody	Anti-BP180NC16a antibody kit	84036000	II	Certification	A kit for measurement or detection of anti-BP180NC16a antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of bullous pemphigoid and for other purposes.	
Antibody against citrullinated antigens	Antibody kit against citrullinated antigens	84035000	II	Certification	A kit for measurement or detection of antibodies against citrullinated antigens, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-RNA polymerase III antibody	Anti-RNA polymerase III antibody kit	84049000	II	Certification	A kit for measurement or detection of anti-RNA polymerase III antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-epidermal basement membrane zone antibody	Anti-epidermal basement membrane zone antibody kit	84066000	II	Certification	A kit for measurement or detection of anti-epidermal basement membrane zone antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of bullous pemphigoid and for other purposes.	
Anti-platelet factor-4/heparin complex IgG, IgM, and IgA antibody Anti-platelet factor-4/heparin complex IgG antibody	Platelet factor-4/heparin complex antibody kit	84067000	II	Certification	A kit for measurement or detection of anti-platelet factor-4/heparin complex IgG, IgM, and IgA antibody, or anti-platelet factor-4/heparin complex IgG antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Antiribosomal P antibody	Antiribosomal P antibody kit	84064000	II	Certification	A kit for measurement or detection of antiribosomal P antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-aquaporin 4 antibody	Anti-aquaporin 4 antibody kit	84065000	II	Certification	A kit for measurement or detection of anti-aquaporin 4 antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-muscle-specific tyrosine kinase antibody (Anti-MuSK antibody)	Anti-muscle-specific tyrosine kinase antibody kit	84071000	II	Certification	A kit for measurement or detection of anti-muscle-specific tyrosine kinase antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-ARS antibody (anti-Jo-1, anti-PL-7, anti-PL-12, anti-EJ, and anti-KS antibodies)	Anti-ARS antibody kit	84074000	II		A kit for measurement or detection of anti-ARS antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-MDA5 antigen	Anti-MDA5 antigen kit	84079000	II		A kit for measurement or detection of anti-MDA5 antigen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Anti-TIF1-γ antibody	Anti-TIF1-gamma antibody kit	84080000	II		A kit for measurement or detection of anti-TIF1-γ antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

Immunohematological test	Anti-Mi-2 antibody	Anti-Mi-2 antibody kit	84081000	II		A kit for measurement or detection of anti-Mi-2 antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Anti-β2-glycoprotein I antibody	Anti-beta2-glycoprotein I antibody kit	84100000	II		A kit for measurement or detection of anti-β2-glycoprotein I antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Anti-calcium channel antibody	Anti-calcium channel antibody kit	84105000	II		A kit for measurement or detection of anti-calcium channel antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Blood group ABO	ABO blood group kit	30597000	III	Approval	A kit for determination of blood group ABO, using specimens of biological origin. ABO blood group kit is mainly used for mandatory testing at a blood transfusion or for other purposes.	
	Rh (factor D, E, e, C, c) blood group Blood type Rho (D, E, e, C, c) group Blood group Rh-Hr	Rh blood group kit	30598000	III	Approval	A kit for determination of Rh (factor D, E, e, C, c) blood group, using specimens of biological origin. Rh blood group kit is mainly used for mandatory testing at a blood transfusion or for other purposes.	
	A-transferase activity and B-transferase activity	A-transferase activity and B-transferase activity kit	43108000	II	Certification	A kit for measurement or detection of A-transferase activity and B-transferase activity, using specimens of biological origin. A-transferase activity and B-transferase activity kit is mainly used for testing at a blood transfusion or for other purposes.	
	Coombs' test (antiglobulin test)	Coombs' test kit	43111000	III	Approval	A kit for Coombs' test (direct or indirect Coombs' test), using specimens of biological origin. It is mainly used for testing at a blood transfusion or for other purposes.	
	Irregular antibody detection/identification	Irregular antibody detection/identification kit	43113000	III	Approval	A kit for irregular antibody detection/identification, using specimens of biological origin. It is mainly used for testing at a blood transfusion or for other purposes.	
	HLA-A,B,C HLA class I Human leukocyte antigen type	Human leukocyte antigen determination kit	30608000	III	Approval	A kit for determination of HLA-A, B, C, HLA class I, and human leukocyte antigen type, using specimens of biological origin. It is mainly used for consideration of histocompatibility in relation to organ transplantation or for other purposes.	
	HLA class II DNA type of HLA-DR Human leukocyte antigen type	Human leukocyte antigen class II determinant antibody kit	30612000	III	Approval	A kit for determination of HLA class II, DNA type of HLA-DR, and human leukocyte antigen type, using specimens of biological origin. It is mainly used for consideration of histocompatibility in relation to organ transplantation or for other purposes.	
	Lymphoblastogenetic ability	Lymphoblastogenetic ability kit	84020000	II	Certification	A kit for measurement or detection of lymphoblastogenetic ability, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	B cell/B lymphocyte (CD19, CD20, CD22, HLA-DR, etc.)	B cell kit	43047000	II	Certification	A kit for analysis, measurement, or detection of B cells, etc., using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

	Activated T cell (HLA-DR, etc.) E-rosette forming T cell (CD2, etc.) Cytotoxic/suppressor T cell (CD3, CD4, CD8, etc.) Helper-inducer T cell (CD4, etc.) T cell subset (CD11b, CD62L, etc.)	T cell subset kit	43098000	II	Certification	A kit for analysis, measurement, or detection of T cell subsets, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	NK cell (CD56, CD57, CD16, etc.)	NK cell kit	43062000	II	Certification	A kit for analysis, measurement, or detection of NK cells, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Monocyte (CD14, CD15, etc.)	Monocyte kit	43055000	II	Certification	A kit for analysis, measurement, or detection of monocytes, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Leukocyte (CD45, etc.)	Leukocyte kit	43052000	II	Certification	A kit for analysis, measurement, or detection of leukocytes, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Platelet (CD61, etc.)	Platelet kit	84025000	II	Certification	A kit for analysis, measurement, or detection of platelet antigens, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Cell cycle (BrdU, etc.)	Cell cycle kit	43086000	II	Certification	A kit for analysis, measurement, or detection of cell cycle, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Common acute lymphoblastic leukaemia antigen (CALLA)-expressing cell (CD10, etc.)	CALLA-expressing cell kit	43092000	II	Certification	A kit for analysis, measurement, or detection of CALLA (common acute lymphoblastic leukaemia antigen)-expressing cells, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Thymocyte (CD1a, etc.)	Thymocyte kit	43059000	II	Certification	A kit for analysis, measurement, or detection of thymocytes, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	LeY-expressing lymphocyte (LeY, etc.)	LeY-expressing lymphocyte kit	43096000	II	Certification	A kit for analysis, measurement, or detection of LeY-expressing lymphocytes, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Granulocyte (CD15, etc.)	Granulocyte kit	43068000	II	Certification	A kit for analysis, measurement, or detection of granulocytes, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Pan T cell	Pan T cell kit	43083000	II	Certification	A kit for analysis, measurement, or detection of pan T cells, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Pan B cell	Pan B cell kit	43084000	II	Certification	A kit for analysis, measurement, or detection of pan B cells, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Reagents for cytokine measurements	Soluble interleukin-2 receptor	IL-1a/IL1b/IL1RA/IL2r/IL6r kit	30619000	II	Certification	A kit for measurement or detection of soluble interleukin-2 receptor, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Hepatocyte growth factor	Hepatocyte growth factor kit	43072000	II	Certification	A kit for measurement or detection of hepatocyte growth factor, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Neopterine	Neopterine kit	30371000	II	Certification	A kit for measurement or detection of neopterine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

