

○ *In vitro* diagnostics with specified criteria designated by the Minister of Health, Labor and Welfare pursuant to the provisions of Article 23-2-5, 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 23-2-5, Paragraph 1 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices are *in vitro* diagnostics listed in the second column of Appendix 1, which have been calibrated with calibration reference materials supplied by institutions listed in the third column of Appendix 1 or supplied as conforming to the standards listed in the third column of Appendix 1 (except for the intended use exclusively for animals. Hereinafter referred to as "Appendix 1 *in vitro* diagnostics".), *in vitro* diagnostics listed in the second column of Appendix 2, which have been calibrated according to the standard measurement method specified by the institutions listed in the third column of Appendix 2 (except for the intended use exclusively for animals. Hereinafter referred to as "Appendix 2 *in vitro* diagnostics".), and *in vitro* diagnostics listed in Appendix 3 , which is composed of Appendix 1 *in vitro* diagnostics or Appendix 2 *in vitro* diagnostics. 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 23-2-5, Paragraph 1 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

Appendix 1

First Column	Second Column	Third Column
1	Haemoglobin kit for blood test	International Committee for Standardization in Haematology
		National Institute for Biological Standards and Control
2	Fibrinogen kit	National Institute for Biological Standards and Control
3	Coagulation factor II kit	National Institute for Biological Standards and Control
4	Coagulation factor VII kit	National Institute for Biological Standards and Control
5	Coagulation factor VIII kit	National Institute for Biological Standards and Control
6	Coagulation factor IX kit	National Institute for Biological Standards and Control
7	Coagulation factor X kit	National Institute for Biological Standards and Control
8	Von Willebrand factor kit	National Institute for Biological Standards and Control
9	Beta-thromboglobulin kit	National Institute for Biological Standards and Control
10	Platelet factor 4 kit	National Institute for Biological Standards and Control
11	Total protein kit for blood test	National Institute of Standards and Technology
		Reference Material Institute for Clinical Chemistry Standards
12	Albumin kit for blood test	Institute for Reference Materials and Measurements
		National Institute of Standards and Technology
13	A/G ratio kit	Institute for Reference Materials and Measurements (limited to albumin)

		National Institute of Standards and Technology
14	Creatine kinase kit	Reference Material Institute for Clinical Chemistry Standards
		National Institute of Standards and Technology
		Institute for Reference Materials and Measurements
15	Aspartate aminotransferase kit	Reference Material Institute for Clinical Chemistry Standards
		National Institute of Standards and Technology
16	Alanine aminotransferase kit	Reference Material Institute for Clinical Chemistry Standards
		National Institute of Standards and Technology
		Institute for Reference Materials and Measurements
17	Lactate dehydrogenase kit	Reference Material Institute for Clinical Chemistry Standards
		National Institute of Standards and Technology
		Institute for Reference Materials and Measurements
18	Lactate dehydrogenase isoenzyme/ LD1 kit	Institute for Reference Materials and Measurements
19	Alkaline phosphatase kit for blood test	Reference Material Institute for Clinical Chemistry Standards
		National Institute of Standards and Technology
		Institute for Reference Materials and Measurements
20	Gamma-glutamyl transpeptidase kit for blood test	Reference Material Institute for Clinical Chemistry Standards
		Institute for Reference Materials and Measurements

21	Amylase kit for blood test	Reference Material Institute for Clinical Chemistry Standards
22	Amylase isoenzyme kit for blood test	Reference Material Institute for Clinical Chemistry Standards
23	Lipase kit	Reference Material Institute for Clinical Chemistry Standards
24	Creatine kit for blood test	Institute for Reference Materials and Measurements
25	Creatinine kit for blood test	National Institute of Standards and Technology
		Institute for Reference Materials and Measurements
		Reference Material Institute for Clinical Chemistry Standards
26	Uric acid kit for blood test	National Institute of Standards and Technology
		Reference Material Institute for Clinical Chemistry Standards
27	Urea nitrogen kit for blood test	National Institute of Standards and Technology
		Reference Material Institute for Clinical Chemistry Standards
28	Ammonia kit for blood test	Chemicals Examination and Research Institute, Japan
29	Methionine kit	The United States Pharmacopia
30	Phenylalanine kit	The United States Pharmacopia
31	Amino acid kit for blood test	The United States Pharmacopia
32	Leucine kit	National Institute of Standards and Technology
33	Histidine kit	National Institute of Standards and Technology
34	Tyrosine kit	National Institute of Standards and Technology
35	Glucose kit for blood test	National Institute of Standards and Technology

