

○ *In vitro* diagnostics with specified criteria designated by the Minister of Health, Labor and Welfare pursuant to the provisions of Article 23-2-23, Paragraph 1 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

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In vitro diagnostics with specified criteria designated by the Minister of Health, Labor and Welfare pursuant to the provisions of Article 23-2-23, Paragraph 1 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices are qualitative reagents listed in Appendix, whose concordance rate shall be 90% or more, when compared with previously approved (or certified) *in vitro* diagnostics or methods for detecting items for previously approved (or certified) *in vitro* diagnostics through primary analysis (except for the intended use exclusively for animals.), and quantitative reagents listed in Appendix, whose the correlation coefficient shall be 0.9 or more and the slope of the regression equation shall be in a range of 0.9 to 1.1, when compared with previously approved (or certified) *in vitro* diagnostics or methods for measuring items for previously approved (or certified) *in vitro* diagnostics through primary analysis (except for the intended use exclusively for animals.). However, if measurement principle or detection sensitivity of the *in vitro* diagnostics are clearly different from one of the existing *in vitro* diagnostics, or those are the radiopharmaceutical prescribed in item 1, Article 1 of the Regulation on Manufacture and Handling of Radiopharmaceuticals (Ministry of Health and Welfare Ordinance No. 4 dated February 1, 1961), those are excluded in *in vitro* diagnostics designated by the Minister of Health, Labor and Welfare pursuant to the provisions of Article 23-2-23, Paragraph 1 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

Appendix

1 General-purpose test reagents

- (1) Leukocyte kit
- (2) pH kit
- (3) Total protein kit
- (4) Glucose kit
- (5) Ketone body kit
- (6) Occult blood kit
- (7) Bilirubin kit
- (8) Urobilinogen kit
- (9) Nitrite kit
- (10) Specific gravity kit
- (11) Ascorbic acid kit
- (12) Sodium chloride kit
- (13) Amylase kit
- (14) Albumin kit
- (15) Catalase kit
- (16) Ammonia kit
- (17) Delta-aminolaevulinic acid kit
- (18) Porphobilinogen kit
- (19) Creatinine kit
- (20) Uropepsin kit
- (21) Human chorionic gonadotropin kit
- (22) Luteinizing hormone kit
- (23) Vanillylmandelic acid kit
- (24) Human growth hormone kit
- (25) Beta2-microglobulin kit
- (26) Alkaline phosphatase kit
- (27) Calcium kit
- (28) Magnesium kit
- (29) Gamma-glutamyl transpeptidase kit
- (30) Phosphorous/inorganic phosphate kit
- (31) Testosterone kit
- (32) Cortisol kit
- (33) Immunoglobulin G kit

- (34) Immunoglobulin A kit
- (35) Immunoglobulin M kit
- (36) Transferrin kit
- (37) Uric acid kit
- (38) Urea nitrogen kit
- (39) C-peptide kit
- (40) Creatine kit
- (41) Amylase isoenzyme kit
- (42) Haemoglobin kit
- (43) Tau protein kit
- (44) Beta-human chorionic gonadotropin kit
- (45) Follicle stimulating hormone kit
- (46) Oestriol kit
- (47) Alpha1-antitrypsin kit
- (48) Haemoglobin/transferrin kit
- (49) Amino acid kit
- (50) Multiple-constituent test strip kit
- (51) Zinc kit for general-purpose test
- (52) Chloride kit for general-purpose test
- (53) Total iodine kit for general-purpose test
- (54) Immunoglobulin E kit for general-purpose test
- (55) Myo-inositol kit

2 Hematological test reagents

- (1) Platelet count kit
- (2) Reticulocyte kit
- (3) Haematocrit set
- (4) Leukocyte count kit
- (5) Erythrocyte count kit
- (6) Mean corpuscular volume kit
- (7) Mean corpuscular haemoglobin kit
- (8) Mean corpuscular haemoglobin concentration kit
- (9) Eosinophil count kit
- (10) Basophil count kit
- (11) Erythrocyte diameter kit
- (12) Differential leukocyte count kit