	Human TARC	Th2 chemokine/TARC kit	84043000	II	Certification	A kit for measurement or detection of human TARC (Th2 chemokine), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Placental growth factor (PIGF)	PIGF kit	84102000	III		A kit for measurement or detection of placental growth factor (PIGF), using specimens of biological origin. It is mainly used to provide information for predicting the short-term onset of preeclampsia (PE) in high-risk pregnant women.	
	Soluble fms-like tyrosine kinase-1 (sFlt-1)	sFlt-1 kit	84101000	III		A kit for measurement or detection of placental growth factor (PIGF), using specimens of biological origin. It is mainly used to provide information for predicting the short-term onset of preeclampsia (PE) in high-risk pregnant women.	
	Interleukin-6 (IL-6)	Interleukin-6 kit	84112000	III		A kit for measurement or detection of interleukin-6 (IL-6), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases.	
	Interferon-λ3 (IFN-λ3)	Interferon-lambda3 kit	84115000	III		A kit for measurement or detection of interferon-λ3 (IFN-λ3), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases.	
	Vascular endothelial growth factor (VEGF)	Vascular endothelial growth factor kit	84117000	III		A kit for measurement or detection of vascular endothelial growth factor (VEGF) using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases.	
	Growth differentiation factor 15 (GDF15)	Growth differentiation factor 15 (GDF15) kit	84124000	II		A kit for measurement or detection of growth differentiation factor 15(GDF15) using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
Other immunologic al test reagents	Eosinophil basic protein	Eosinophil basic protein kit	43419000	II	Certification	A kit for measurement or detection of eosinophil basic protein, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Pepsinogen I Pepsinogen II	Pepsinogen kit	30373000	II	Certification	A kit for measurement or detection of pepsinogen I or pepsinogen II, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	KRAS gene mutation determination	KRAS gene mutation detection kit	84053000	III		A kit for measurement or detection of KRAS gene mutation, using specimens of biological origin. It is mainly used to provide information for the determination of KRAS gene mutation.	
	Liver cytochrome p450 genotyping (CYP2D6, CYP2C19, etc.)	Cytochrome p450 (CYP) genotyping kit	84047000	III		A kit for analysis of the genotype of liver cytochrome p450 (CYP450), a drug-metabolizing enzyme, using specimens of biological origin. It is mainly used to provide information for predicting the drug-metabolizing enzyme activity.	
	EGFR gene mutation determination	EGFR gene mutation detection kit	84063000	III		A kit for detection of EGFR gene mutation, using specimens of biological origin. It is mainly used to provide information for the determination of EGFR gene mutation. In some cases, it is also used to provide information for the determination of indications for EGFR tyrosine kinase inhibitors.	
	Anti-Trichosporon asahii antibody	Anti-Trichosporon asahii antibody kit	84069000	III	Approval	A kit for measurement or detection of anti-Trichosporon asahii antibody, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	BRAF gene mutation	BRAF gene mutation detection kit	84075000	III		A kit for detection of BRAF gene mutation, using specimens of biological origin. It is mainly used to provide information for the determination of indications for BRAF inhibitors and in the diagnosis/treatment selection for malignant tumors by detection of BRAF gene mutation.	
	RAS gene mutation	RAS gene mutation detection kit	84076000	III		A kit for detection of RAS (KRAS and NRAS) gene mutation, using specimens of biological origin. It is mainly used to provide information for the determination of RAS gene mutation.	
	Neutrophil gelatinase-associated lipocalin (NGAL)	Neutrophil gelatinase-associated lipocalin kit	84078000	II		A kit for measurement or detection of neutrophil gelatinase-associated lipocalin (NGAL), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

		Calprotectin	Calprotectin kit	84089000	II		A kit for measurement or detection of calprotectin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		ROS1 gene fusions mRNA	ROS1 gene fusion detection kit	84090000	III		A kit for detection of ROS1 gene fusion, using specimens of biological origin. It is mainly used to provide information for the determination of indications for ALK inhibitors.	
		Microsatellite instability	Microsatellite instability detection kit	84099000	III		A kit for detection of microsatellite instability, using specimens of biological origin. It is mainly used to provide information for the determination of indications for immune checkpoint inhibitors.	
		FLT3 gene mutation	FLT3 gene mutation detection kit	84098000	III		A kit for detection of FLT3 gene mutation, using specimens of biological origin. It is mainly used to provide information for the determination of indications for FLT3 inhibitors.	
		Squamous cell carcinoma antigen 2 (SCCA2)	SCCA2 kit	84103000	II		A kit for measurement or detection of SCCA2(SERPIN B4), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Cochlin-tomoprotein (CTP)	CTP kit	84107000	II		A kit for measurement or detection of CTP (Cochlin-tomoprotein), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Anti-Adeno-Associated virus 9 (AAV9) antibody	Anti-AAV antibody kit	84108000	III		A kit for measurement or detection of Anti-Adeno-Associated virus (AAV) antibody, using specimens of biological origin. It is mainly used to provide information for the determination of indications for AAV-based gene therapy products.	
		Copy number mutation, loss of heterozygosity	Chromosomal mutation analysis kit	84113000	III		A kit for analysis, measurement or detection of chromosomal copy number mutations and loss of heterozygosity, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		EZH2 gene mutation	EZH2 gene mutation detection kit	84118000	III		A kit for detection of EZH2 gene mutation, using specimens of biological origin. It is mainly used to provide information for the determination of indications for EZH2 inhibitors.	
		MET gene mutation	MET gene mutation detection kit	84120000	III		A kit for detection of MET gene mutation, using specimens of biological origin. It is mainly used to provide information for the determination of indications for MET inhibitors.	
		Y-chromosome microdeletion	Y-chromosome microdeletion detection kit	84126000	III		A kit for detection of Y-chromosome microdeletion, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases.	