		Reference Material Institute for Clinical Chemistry Standards
36	Glycated haemoglobin A _{1c} kit	Reference Material Institute for Clinical Chemistry Standards
		The Japan Diabetes Society
		Institute for Reference Materials and Measurements
37	Lactate kit	The United States Pharmacopia
		National Institute of Standards and Technology
38	Triglyceride kit	National Institute of Standards and Technology
		Reference Material Institute for Clinical Chemistry Standards
39	Cholesterol kit	Reference Material Institute for Clinical Chemistry Standards
		National Institute of Standards and Technology
		National Institute of Advanced Industrial Science and Technology
40	Free cholesterol kit	National Institute of Standards and Technology
41	HDL-cholesterol kit	Reference Material Institute for Clinical Chemistry Standards
42	Apolipoprotein A-I kit	Institute for Reference Materials and Measurements
43	Apolipoprotein A-II kit	Institute for Reference Materials and Measurements
44	Sodium kit	National Institute of Standards and Technology
		Reference Material Institute for Clinical Chemistry Standards
45	Potassium kit	National Institute of Standards and Technology

		Reference Material Institute for Clinical Chemistry Standards
46	Chloride kit	National Institute of Standards and Technology
		Reference Material Institute for Clinical Chemistry Standards
47	Magnesium kit for blood test	National Institute of Standards and Technology
		Institute for Reference Materials and Measurements
		Reference Material Institute for Clinical Chemistry Standards
		Chemicals Examination and Research Institute, Japan
48	Calcium kit for blood test	National Institute of Standards and Technology
		Institute for Reference Materials and Measurements
		Reference Material Institute for Clinical Chemistry Standards
		Chemicals Examination and Research Institute, Japan
49	Phosphorous/inorganic phosphate kit for blood test	National Institute of Standards and Technology
		Chemicals Examination and Research Institute, Japan
		Reference Material Institute for Clinical Chemistry Standards
50	Bicarbonate kit	National Institute of Standards and Technology
51	Aluminium kit	National Institute of Standards and Technology
		Institute for Reference Materials and Measurements
		Chemicals Examination and Research Institute, Japan

52	Cadmium kit	National Institute of Standards and Technology
		Institute for Reference Materials and Measurements
53	Chromium kit	National Institute of Standards and Technology
54	Molybdenum kit	National Institute of Standards and Technology
55	Lead kit	National Institute of Standards and Technology
56	Selenium kit	National Institute of Standards and Technology
57	Cobalt kit	National Institute of Standards and Technology
58	Manganese kit	National Institute of Standards and Technology
59	Lithium kit	National Institute of Standards and Technology
		Reference Material Institute for Clinical Chemistry Standards
60	Iron kit	National Institute of Standards and Technology
		Reference Material Institute for Clinical Chemistry Standards
		Chemicals Examination and Research Institute, Japan
61	Iron binding capacity kit	National Institute of Standards and Technology
		Chemicals Examination and Research Institute, Japan
62	Unsaturated iron binding capacity kit	National Institute of Standards and Technology
		Chemicals Examination and Research Institute, Japan
63	Copper kit	Chemicals Examination and Research Institute, Japan

		Institute for Reference Materials and Measurements
		National Institute of Standards and Technology
64	Zinc kit	National Institute of Standards and Technology
		Institute for Reference Materials and Measurements
		Chemicals Examination and Research Institute, Japan
65	Total bilirubin kit for blood test	National Institute of Standards and Technology
		Reference Material Institute for Clinical Chemistry Standards
66	Acetaminophen kit	The Japanese Pharmacopoeia
		The United States Pharmacopoeia
67	Carbamazepine kit	The United States Pharmacopoeia
68	Ethosuximide kit	The United States Pharmacopoeia
69	Phenobarbital kit	The United States Pharmacopoeia
70	Primidone kit	The United States Pharmacopoeia
		The Japanese Pharmacopoeia
71	Free phenytoin kit	The United States Pharmacopoeia
72	Phenytoin kit	The United States Pharmacopoeia
73	Valproic acid kit	The United States Pharmacopoeia
74	Digitoxin kit	The Japanese Pharmacopoeia
		The United States Pharmacopoeia
75	Digoxin kit	The Japanese Pharmacopoeia
		The United States Pharmacopoeia
76	Disopyramide kit	The United States Pharmacopoeia
77	Lidocaine kit	The United States Pharmacopoeia
78	Procainamide kit	The United States Pharmacopoeia
79	Theophylline kit	The United States Pharmacopoeia
80	Heparin kit	National Institute for Biological Standards and Control
81	Amikacin kit	The United States Pharmacopoeia