- (13) Activated partial thromboplastin time kit
- (14) Coagulation factor II, VII, X kit
- (15) Intrinsic coagulation factor kit
- (16) Thrombin time kit
- (17) Soluble fibrin monomer complex kit
- (18) Fibrin/fibrinogen degradation product kit
- (19) Fibrin/fibrinogen degradation product/fraction E kit
- (20) Fibrin degradation product kit
- (21) Fibrinopeptide A kit
- (22) Prothrombin fragment 1+2 kit
- (23) Antithrombin III kit
- (24) Thrombin-antithrombin III-complex kit
- (25) Plasminogen kit
- (26) Alpha2-antiplasmin kit
- (27) Plasmin-alpha2-antiplasmin complex kit
- (28) Plasminogen activator inhibitor-1 kit
- (29) Tissue plasminogen activator inhibitor-1 complex kit
- (30) Coagulation factor V kit
- (31) Coagulation factor XI kit
- (32) Coagulation factor XII kit
- (33) Coagulation factor XIIIa kit
- (34) Coagulation factor XIII kit
- (35) Factor Xa inhibitor kit
- (36) Factor VIII-associated antigen kit
- (37) Factor VIII ristocetin cofactor kit
- (38) PIVKA-II kit for blood coagulation factor test
- (39) Protein C kit
- (40) Protein S kit
- (41) Thrombomodulin kit
- (42) Activated protein C-resistant factor V kit
- (43) Platelet aggregation kit
- (44) Terminal deoxynucleotidyl transferase kit
- (45) Erythropoietin kit
- (46) Deoxythymidine kinase kit for blood chemistry test
- (47) ESR kit
- (48) Blood specific gravity kit

(49) Prekallikrein/kallikrein kit

3 Biochemical test reagents

- (1) Protein fraction kit
- (2) Thymol turbidity test kit
- (3) Zinc sulfate turbidity test kit
- (4) Cephalin-cholesterol kit
- (5) Cobalt reaction kit
- (6) Creatine kinase isoenzyme kit
- (7) Creatine kinase isoform kit
- (8) Aspartate aminotransferase isoenzyme kit
- (9) Lactate dehydrogenase isoenzyme kit
- (10) Alkaline phosphatase isoenzyme kit
- (11) Aldolase kit
- (12) Monoamine oxidase kit
- (13) Cholinesterase kit
- (14) Guanase kit
- (15) Adenosine deaminase kit
- (16) Leucine aminopeptidase kit
- (17) Cystine aminopeptidase kit
- (18) Gamma-glutamyl transpeptidase isoenzyme kit
- (19) Trypsin kit
- (20) Periodontopathic peptidase kit
- (21) Chymotrypsin kit
- (22) Trypsin inhibitor kit
- (23) Phospholipase A2 kit
- (24) 5'-nucleotidase kit
- (25) Acid phosphatase kit
- (26) Acid phosphatase isoenzyme kit
- (27) Glutamate dehydrogenase kit
- (28) Isocitric dehydrogenase kit
- (29) Ornithine carbamoyl transferase kit
- (30) Alpha-hydroxybutyrate dehydrogenase kit
- (31) Lysozyme kit
- (32) Pyruvate kinase kit
- (33) Glucose-6-phosphate dehydrogenase kit

- (34) Phospho-hexose isomerase kit
- (35) 2-5A synthetase kit
- (36) Prolyl hydroxylase kit
- (37) Super oxide dismutase kit
- (38) Angiotensin converting enzyme kit
- (39) N-acetyl-beta-D-glucosaminidase kit
- (40) Galactose-1-phosphate kit
- (41) Cystatin C kit
- (42) Restnitrogen kit
- (43) Amino acid fractionation kit
- (44) Polyamine kit
- (45) Branched-chain amino acid kit
- (46) p-Aminohippuric acid kit
- (47) p-Aminobenzoic acid kit
- (48) Branched-chain amino acid/tyrosine kit
- (49) Galactose kit
- (50) Glycated haemoglobin A₁ kit
- (51) Fructosamine kit
- (52) Glycated albumin kit
- (53) Mucoprotein kit
- (54) Hyaluronic acid kit
- (55) 1,5-anhydroglucitol kit
- (56) Sialic acid kit
- (57) Sorbitol kit
- (58) Pentosidine kit
- (59) Pyruvate kit
- (60) 3-hydroxybutyric acid kit
- (61) 2,3-diphosphoglycerate kit
- (62) Total lipids kit
- (63) Triglyceride fraction kit
- (64) Phospholipid kit
- (65) Non-esterified fatty acid kit
- (66) Cholesterol fraction kit
- (67) Remnant like lipoprotein particle cholesterol kit
- (68) Lipid peroxide kit
- (69) Bile acid kit

- (70) Beta-Lipoprotein kit
- (71) Lipoprotein fraction kit
- (72) Lipoprotein X kit
- (73) Lipoprotein (a) kit
- (74) Lipoprotein lipase kit
- (75) Lecithin-cholesterol acyltransferase kit
- (76) Apolipoprotein B kit
- (77) Apolipoprotein C-II kit
- (78) Apolipoprotein C-III kit
- (79) Apolipoprotein E kit
- (80) Cholesteryl ester transfer protein kit
- (81) Vitamin B12 kit
- (82) Folate kit
- (83) Vitamin D kit, 1-25-dihydroxyvitamin D3
- (84) Direct bilirubin kit
- (85) Free carbamazepine kit
- (86) Free valproic acid kit
- (87) N-acetylprocainamide kit
- (88) Quinidine kit
- (89) Salicylate kit
- (90) Dibekacin kit
- (91) Netilmicin kit
- (92) Methotrexate kit
- (93) Ethanol kit
- (94) Bromperidol kit
- (95) Zonisamide kit
- (96) Aprindine kit
- (97) Arbekacin kit
- (98) Isepamicin kit
- (99) Tacrolimus kit
- (100) Tricyclic antidepressant kit
- (101) Teicoplanin kit
- (102) Morphine kit
- (103) Mexiletine kit
- (104) Unbound bilirubin kit
- (105) Inulin kit