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As of May, 2022

Large classification	Middle classification	Test item	Japanese Medical Device Nomenclature (JMDN)	JMDN Code	Classification	Regulation	Definition	Calibration reference materials supplier
Endocrinological test reagents	Reagents for hypothalamus/pituitary gland hormone measurements	Human growth hormone (HGH) Growth hormone (GH)	Human growth hormone kit for blood test	30358001	I	Self-declaration	A kit for measurement or detection of human growth hormone, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC, JPC
		Insulin-like growth factor I (IGF-1) Somatomedin C	Insulin-like growth factor I kit	30359000	II	Certification	A kit for measurement or detection of insulin-like growth factor I (somatomedin C), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Human insulin-like growth factor binding protein 1 (IGFBP-1) Insulin-like growth factor binding protein 1 (IGFBP-1)	Insulin-like growth factor binding protein 1 kit	30361000	II	Certification	A kit for measurement or detection of insulin-like growth factor binding protein 1, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Insulin-like growth factor binding protein 3 (IGFBP-3)	Insulin-like growth factor binding protein 3 kit	30362000	II	Certification	A kit for measurement or detection of insulin-like growth factor binding protein 3, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Prolactin (PRL) Human prolactin (PRL)	Prolactin kit	30325000	II	Certification	A kit for measurement or detection of prolactin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Adrenocorticotrophic hormone (ACTH) Human adrenocorticotrophic hormone (ACTH)	Adrenocorticotrophic hormone kit	30357000	II	Certification	A kit for measurement or detection of adrenocorticotrophic hormone, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
		Luteinizing hormone (LH) Human luteinizing hormone (LH)	Luteinizing hormone kit for blood test	38246001	I	Self-declaration	A kit for measurement or detection of luteinizing hormone, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
		Luteinizing hormone (LH) Human luteinizing hormone (LH)	Luteinizing hormone self-test kit	30515003	III	Approval	A kit for measurement or detection of luteinizing hormone by patients themselves, using specimens of biological origin. It is mainly used for follow-up of diseases.	
		Estrone-3-glucuronide (E3G)	Estrone-3-glucuronide self-test kit	43148003	III	Approval	A kit for measurement or detection of estrone-3-glucuronide by patients themselves, using specimens of biological origin. It is mainly used for follow-up of diseases.	
		Follicle stimulating hormone (FSH)	Follicle stimulating hormone kit for blood test	30322001	I	Self-declaration	A kit for measurement or detection of follicle stimulating hormone, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
		Arginine vasopressin (AVP)	Arginine vasopressin kit	44329000	II	Certification	A kit for measurement or detection of arginine vasopressin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

Reagents for thyroid/parathyroid hormone measurements	Prolactin (PRL) Human prolactin (PRL)	Prolactin kit for blood test	30325001	I	Self-declaration	A kit for measurement or detection of prolactin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
	Thyroid stimulating hormone (TSH) Human thyroid stimulating hormone (TSH)	Thyroid stimulating hormone kit	30318000	I	Self-declaration	A kit for measurement or detection of thyroid stimulating hormone, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
	Triiodothyronine (T ₃)	Triiodothyronine kit	30312000	I	Self-declaration	A kit for measurement or detection of triiodothyronine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	USP, IRMM
	Free triiodothyronine (FT ₃) Free T3 (FT3)	Free triiodothyronine kit	30308000	I	Self-declaration	A kit for measurement or detection of free triiodothyronine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	USP, IRMM
	Triiodothyronine uptake (T3-uptake) T3 uptake	Triiodothyronine uptake kit	30313000	II	Certification	A kit for measurement of triiodothyronine uptake, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Thyroxine (T ₄)	Thyroxine kit	30314000	I	Self-declaration	A kit for measurement or detection of thyroxine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	USP, IRMM
	Free thyroxine (FT ₄)	Free thyroxine kit	30309000	I	Self-declaration	A kit for measurement or detection of free thyroxine, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	USP, IRMM
	Thyroglobulin (Tg)	Thyroglobulin kit	30315000	I	Self-declaration	A kit for measurement or detection of thyroglobulin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
	Thyroxine binding globulin (TBG) Human thyroxine binding globulin (TBG)	Thyroxine binding globulin kit	30316000	II	Certification	A kit for measurement or detection of thyroxine binding globulin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Thyroxine binding capacity (TBC)	Thyroxine binding capacity kit	43297000	II	Certification	A kit for measurement or detection of thyroxine binding capacity, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Parathyroid hormone (PTH) Parathyroid hormone fragment (PTH-C) Parathyroid hormone fragment (PTH-M)	Parathyroid hormone kit	30354000	II	Certification	A kit for measurement or detection of parathyroid hormone or parathyroid hormone fragment, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Parathyroid hormone intact (PTH-I)	Parathyroid hormone intact kit	30353000	II	Certification	A kit for measurement or detection of parathyroid hormone intact, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Parathyroid hormone-related peptide (PTHrP)	Parathyroid hormone-related peptide kit	30355000	II	Certification	A kit for measurement or detection of parathyroid hormone-related peptide, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Calcitonin	Calcitonin kit	30342000	II	Certification	A kit for measurement or detection of calcitonin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

Reagents for gastrointestinal hormone measurements	Insulin (IRI : immunoreactive insulin)	Insulin kit	30338000	I	Self-declaration	A kit for measurement or detection of insulin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC, JP
	C-peptide (CPR : connecting peptide immunoreactivity)	C-peptide kit for blood test	30336001	I	Self-declaration	A kit for measurement or detection of C-peptide, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
	Glucagon	Glucagon kit	30337000	I	Self-declaration	A kit for measurement or detection of glucagon, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC, USP
	Gastrin	Gastrin kit	42862000	II	Certification	A kit for measurement or detection of gastrin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Secretin	Secretin kit	44239000	II	Certification	A kit for measurement or detection of secretin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Proinsulin	Proinsulin kit	42852000	I	Self-declaration	A kit for measurement or detection of proinsulin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
Reagents for corticosteroid measurements	17-ketosteroid (17-KS)	17-ketosteroid kit	30369000	II	Certification	A kit for measurement or detection of 17-ketosteroid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	17-hydroxycorticosteroid (17-OHCS)	17-hydroxycorticosteroid kit	33238000	II	Certification	A kit for measurement or detection of 17-hydroxycorticosteroid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Cortisol	Cortisol kit for blood test	43259000	I	Self-declaration	A kit for measurement or detection of cortisol, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM
	Dehydroepiandrosterone (DHEA)	Dehydroepiandrosterone kit	30320000	II	Certification	A kit for measurement or detection of dehydroepiandrosterone, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Dehydroepiandrosterone-sulfate (DHEA-S)	Dehydroepiandrosterone-sulfate kit	43159000	II	Certification	A kit for measurement or detection of dehydroepiandrosterone-sulfate, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Aldosterone (ALD)	Aldosterone kit	31428000	II	Certification	A kit for measurement or detection of aldosterone, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Androstenedione	Androstenedione kit	30319000	II	Certification	A kit for measurement or detection of androstenedione, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Aldosterone	Aldosterone kit for blood test	85008000	I	Self-declaration	A kit for measurement or detection of aldosterone, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NMIJ
Reagents for adrenal medullary hormone measurements	Catecholamine	Catecholamine kit	30440000	II	Certification	A kit for measurement or detection of catecholamine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