		The Japanese Pharmacopoeia
82	Tobramycin kit	The United States Pharmacopia
		The Japanese Pharmacopoeia
83	Gentamicin kit	The United States Pharmacopia
		The Japanese Pharmacopoeia
84	Methotrexate kit for blood test	The Japanese Pharmacopoeia
		The United States Pharmacopia
85	Haloperidol kit	The United States Pharmacopia
86	Cyclosporine kit	The United States Pharmacopia
		The Japanese Pharmacopoeia
87	Vancomycin kit	The United States Pharmacopia
88	Immunoglobulin G kit for blood test	Institute for Reference Materials and Measurements
89	Immunoglobulin A kit for blood test	Institute for Reference Materials and Measurements
90	Immunoglobulin M kit for blood test	Institute for Reference Materials and Measurements
91	Immunoglobulin D kit	National Institute for Biological Standards and Control
92	Immunoglobulin E kit	National Institute for Biological Standards and Control
93	Complement component C3 kit	Institute for Reference Materials and Measurements
94	Complement component C4 kit	Institute for Reference Materials and Measurements
95	Prealbumin/transthyretin kit	Institute for Reference Materials and Measurements
96	Alpha1-antitrypsin kit for blood test	Institute for Reference Materials and Measurements
97	Alpha2-macroglobulin kit	Institute for Reference Materials and Measurements
98	Haptoglobin kit	Institute for Reference Materials and Measurements
99	Ceruloplasmin kit	Institute for Reference Materials and Measurements

100	Transferrin kit for blood test	Institute for Reference Materials and Measurements
101	Beta2-microglobulin kit for blood test	National Institute for Biological Standards and Control
102	C-reactive protein kit	Institute for Reference Materials and Measurements
103	Ferritin kit	National Institute for Biological Standards and Control
104	Amyloid A protein kit	National Institute for Biological Standards and Control
105	Human growth hormone kit for blood test	National Institute for Biological Standards and Control
		The Japanese Pharmaceutical Code x
106	Luteinizing hormone kit for blood test	National Institute for Biological Standards and Control
107	Follicle stimulating hormone kit for blood test	National Institute for Biological Standards and Control
108	Thyroid stimulating hormone kit	National Institute for Biological Standards and Control
109	Triiodothyronine kit	The United States Pharmacopoeia
		Institute for Reference Materials and Measurements
110	Free triiodothyronine kit	The United States Pharmacopoeia
		Institute for Reference Materials and Measurements
111	Thyroxine kit	The United States Pharmacopoeia
		Institute for Reference Materials and Measurements
112	Free thyroxine kit	The United States Pharmacopoeia
		Institute for Reference Materials and Measurements
113	Thyroglobulin kit	Institute for Reference Materials and Measurements

114	Insulin kit	National Institute for Biological Standards and Control
		The Japanese Pharmacopoeia
115	C-peptide kit for blood test	National Institute for Biological Standards and Control
116	Glucagon kit	National Institute for Biological Standards and Control
		The United States Pharmacopia
117	Proinsulin kit	National Institute for Biological Standards and Control
118	Cortisol kit for blood test	Institute for Reference Materials and Measurements
119	Vanilmandelic acid kit for blood test	National Institute of Standards and Technology
120	Oestriol kit for blood test	The United States Pharmacopia
		The Japanese Pharmacopoeia
121	Oestradiol kit	Institute for Reference Materials and Measurements
		The Japanese Pharmaceutial Code x
122	Progesterone kit	Institute for Reference Materials and Measurements
		The United States Pharmacopia
		The Japanese Pharmacopoeia
123	Testosterone kit for blood test	The United States Pharmacopia
124	Human chorionic gonadotropin kit for blood test	National Institute for Biological Standards and Control
		The Japanese Pharmacopoeia
125	Beta-human chorionic gonadotropin kit for blood test	National Institute for Biological Standards and Control
126	Human placental lactogen kit	National Institute for Biological Standards and Control
127	Antibiotic susceptibility (general bacteria/disk method) kit	The Japanese Pharmacopoeia
		The Japanese Pharmaceutial Code x

		Type Strain deposited at the American Type Culture Collection
128	Antibiotic susceptibility (general bacteria/liquid culture medium dilution method) kit	The Japanese Pharmacopoeia
		The Japanese Pharmaceutical Code x
		Type Strain deposited at the American Type Culture Collection
129	Antibiotic susceptibility (acid-fast bacteria) kit	The Japanese Pharmacopoeia
		The Japanese Pharmaceutical Code x
		Type Strain deposited at the American Type Culture Collection
130	Antibiotic susceptibility (fungus) kit	The Japanese Pharmacopoeia
		The Japanese Pharmaceutical Code x
		Type Strain deposited at the American Type Culture Collection
131	LDL-cholesterol kit	Reference Material Institute for Clinical Chemistry Standards
132	Alpha1-acid glycoprotein kit for blood test	Institute for Reference Materials and Measurements
133	Antithrombin III kit for blood test	National Institute for Biological Standards and Control
134	Ethanol kit for blood test	National Institute of Standards and Technology
135	Quinidine kit for blood test	The United States Pharmacopoeia
136	Thyroid stimulating hormone receptor antibody kit for blood test	National Institute for Biological Standards and Control
137	Thyroid peroxidase antibody kit for blood test	National Institute for Biological Standards and Control
138	Cholinesterase kit for blood test	Reference Material Institute for Clinical Chemistry Standards
		Japanese Committee for Clinical Laboratory Standards