- (106) MDA-LDL (Oxidized LDL) kit
- (107) Indirect bilirubin kit
- (108) Trypsinogen-2 kit
- (109) Phenolsulfonphthalein kit
- (110) Phosphorylated tau protein kit
- (111) Everolimus kit
- (112) Topiramate kit
- (113) Vitamin D kit, 25-hydroxyvitamin D

4 Immunological test reagents

- (1) Immunoglobulin G monotest/monoresult multiantigen kit
- (2) Secretory immunoglobulin A kit
- (3) Immunoglobulin E monotest/monoresult multiantigen kit
- (4) Immunoglobulin E monotest/pluriresult multiantigen kit
- (5) Immunoglobulin kappa/lambda chain kit
- (6) Immunoglobulin G subclass kit
- (7) Multi-isotype immunoglobulin kit
- (8) Complement CH₅₀ kit
- (9) Complement component C3c kit
- (10) Complement component C1 inactivator kit
- (11) C3 proactivator kit
- (12) Complement control factor kit
- (13) Alpha1-microglobulin kit
- (14) Alpha1-acid glycoprotein kit
- (15) Retinol binding protein kit
- (16) Haemopexin kit
- (17) APR score kit
- (18) Human heart fatty acid binding protein kit
- (19) Myoglobin kit
- (20) Troponin kit
- (21) Myosin light chain kit
- (22) Fibronectin kit
- (23) Chondrocalcin kit
- (24) Procollagen III peptide kit
- (25) Type IV collagen kit
- (26) Type IV collagen 7S kit

- (27) Matrix metalloproteinase-3 kit
- (28) Histamine release test kit
- (29) Pulmonary surfactant apoprotein A kit
- (30) Surfactant protein D kit
- (31) Sialylated carbohydrate antigen KL-6 kit
- (32) Granulocyte elastase kit
- (33) Beta-closlap kit
- (34) Antinuclear antibody kit
- (35) Anti-smooth muscle antibody kit
- (36) Anti-gastric parietal cell antibody kit
- (37) Antinuclear antibody/LE factor kit
- (38) Antinuclear antibody/anticentromere antibody kit
- (39) Anti-deoxyribonucleic acid antibody kit
- (40) Anti-ENA antibody kit
- (41) Anti-Sm antibody kit
- (42) Anti-ribonucleoprotein antibody kit
- (43) Anti-SS-A/Ro antibody kit
- (44) Anti-SS-B/La antibody kit
- (45) Anti-Scl-70 antibody kit
- (46) Rheumatoid factor kit
- (47) Immunoglobulin G rheumatoid factor kit
- (48) Anti-agalactyl immunoglobulin G antibody kit
- (49) Antimitochondrial antibody kit
- (50) Antimitochondrial antibody M2 kit
- (51) Thyroglobulin autoantibody kit
- (52) Thyroid microsomal antibody kit
- (53) Thyroid peroxydase antibody kit
- (54) Thyroid stimulating hormone receptor antibody kit
- (55) Thyroid-stimulating autoantibody kit
- (56) Acetylcholine receptor antibody kit
- (57) Anticardiolipin antibody kit
- (58) Anticardiolipin-beta2-glycoprotein I complex antibody kit
- (59) Platelet antibody kit
- (60) Proteinase 3-antineutrophil cytoplasmic autoantibody kit
- (61) Myeloperoxidase antineutrophil cytoplasmic autoantibody kit
- (62) Circulating immune complex kit