Reagents for gonadal hormone measurements	Homovanillic acid (HVA)	Homovanillic acid kit	43149000	II	Certification	A kit for measurement or detection of homovanillic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Vanilmandelic acid (VMA)	Vanilmandelic acid kit for blood test	30453001	I	Self-declaration	A kit for measurement or detection of vanilmandelic acid, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIST
	Free metanephrine, free normetanephrine	Free metanephrine 2 fractions kit	85005000	II		A kit for measurement or detection of free metanephrine 2 fractions (free metanephrine, free normetanephrine), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Oestrogen	Oestrogen kit	33293000	II	Certification	A kit for measurement or detection of oestrogen, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Oestrinol (E ₃) Total oestrinol (E ₃)	Oestrinol kit for blood test	30329001	I	Self-declaration	A kit for measurement or detection of oestrinol, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	USP, JP
	Estriol-16 α -glucuronide (E ₃ -16G)	Estriol-16- α -glucuronide kit	43443000	II	Certification	A kit for measurement or detection of estriol-16 α -glucuronide, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Oestradiol (E ₂)	Oestradiol kit	30321000	I	Self-declaration	A kit for measurement or detection of oestradiol, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM, JPC
	Oestrone (E1)	Oestrone kit	30331000	II	Certification	A kit for measurement or detection of oestrone, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Progesterone (P ₄)	Progesterone kit	30323000	I	Self-declaration	A kit for measurement or detection of progesterone, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	IRMM, USP, JP
	17 α -hydroxyprogesterone (17 α -OHP)	17-hydroxyprogesterone kit	30324000	II	Certification	A kit for measurement or detection of 17 α -hydroxyprogesterone, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Testosterone	Testosterone kit for blood test	30327001	I	Self-declaration	A kit for measurement or detection of testosterone, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	USP
	Free testosterone	Free testosterone kit	30327002	II	Certification	A kit for measurement or detection of free testosterone, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Human chorionic gonadotropin (HCG) Total human chorionic gonadotropin (HCG)	Human chorionic gonadotropin kit for blood test	30332001	I	Self-declaration	A kit for measurement or detection of human chorionic gonadotropin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC, JP
	Human chorionic gonadotropin β -subunit (β -HCG), Beta-human chorionic gonadotropin (β -HCG)	Beta-human chorionic gonadotropin kit for blood test	30333001	I	Self-declaration	A kit for measurement or detection of beta-human chorionic gonadotropin, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
	Human chorionic gonadotropin β -subunit core (HCG β -core)	Human chorionic gonadotropin beta-subunit core kit	43456000	III	Approval	A kit for measurement or detection of human chorionic gonadotropin β -subunit core, using specimens of biological origin. It is mainly used to provide information for the diagnosis of produced tumors by measurement or detection of human chorionic gonadotropin β -subunit core.	

Other endocrinological test reagents	Human placental lactogen (HPL) Placental lactogen (HPL)	Human placental lactogen kit	30334000	I	Self-declaration	A kit for measurement or detection of human placental lactogen, using blood (serum, plasma, or whole blood) specimens. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	NIBSC
	Pregnanediol-3 α -glucuronide (Pd-3G)	Pregnanediol-3 α -glucuronide kit	85001000	II	Certification	A kit for measurement or detection of pregnanediol-3 α -glucuronide, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Anti-Müllerian hormone (AMH)	Anti-Müllerian hormone kit	85004000	II	Certification	A kit for measurement or detection of anti-Müllerian hormone, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and the prediction of the method for treating controlled ovarian stimulation (COS) or the degree of its effects.	
	Plasma renin activity (PRA)	Renin kit	43444000	II	Certification	A kit for measurement or detection of renin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Total renin concentration (TRC) Angiotensin I/renin	Angiotensin I/renin kit	31410000	II	Certification	A kit for measurement or detection of angiotensin I/renin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Plasma renin concentration (PRC)	Plasma renin concentration kit	43439000	II	Certification	A kit for measurement or detection of plasma renin concentration, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Histamine	Histamine kit	43457000	II	Certification	A kit for measurement or detection of histamine, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Cyclic adenosine monophosphate (C-AMP) Cyclic AMP (C-AMP)	Cyclic adenosine monophosphate kit	30347000	II	Certification	A kit for measurement or detection of cyclic adenosine monophosphate, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Human atrial natriuretic peptide (HANP) Atrial natriuretic peptide (HANP)	Atrial natriuretic peptide kit	30260000	II	Certification	A kit for measurement or detection of atrial natriuretic peptide, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Human brain natriuretic peptide (BNP)	Human brain natriuretic peptide kit	44443000	II	Certification	A kit for measurement or detection of human brain natriuretic peptide, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Osteocalcin (BGP : Bone Gla protein)	Osteocalcin kit	30352000	II	Certification	A kit for measurement or detection of osteocalcin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Glycocholic acid (CG : Cholyglycine)	Glycocholic acid kit	42868000	II	Certification	A kit for measurement or detection of glycocholic acid, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Undercarboxylated osteocalcin (ucOC)	Undercarboxylated osteocalcin kit	85003000	II	Certification	A kit for measurement or detection of undercarboxylated osteocalcin (ucOC), using specimens of biological origin. It is mainly to select drug and to provide information for the determination of drug effects for osteoporosis.	
	N-terminal prohormone brain natriuretic peptide (NT-proBNP)	N-terminal prohormone brain natriuretic peptide kit	85002000	II	Certification	A kit for measurement or detection of N-terminal prohormone brain natriuretic peptide (NT-proBNP), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Fibroblast growth factor 23 (FGF23)	Fibroblast growth factor 23 kit	85006000	II		A kit for measurement or detection of fibroblast growth factor 23 (FGF23), using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	
	Leptin	Leptin kit	85007000	II		A kit for measurement or detection of leptin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of clinical diseases and for other purposes.	