139	Thyroglobulin autoantibody kit for blood kit	National Institute for Biological Standards and Control
140	Protein S kit for blood test	National Institute for Biological Standards and Control
141	Protein C kit for blood test	National Institute for Biological Standards and Control
142	Prolactin kit for blood test	National Institute for Biological Standards and Control
143	Calcium kit for blood/urine test	Institute for Reference Materials and Measurements
		Chemicals Examination and Research Institute, Japan
		Reference Material Institute for Clinical Chemistry Standards
		National Institute of Standards and Technology
144	Glucose kit for blood/urine test	Reference Material Institute for Clinical Chemistry Standards
		National Institute of Standards and Technology
145	Creatinine kit for blood/urine test	Institute for Reference Materials and Measurements
		Reference Material Institute for Clinical Chemistry Standards
		National Institute of Standards and Technology
146	Uric acid kit for blood/urine test	Reference Material Institute for Clinical Chemistry Standards
		National Institute of Standards and Technology
147	Urea nitrogen kit for blood/urine test	Reference Material Institute for Clinical Chemistry Standards
		National Institute of Standards and Technology
148	Magnesium kit for blood/urine test	Institute for Reference Materials and Measurements

		Chemicals Examination and Research Institute, Japan
		Reference Material Institute for Clinical Chemistry Standards
		National Institute of Standards and Technology
149	Phosphorous/inorganic phosphate kit for blood/urine test	Chemicals Examination and Research Institute, Japan
		Reference Material Institute for Clinical Chemistry Standards
		National Institute of Standards and Technology
150	Calcium kit for urine test	Reference Material Institute for Clinical Chemistry Standards
151	Glucose kit for urine test	Reference Material Institute for Clinical Chemistry Standards
152	Creatinine kit for urine test	Reference Material Institute for Clinical Chemistry Standards
153	Uric acid kit for urine test	Reference Material Institute for Clinical Chemistry Standards
154	Urea nitrogen kit for urine test	Reference Material Institute for Clinical Chemistry Standards
155	Magnesium kit for urine test	Reference Material Institute for Clinical Chemistry Standards
156	Phosphorous/inorganic phosphate kit for urine test	Reference Material Institute for Clinical Chemistry Standards
157	Aldosterone kit for blood test	National Institute of Advanced Industrial Science and Technology
158	Salicylate kit for blood test	The Japanese Pharmacopoeia
		The United States Pharmacopoeia
159	Vitamin B12 kit for blood test	National Institute for Biological Standards and Control
		The Japanese Pharmacopoeia
		The United States Pharmacopoeia

160	25-hydroxyvitamin D kit for blood test	National Institute of Standards and Technology
161	Folate kit for blood test	National Institute for Biological Standards and Control
		The Japanese Pharmacopoeia
		The United States Pharmacopoeia
162	Antibiotic susceptibility test (general bacteria/colorimetric method) kit	Type Strain deposited at the American Type Culture Collection
		The Japanese Pharmacopoeia
		The Japanese Pharmaceutical Codex

Appendix 2

First Column	Second Column	Third Column
1	LDL-cholesterol kit	Centers for Disease Control and Prevention
2	HDL-cholesterol kit	Centers for Disease Control and Prevention
3	Glycated haemoglobin A1c kit	International Federation of Clinical Chemistry
4	Cholinesterase kit for blood test	German Society for Clinical Chemistry
5	Haemoglobin kit for blood test	International Council for Standardization in Haematology
		Clinical and Laboratory Standards Institute

Appendix 3

- 1 Class I blood test series
- 2 Class I biochemical test series
- 3 Class I immunological test series
- 4 Class I endocrine test series
- 5 Class I bacteriological test series
- 6 Class I immunohistological test series
- 7 Class I blood/biochemical test series
- 8 Class I blood/immunological test series
- 9 Class I blood/endocrine test series
- 10 Class I biochemical/immunological test series
- 11 Class I biochemical/endocrine test series
- 12 Class I immunological/endocrine test series
- 13 Class I biochemical/immunological/endocrine test series