- (63) Anti-Jo-1 antibody kit
- (64) Anti-glutamic acid decarboxylase antibody/anti-islet cell antibody kit
- (65) Lupus anticoagulant kit
- (66) Anti-GBM antibody kit
- (67) Anti-LKM-1 antibody kit
- (68) Anti-desmoglein antibody kit
- (69) Insulin antibody kit
- (70) Anti-IA-2 antibody kit
- (71) A-transferase activity and B-transferase activity kit
- (72) Lymphoblastogenetic ability kit
- (73) B cell kit
- (74) B cell subset kit
- (75) T cell kit
- (76) T cell subset kit
- (77) NK cell kit
- (78) Monocyte kit
- (79) Leukocyte kit
- (80) Platelet kit
- (81) Cell cycle kit
- (82) CALLA-expressing cell kit
- (83) Thymocyte kit
- (84) LeY-expressing lymphocyte kit
- (85) Granulocyte kit
- (86) Pan T cell kit
- (87) IL-1a/IL1b/IL1RA/IL2r/IL6r kit
- (88) Hepatocyte growth factor kit
- (89) Neopterin kit
- (90) Eosinophil basic protein kit
- (91) Pepsinogen kit
- (92) IgG anti-GM1 antibody kit
- (93) IgG anti-GQ1b antibody kit
- (94) Anti-BP180NC16a antibody kit
- (95) Antibody kit against citrullinated antigens
- (96) Th2 chemokine/TARC kit
- (97) Type I procollagen-N-propeptide kit
- (98) Human liver-type fatty acid binding protein (L-FABP) kit

- (99) Cytochrome c kit
- (100) Anti-RNA polymerase III antibody kit
- (101) Antiribosomal P antibody kit
- (102) Anti-aquaporin 4 antibody kit
- (103) Anti-epidermal basement membrane zone antibody kit
- (104) Platelet factor-4/heparin complex antibody kit
- (105) Anti-muscle-specific tyrosine kinase antibody kit

5 Endocrinological test reagents

- (1) Insulin-like growth factor I kit
- (2) Insulin-like growth factor binding protein 1 kit
- (3) Insulin-like growth factor binding protein 3 kit
- (4) Prolactin kit
- (5) Adrenocorticotrophic hormone kit
- (6) Arginine vasopressin kit
- (7) Triiodothyronine uptake kit
- (8) Thyroxine binding globulin kit
- (9) Thyroxine binding capacity kit
- (10) Parathyroid hormone kit
- (11) Parathyroid hormone intact kit
- (12) Parathyroid hormone-related peptide kit
- (13) Calcitonin kit
- (14) Gastrin kit
- (15) Secretin kit
- (16) 17-ketosteroid kit
- (17) 17-hydroxycorticosteroid kit
- (18) Dehydroepiandrosterone kit
- (19) Dehydroepiandrosterone-sulfate kit
- (20) Aldosterone kit
- (21) Androstenedione kit
- (22) Catecholamine kit
- (23) Homovanillic acid kit
- (24) Oestrogen kit
- (25) Estriol-16-alpha-glucuronide kit
- (26) Oestrone kit
- (27) 17-hydroxyprogesterone kit

- (28) Free testosterone kit
- (29) Pregnanediol-3 α -glucuronide kit
- (30) Renin kit
- (31) Angiotensin I/renin kit
- (32) Plasma renin concentration kit
- (33) Histamine kit
- (34) Cyclic adenosine monophosphate kit
- (35) Atrial natriuretic peptide kit
- (36) Human brain natriuretic peptide kit
- (37) Osteocalcin kit
- (38) Glycolic acid kit
- (39) Undercarboxylated osteocalcin kit
- (40) N-terminal prohormone brain natriuretic peptide kit
- (41) Anti-Müllerian hormone kit

6 Immunohistological test reagents

- (1) Cell-mediated immunity kit for histological test
- (2) Hypothalamic-pituitary hormone kit for histological test
- (3) Thyroid/parathyroid hormone kit for histological test
- (4) Gastrointestinal hormone kit for histological test
- (5) Gonadal hormone kit for histological test
- (6) Neurohormone kit for histological test
- (7) Protein kit for histological test
- (8) Immunoglobulin kit for histological test
- (9) Coagulation/fibrinolysis-associated substance kit for histological test
- (10) Enzyme kit for histological test

7 Over-the-counter (OTC) device

- (1) Over-the-counter glucose kit
- (2) Over-the-counter total protein kit
- (3) Over-the-counter human chorionic gonadotropin kit

8 Test reagents for series

- (1) Class II general-purpose test series
- (2) Class II blood test series
- (3) Class II biochemical test series

- (4) Class II immunological test series
- (5) Class II endocrine test series
- (6) Class II bacteriological test series
- (7) Class II immunohistological test series
- (8) Class II general-purpose/blood test series
- (9) Class II general-purpose/biochemical test series
- (10) Class II general-purpose/endocrine test series
- (11) Class II blood/biochemical test series
- (12) Class II blood/immunological test series
- (13) Class II blood/endocrine test series
- (14) Class II biochemical/immunological test series
- (15) Class II biochemical/endocrine test series
- (16) Class II immunological/endocrine test series
- (17) Class II general-purpose/blood/endocrine test series
- (18) Class II general-purpose/biochemical/immunological test series
- (19) Class II general-purpose/immunological/endocrine test series
- (20) Class II biochemical/immunological/endocrine test series
- (21) Class II general-purpose/biochemical/immunological/endocrine test series
- (22) Class II general-purpose/blood/immunological/endocrine test series