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As of May, 2022

Large classification	Middle classification	Test item	Japanese Medical Device Nomenclature (JMDN)	JMDN Code	Classification	Regulation	Definition	Calibration reference materials supplier
Bacteriological test reagents	Culture, nucleic acid, and serological identification test reagents	Culture identification/general bacteria (Gram-positive bacteria) (MRSA/staphylococcus identification) (Streptococcus) (Glucose-fermenting gram-negative bacilli) (Intestinal bacteria) (Genus Neisseria bacteria) (Corynebacterium) (Helicobacter pylori) (Genus Bacillus bacteria) (Bacteria in urine) (Multiple bacterial species) (Gram-negative bacteria) (Genus Neisseria and Haemophilus) (Genus Staphylococcus) Enterohemorrhagic Escherichia coli	Culture identification/general bacteria kit	44456000	Ⅲ	Approval	A kit for culture identification of general bacteria, etc., using specimens of biological origin. It is mainly used to provide information for the diagnosis of pathogenic bacterial infection.	
		Glucose-nonfermenting gram-negative bacilli	Glucose-nonfermenting gram-negative bacilli kit	33361000	Ⅲ	Approval	A kit for culture identification of glucose-nonfermenting gram-negative bacilli, using specimens of biological origin. It is mainly used to provide information for the diagnosis of glucose-nonfermenting gram-negative bacilli infection.	
		MRSA/Staphylococcus identification (identification/differentiation)	Staphylococcus kit	30656003	Ⅲ	Approval	A kit for identification of MRSA and staphylococci, using specimens of biological origin. It is mainly used to provide information for the diagnosis of MRSA or staphylococcal infection.	
		Mycobacterium tuberculosis complex rifampicin-resistant gene identification	Mycobacterium tuberculosis complex rifampicin-resistant gene identification kit	86001000	Ⅲ		A kit for nucleic acid identification of rifampicin-resistant Mycobacterium tuberculosis complex, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Mycobacterium tuberculosis complex infection.	

Nucleic acid identification/methicillin-resistant Staphylococcus aureus Nucleic acid identification/methicillin-resistant gene (mecA, mecC)	Nucleic acid identification/staphylococcus kit	30656013	III		A kit for nucleic acid identification of methicillin-resistant gene (mecA, mecC), using specimens of biological origin. It is mainly used to provide information for the diagnosis of infection with staphylococci indicating methicillin resistance (MRSA, etc.).	
Nucleic acid identification/acid-fast bacillus group	Nucleic acid identification/acid-fast bacillus group kit	44172000	III		A kit for nucleic acid identification of acid-fast bacillus group, using specimens of biological origin. It is mainly used to provide information for the diagnosis of acid-fast bacillus group (Mycobacterium tuberculosis complex, etc.) infection.	
Nucleic acid identification/Legionella group	Nucleic acid identification/Legionella group kit	86002000	III		A kit for nucleic acid identification of Legionella group, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Legionella infection.	
Nucleic acid identification/general bacteria Enterococci Coliform group Pseudomonas aeruginosa Staphylococcus aureus Staphylococcus epidermidis	Nucleic acid identification/general bacteria kit	86003000	III		A kit for nucleic acid identification of general bacteria, using specimens of biological origin. It is mainly used to provide information for the diagnosis of pathogenic bacterial infection.	
MRSA coagulase typing/staphylococcal coagulase typing	MRSA coagulase typing/ staphylococcal coagulase typing kit	44376000	III	Approval	A kit for determination of MRSA and staphylococcal coagulase typing, using specimens of biological origin. It is mainly used to provide information for the diagnosis of MRSA or staphylococcal infection.	
Culture identification/fungi (yeast and yeast-like fungi)	Culture identification/fungus kit	43162000	III	Approval	A kit for culture identification of fungi (yeast and yeast-like fungi), using specimens of biological origin. It is mainly used to provide information for the diagnosis of fungal infection.	
Culture identification/acid-fast bacteria (detection of acid fast bacteria)	Culture identification/acid-fast bacteria kit	44408013	III	Approval	A kit for culture identification of acid-fast bacteria, using specimens of biological origin. It is mainly used to provide information for the diagnosis of acid-fast bacterial infection.	
Culture identification/niacin test	Culture identification/niacin test kit	44408003	III	Approval	A kit for niacin test for acid-fast bacteria, using specimens of biological origin. It is mainly used to provide information for the diagnosis of acid-fast bacterial infection.	
Culture identification/anaerobic bacteria	Anaerobic bacteria biochemical identification kit	30654000	III	Approval	A kit for culture identification of anaerobic bacteria, using specimens of biological origin. It is mainly used to provide information for the diagnosis of anaerobic bacterial infection.	

Serological identification/hemolytic streptococcus typing (including various groups) Serological identification/pneumococci (streptococcus pneumoniae, capsular polysaccharide antigen) Serological identification/pneumococci Serological identification/group A hemolytic streptococci/T typing Serological identification/group B hemolytic streptococcus typing	Streptococcus kit	30710000	III	Approval	A kit for serological identification or culture identification of hemolytic streptococcus typing (including various groups), pneumococci (streptococcus pneumoniae, capsular polysaccharide antigen), and group A hemolytic streptococci/T typing, using specimens of biological origin. It is mainly used to provide information for the diagnosis of infection with hemolytic streptococci, pneumococci (streptococcus pneumoniae), and group A hemolytic streptococci.	
Serological identification/Haemophilus influenzae type b	Haemophilus influenzae type B kit	86004000	III	Approval	A kit for serological identification of Haemophilus influenzae type b, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Haemophilus influenzae type b infection.	
Salmonella serotyping/enterobacteria serotyping	Salmonella kit	30707000	III	Approval	A kit for Salmonella serotyping or enterobacteria serotyping by serological identification, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Salmonella and enterobacterial infections.	
Shigella serotyping	Shigella kit	37726000	III	Approval	A kit for Shigella serotyping by serological identification, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Shigella infection.	
Pathogenic Escherichia coli serotyping	Escherichia coli kit	37727000	III	Approval	A kit for pathogenic Escherichia coli serotyping by serological identification, using specimens of biological origin. It is mainly used to provide information for the diagnosis of pathogenic Escherichia coli infection.	
Yersinia enterocolitica O serogroup	Yersinia kit	30718000	III	Approval	A kit for identification of Yersinia enterocolitica O serogroup, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Yersinia enterocolitica infection.	
Klebsiella capsular typing	Klebsiella kit	37752000	III	Approval	A kit for identification of Klebsiella capsular typing, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Klebsiella infection.	
Serratia O serotyping	Serratia marcesans kit	32508000	III	Approval	A kit for identification of Serratia O serotyping, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Serratia infection.	
Yersinia pseudotuberculosis typing	Yersinia pseudotuberculosis typing kit	43354000	III	Approval	A kit for identification of Yersinia pseudotuberculosis typing, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Yersinia pseudotuberculosis infection.	
Pseudomonas aeruginosa O grouping/Glucose-nonfermenting bacteria	Pseudomonas kit	30705000	III	Approval	A kit for identification of Pseudomonas aeruginosa O grouping and glucose-nonfermenting bacteria, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Pseudomonas aeruginosa and glucose-nonfermenting bacterial infections.	
Flavobacterium grouping	Flavobacterium grouping kit	32506000	III	Approval	A kit for identification of Flavobacterium grouping, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Flavobacterium infection.	

Vibrio parahaemolyticus serotyping/Vibrionaceae serotyping	Vibrio parahaemolyticus serotyping/Vibrionaceae serotyping kit	42957000	III	Approval	A kit for Vibrio parahaemolyticus serotyping or Vibrionaceae serotyping by serological identification, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Vibrio parahaemolyticus and Vibrionaceae infections.	
Vibrio cholerae serotyping	Vibrio cholerae kit	32504000	III	Approval	A kit for Vibrio cholerae serotyping by serological identification, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Vibrio cholerae infection.	
Influenzae capsular typing/haemophilus capsular typing	Influenzae capsular typing/haemophilus capsular typing kit	43353000	III	Approval	A kit for identification of influenzae capsular typing or Haemophilus capsular typing, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Haemophilus influenzae or other Haemophilus bacterial infection.	
Clostridium perfringens type A, heat-resistant	Heat-resistant Clostridium perfringens type A kit	43175000	III	Approval	A kit for identification of heat-resistant Clostridium perfringens type A, using specimens of biological origin. It is mainly used to provide information for the diagnosis of heat-resistant Clostridium perfringens type A infection.	
Serological identification/Campylobacter	Campylobacter kit	37758000	III	Approval	A kit for serological identification of Campylobacter, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Campylobacter infection.	
Serological identification/Alkalescens-Dispar	Serological identification/Alkalescens-Dispar kit	43193000	III	Approval	A kit for serological identification of Alkalescens-Dispar, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Alkalescens-Dispar infection.	
Serological identification/fungus	Serological identification/fungus kit	44450000	III	Approval	A kit for serological identification of fungi, using specimens of biological origin. It is mainly used to provide information for the diagnosis of fungal infection.	
For toxin detection Genus Bacillus bacteria Vibrionaceae Staphylococcal enterotoxin Staphylococcal exfoliative toxin Escherichia coli Escherichia coli thermolabile toxin Escherichia coli thermostable toxin Escherichia coli vero toxin Clostridium perfringens toxin MRSA TSST-1 toxigenicity/staphylococcus TSST-1 toxigenicity Cholera enterotoxin Vibrio parahaemolyticus thermostable direct hemolysin Bacillus cereus enterotoxin	Bacterial toxin detection kit	44449000	III	Approval	A kit for detection of bacterial toxin, using specimens of biological origin. It is mainly used to provide information for the diagnosis of pathogenic bacterial infection.	
Mycobacterium tuberculosis complex pyrazinamide-resistant gene identification	Mycobacterium tuberculosis complex pyrazinamide-resistant gene identification kit	86005000	III		A kit for nucleic acid identification of pyrazinamide-resistant Mycobacterium tuberculosis complex, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Mycobacterium tuberculosis complex infection.	

		Mycobacterium tuberculosis complex isoniazid-resistant gene identification	Mycobacterium tuberculosis complex isoniazid-resistant gene identification kit	86006000	III		A kit for nucleic acid identification of isoniazid-resistant Mycobacterium tuberculosis complex, using specimens of biological origin. It is mainly used to provide information for the diagnosis of Mycobacterium tuberculosis complex infection.	
		Vancomycin-resistant gene	Vancomycin-resistant gene kit	86008000	III		A kit for detection of vancomycin-resistant gene, using specimens of biological origin. It is mainly used to provide information for the diagnosis of infection with bacteria resistant to vancomycin.	
		β -lactamase gene (CTX-M, KPC, NDM, VIM, IMP, OXA)	β -lactamase gene kit	86007000	III		A kit for detection of β -lactamase gene, using specimens of biological origin. It is mainly used to provide information for the diagnosis of infection with bacteria resistant to β -lactam antimicrobial drugs.	
		Nucleic acid identification/fungus	Nucleic acid identification/fungus kit	86009000	III		A kit for nucleic acid identification of fungi, using specimens of biological origin. It is mainly used to provide information for the diagnosis of fungal infection.	
		Nucleic acid identification/virus	Nucleic acid identification/virus kit	86010000	III		A kit for nucleic acid identification of viruses, using specimens of biological origin. It is mainly used to provide information for the diagnosis of virus infection.	
		Nucleic acid identification/parasite	Nucleic acid identification/parasite kit	86012000	III		A kit for nucleic acid identification of parasites, using specimens of biological origin. It is mainly used to provide information for the diagnosis of parasite infection.	
		Colistin resistant gene (mcr-1)	Colistin resistant gene kit	86013000	III		A kit for detection of colistin resistant gene, using specimens of biological origin. It is mainly used to provide information for the diagnosis of infection with bacteria resistant to colistin.	
	Antibiotic susceptibility test reagents	Antibiotic susceptibility test/general bacteria (disk diffusion)	Antibiotic susceptibility (general bacteria/disk method) kit	38852000	I	Self-declaration	A kit for measurement of the susceptibility to antimicrobial substances against general bacteria of high clinical importance, using the disk-agar diffusion technique or disk-medium elution technique. It is mainly used for treatment selection of clinical diseases and for other purposes.	JP, JPC, ATCC
		Antibiotic susceptibility test/general bacteria (liquid culture medium dilution method)	Antibiotic susceptibility (general bacteria/liquid culture medium dilution method) kit	30631000	I	Self-declaration	A kit for measurement of the susceptibility to antimicrobial substances against general bacteria of high clinical importance, using the liquid medium dilution method. It is mainly used for treatment selection of clinical diseases and for other purposes.	JP, JPC, ATCC
		Antibiotic susceptibility test/acid-fast bacteria	Antibiotic susceptibility (acid-fast bacteria) kit	30658000	I	Self-declaration	A kit for measurement of the susceptibility to antimicrobial substances against acid-fast bacteria of high clinical importance. It is mainly used for treatment selection of clinical diseases and for other purposes.	JP, JPC, ATCC
		Antibiotic susceptibility test/fungus	Antibiotic susceptibility (fungus) kit	43242000	I	Self-declaration	A kit for measurement of the susceptibility to antimicrobial substances against yeast-like fungi and other fungi of high clinical importance. It is mainly used for treatment selection of clinical diseases and for other purposes.	JP, JPC, ATCC
		Antibiotic susceptibility (general bacteria/colorimetric method)	Antibiotic susceptibility test (general bacteria/colorimetric method) kit	86011000	I	Self-declaration	A kit for measurement or detection of the susceptibility to antimicrobial substances against general bacteria of high clinical importance, using the colorimetric method. It is mainly used for treatment selection of clinical diseases and for other purposes.	JP, JPC, ATCC

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Immunohistological test reagents	Immunohistological test reagents	Hepatitis B virus core antigen (HBc antigen) Hepatitis B virus surface antigen (HBs antigen) Papillomavirus Human papillomavirus (HPV) Herpes simplex virus type 1 (HSV-1) HSV-1 Herpes simplex virus type 2 (HSV-2) Cytomegalovirus	Viral disease kit for histological test	30628003	Ⅲ	Approval	It is mainly used to provide information for the diagnosis of virus infection, using pathological tissues of biological origin.	
		Chlamydia	Non-viral disease kit for histological test	30628013	Ⅲ	Approval	It is mainly used to provide information for the diagnosis of non-virus infection, using pathological tissues of biological origin.	
		CA125 CA19-9 α1-antichymotrypsin (AACT) α-fetoprotein (AFP) Actin protein Actin Oestrogen receptor (ER) Carcinoembryonic antigen (CEA) Cytokeratin Prostate specific antigen (PSA) Prostatic acid phosphatase (PSAP, PAP) Neuron specific enolase (NSE) Desmin protein Desmin Keratin Progesterone receptor ErbB-2 HER2/neu protein HER2/neu gene EGFR protein ALK protein CD30	Tumour marker kit for histological test	30628023	Ⅲ	Approval	It is mainly used to provide information for the diagnosis of malignant tumors, using pathological tissues of biological origin.	

Blood group O(H) substance Blood group A antigen Blood group B antigen Blood group H antigen	Blood group/cell group kit for histological test	30628033	III	Approval	It is mainly used to provide information for the diagnosis of blood groups, using pathological tissues of biological origin.	
B cells B-cell surface antigen with an epitope called CDw75 (LN1) B-cell surface antigen with an epitope called CD74 (LN2) E-rosette positive T cells T cells T-cell surface antigen (T-cell UCHL-1) Inducer/helper T cells Suppressor/cytotoxic T cells Leukocyte common antigen (LCA)	Cell-mediated immunity kit for histological test	30628042	II	Certification	It is mainly used to provide information for the diagnosis of clinical diseases related to cell-mediated immunity, using pathological tissues of biological origin, and for other purposes.	
Growth hormone (GH) Human growth hormone (HGH) Adrenocorticotrophic hormone (ACTH) Follicle stimulating hormone (FSH) Prolactin Pro-γ-MSH	Hypothalamic-pituitary hormone kit for histological test	30628052	II	Certification	It is mainly used to provide information for the diagnosis of clinical diseases related to hypothalamic-pituitary hormones, using pathological tissues of biological origin, and for other purposes.	
Thyroid stimulating hormone (TSH) Thyroid hormone (Thyroglobulin) Thyroxine Calcitonin	Thyroid/parathyroid hormone kit for histological test	30628062	II	Certification	It is mainly used to provide information for the diagnosis of clinical diseases related to thyroid/parathyroid hormones, using pathological tissues of biological origin, and for other purposes.	
Vasoactive intestinal peptide (VIP) Insulin Gastrin Glucagon Secretin Pancreatic polypeptide Somatostatin	Gastrointestinal hormone kit for histological test	30628072	II	Certification	It is mainly used to provide information for the diagnosis of clinical diseases related to gastrointestinal hormones, using pathological tissues of biological origin, and for other purposes.	

β-human chorionic gonadotropin (β-HCG) Human chorionic gonadotropin β-subunit (β-HCG) Human chorionic gonadotropin (HCG) Luteinizing hormone (LH) Testosterone Placental lactogen (HPL) Oestradiol	Gonadal hormone kit for histological test	30628082	II	Certification	It is mainly used to provide information for the diagnosis of clinical diseases related to gonadal hormones, using pathological tissues of biological origin, and for other purposes.	
Substance P Bombesin β-endorphin	Neurohormone kit for histological test	30628092	II	Certification	It is mainly used to provide information for the diagnosis of clinical diseases related to neurohormones, using pathological tissues of biological origin, and for other purposes.	
α1-antitrypsin (α1-AT) Glial fibrillary acidic protein (GFAP) Ferritin Myelin basic protein Dystrophin Myoglobin Vimentin Vimentin protein Pancreatic polypeptide (PP) Epithelial membrane antigen (EMA) S-100 S100 protein Fibronectin Myosin	Protein kit for histological test	30628102	II	Certification	It is mainly used to provide information for the diagnosis of clinical diseases related to cell-mediated immunity, using pathological tissues of biological origin, and for other purposes.	
Immunoglobulin A (IgA) Immunoglobulin G (IgG) Immunoglobulin M (IgM) Kappa chain of immunoglobulin molecule Kappa chain Kappa light chain Lambda chain of immunoglobulin molecule Lambda chain Lambda light chain	Immunoglobulin kit for histological test	30628112	II	Certification	It is mainly used to provide information for the diagnosis of clinical diseases related to immunoglobulins, using pathological tissues of biological origin, and for other purposes.	
Factor VIII-associated antigen (VIII R:Ag)	Coagulation/fibrinolysis-associated substance kit for histological test	30628122	II	Certification	It is mainly used to provide information for the diagnosis of clinical diseases related to coagulation/fibrinolysis-associated substances, using pathological tissues of biological origin, and for other purposes.	
Lysozyme (muramidase)	Enzyme kit for histological test	30628132	II	Certification	It is mainly used to provide information for the diagnosis of clinical diseases related to biological enzymes, using pathological tissues of biological origin, and for other purposes.	

		ALK fusion gene	ALK fusion gene detection kit	87001000	Ⅲ		A kit for detection of ALK fusion gene, using specimens of biological origin. It is mainly used to provide information for the determination of indications for ALK inhibitors.	
		ALK fusion protein	ALK fusion protein kit	87002000	Ⅲ		A kit for detection of ALK fusion protein, using specimens of biological origin. It is mainly used to provide information for the determination of indications for ALK inhibitors.	
		FIP1L1-PDGFRα fusion gene	FIP1L1-PDGFRα fusion gene detection	87003000	Ⅲ		A kit for detection of FIP1L1-PDGFRα fusion gene, using specimens of biological origin. It is mainly used to provide information for the determination of FIP1L1-PDGFRα fusion gene.	
		PD-L1	PD-L1 kit	87004000	Ⅲ		A kit for measurement or detection of PD-L1, using specimens of biological origin. It is mainly used to provide information for the determination of indications for drugs acting on PD-L1 pathway.	
		Bladder cancer-associated chromosome abnormality	Bladder cancer-associated chromosome abnormality detection kit	87005000	Ⅲ		A kit for detection of bladder cancer-associated chromosome abnormality, using specimens of biological origin. It is mainly used to provide information for the diagnosis of malignant tumors.	
		PMS2 protein, MSH2 protein, MSH6 protein, MLH1 protein	Mismatch repair deficiency detection kit	87007000	Ⅲ		A kit for detection of mismatch repair deficiency, using specimens of biological origin. It is mainly used to provide information for the diagnosis and treatment selection of malignant tumors and for the determination of indication for immune checkpoint inhibitor.	
		BRAF mutation protein	BRAF mutation protein kit	87006000	Ⅲ		A kit for detection of BRAF mutation protein, using specimens of biological origin. It is mainly used to provide information for the diagnosis and treatment selection of malignant tumors.	

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Over-the-counter (OTC) device	Glucosuria test kit	Sugar (glucose)	Over-the-counter glucose kit	30167012	II	Certification	A kit for measurement or detection of glucose by users themselves, using urine specimens of biological origin. It is used as an indicator for the user's health management with specimens collected by users themselves.	
	Proteinuria test kit	Total protein	Over-the-counter total protein kit	30181012	II	Certification	A kit for measurement or detection of total protein by users themselves, using urine specimens of biological origin. It is used as an indicator for the user's health management with specimens collected by users themselves.	
	Pregnancy test kit	Human chorionic gonadotropin (hCG)	Over-the-counter human chorionic gonadotropin kit	33819002	II	Certification	A kit for measurement or detection of human chorionic gonadotropin by users themselves, using urine specimens of biological origin. It is used to provide information for early determination of pregnancy with specimens collected by users themselves.	
	Ovulation date prediction test kit	Luteinizing hormone (LH)	Over-the-counter luteinizing hormone kit	88001000	II		A kit for detection of luteinizing hormone by users themselves, using urine specimens of biological origin. It is used to provide information for predicting ovulation days with specimens collected by users themselves.	

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Large classification	Middle classification	Test item	Japanese Medical Device Nomenclature (JMDN)	JMDN Code	Classification	Regulation	Definition	Calibration reference materials supplier
Test reagents for series	Multi-item kit (series)	Series for general-purpose test item (Class II)	Class II general-purpose test series	80001002	Ⅱ	Certification	A series that combines multiple Class I and Class II test items for general-purpose test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for general-purpose test item (Class III)	Class III general-purpose test series	80003003	Ⅲ		A series that combines multiple Class I, Class II, and Class III test items for general-purpose test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for blood test item (Class I)	Class I blood test series	80002001	I	Self-declaration	A series that combines multiple Class I test items for hematological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for blood test item (Class II)	Class II blood test series	80003002	Ⅱ	Certification	A series that combines multiple Class I and Class II test items for hematological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for blood test item (Class III)	Class III blood test series	80004003	Ⅲ	Approval	A series that combines multiple Class I, Class II, and Class III test items for hematological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for biochemical test item (Class I)	Class I biochemical test series	80005001	I	Self-declaration	A series that combines multiple Class I test items for biochemical test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for biochemical test item (Class II)	Class II biochemical test series	80006002	Ⅱ	Certification	A series that combines multiple Class I and Class II test items for biochemical test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for biochemical test item (Class III)	Class III biochemical test series	80007003	Ⅲ	Approval	A series that combines multiple Class I, Class II, and Class III test items for biochemical test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for immunological test item (Class I)	Class I immunological test series	80008001	I	Self-declaration	A series that combines multiple Class I test items for immunological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for immunological test item (Class II)	Class II immunological test series	80009002	Ⅱ	Certification	A series that combines multiple Class I and Class II test items for immunological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for immunological test item (Class III)	Class III immunological test series	80010003	Ⅲ	Approval	A series that combines multiple Class I, Class II, and Class III test items for immunological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for endocrine test item (Class I)	Class I endocrine test series	80011001	I	Self-declaration	A series that combines multiple Class I test items for endocrinological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	

Series for endocrine test item (Class II)	Class II endocrine test series	80012002	II	Certification	A series that combines multiple Class I and Class II test items for endocrinological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
Series for endocrine test item (Class III)	Class III endocrine test series	80013003	III	Approval	A series that combines multiple Class I, Class II, and Class III test items for endocrinological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
Series for bacteriological test item (Class I)	Class I bacteriological test series	80014001	I	Self-declaration	A series that combines multiple Class I test items for bacteriological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
Series for bacteriological test item (Class II)	Class II bacteriological test series	80015002	II	Certification	A series that combines multiple Class I and Class II test items for bacteriological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
Series for bacteriological test item (Class III)	Class III bacteriological test series	80016003	III	Approval	A series that combines multiple Class I, Class II, and Class III test items for bacteriological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
Series for immunohistological test item (Class I)	Class I immunohistological test series	80017001	I	Self-declaration	A series that combines multiple Class I test items for immunohistological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
Series for immunohistological test item (Class II)	Class II immunohistological test series	80018002	II	Certification	A series that combines multiple Class I and Class II test items for immunohistological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
Series for immunohistological test item (Class III)	Class III immunohistological test series	80019003	III	Approval	A series that combines multiple Class I, Class II, and Class III test items for immunohistological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
Series for general-purpose/blood test item (Class II)	Class II general-purpose/blood test series	80020002	II	Certification	A series that combines multiple Class I and Class II test items for general-purpose test reagents and hematological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
Series for general-purpose/blood test item (Class III)	Class III general-purpose/blood test series	80021003	III	Approval	A series that combines multiple Class I, Class II, and Class III test items for general-purpose test reagents and hematological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
Series for general-purpose/biochemical test item (Class II)	Class II general-purpose/biochemical test series	80022002	II	Certification	A series that combines multiple Class I and Class II test items for general-purpose test reagents and biochemical test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
Series for general-purpose/biochemical test item (Class III)	Class III general-purpose/biochemical test series	80023003	III	Approval	A series that combines multiple Class I, Class II, and Class III test items for general-purpose test reagents and biochemical test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
Series for general-purpose/endocrine test item (Class II)	Class II general-purpose/endocrine test series	80024002	II	Certification	A series that combines multiple Class I and Class II test items for general-purpose test reagents and endocrinological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	

		Series for biochemical/immunological/endocrine test item (Class II)	Class II biochemical/immunological/endocrine test series	80051002	II	Certification	A series that combines multiple Class I and Class II test items for biochemical test reagents, immunological test reagents, and endocrinological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for biochemical/immunological/endocrine test item (Class III)	Class III biochemical/immunological/endocrine test series	80052003	III	Approval	A series that combines multiple Class I, Class II, and Class III test items for biochemical test reagents, immunological test reagents, and endocrinological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for general-purpose/biochemical/immunological/endocrine test item (Class II)	Class II general-purpose/biochemical/immunological/endocrine test series	80053002	II	Certification	A series that combines multiple Class I and Class II test items for general-purpose test reagents, biochemical test reagents, immunological test reagents, and endocrinological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for general-purpose/biochemical/immunological/endocrine test item (Class III)	Class III general-purpose/biochemical/immunological/endocrine test series	80054003	III	Approval	A series that combines multiple Class I, Class II, and Class III test items for general-purpose test reagents, biochemical test reagents, immunological test reagents, and endocrinological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for general-purpose/blood/immunological/endocrine test item (Class II)	Class II general-purpose/blood/immunological/endocrine test series	80055002	II	Certification	A series that combines multiple Class I and Class II test items for general-purpose test reagents, hematological test reagents, immunological test reagents, and endocrinological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	
		Series for general-purpose/blood/immunological/endocrine test item (Class III)	Class III general-purpose/blood/immunological/endocrine test series	80056003	III	Approval	A series that combines multiple Class I, Class II, and Class III test items for general-purpose test reagents, hematological test reagents, immunological test reagents, and endocrinological test reagents. A series is one that is expected to be supplied to medical institutions as an integral part of a series, or one for which there is a recognized clinical need to be supplied as a set.	