



Medicines & Healthcare products
Regulatory Agency

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United Kingdom

[mhra.gov.uk](https://www.mhra.gov.uk)

Certificate number: **2021082302212784/1**

Order date: **23/08/2021**

CFS Expiry date: **23/08/2026**

**Medicines and Healthcare products
Regulatory Agency**
On behalf of the Secretary of State for Health and Social Care

CERTIFICATE OF FREE SALE FOR EXPORTATION OF MEDICAL PRODUCTS

It is hereby certified that, on the basis of information provided, the products named below and detailed in the attached schedule (if applicable), which are manufactured by: Legal Manufacturer: **Prestige Diagnostics U.K. Ltd**, 40 Ballymena Business Centre, Galgorm, Ballymena, County Antrim, BT42 1FL, Northern Ireland, United Kingdom, have been affixed with the relevant conformity marking(s) e.g. UKCA, CE or CE UKNI mark under the in vitro diagnostic Medical Devices Directive 98/79/EC as transposed into UK legislation (UK Medical Devices Regulations 2002 S.I. No. 618, as amended) and therefore may be freely sold in the United Kingdom (England, Scotland, Wales, Northern Ireland).

Please see attached schedule

Where appropriate, Certificates of Free Sale are issued as a service to UK exporters. A Certificate of Free Sale should not be taken as a Government endorsement of any product that is referred to on the certificate.

Yours sincerely,

Ngozi Onyeukwu

Certificate of Free Sale Administration Team
Signed on Behalf of MHRA

Certificate Reference: 2021082302212784/1

Ordered on: 23/08/2021

Directive/Regulation: in vitro diagnostic Medical Devices Directive 98/79/EC

Manufacturer Name: Prestige Diagnostics U.K. Ltd

CFS Expiry Date: 23/08/2026

#	Medical Device Name	Model/Version
1	Carcinoembryonic Antigen (CEA) ELISA	Carcinoembryonic Antigen (CEA) IVD, Kit, Enzyme Immunoassay (EIA)
2	Fibrinogen Assay (factor I) Reagent	Fibrinogen assay (factor I) IVD, reagent
3	2019-nCoV and Influenza A+B Antigen Device	SARS-CoV-2/Influenza A/B antigen IVD, kit, immunochromatographic test (ICT), rapid
4	2019-nCoV Antigen Device	SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid
5	2019-nCoV Antigen Device (Anterior Nasal Swab)	SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid
6	2019-nCoV Antigen Device (Saliva)	SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid
7	2019-nCoV IgG/IgM Device	Covid Antibody Rapid Test Device
8	2019-nCoV IgG/IgM WB Device	Covid Antibody Rapid Test Device
9	2019-nCoV Neutralising Antibody Device	SARS-CoV-2 neutralizing antibody IVD, kit, immunochromatographic test (ICT), rapid
10	Activated partial thromboplastin time (APTT) Reagent	Activated partial thromboplastin time (APTT) IVD, Reagent
11	Adenovirus antigen Rapid Test Device	Adenovirus antigen IVD, kit, immunochromatographic test (ICT), rapid
12	AFP Device	Alpha-fetoprotein (AFP) IVD, kit, immunochromatographic test (ICT), rapid
13	Alanine Aminotransferase Reagent	Alanine aminotransferase (ALT) IVD, reagent
14	Albumin Reagent	Albumin IVD, Reagent

15	Alkaline phosphatase (ALP) Reagent	Total alkaline phosphatase (ALP) IVD, reagent
16	Alkaline Phosphatase (AMP) Reagent	Alkaline phosphatase (ALP) Isoenzyme IVD, Reagent
17	Alkaline phosphatase (DEA) Reagent	Alkaline phosphatase (ALP) isoenzyme IVD, reagent
18	Alpha 1 antitrypsin immunoturbidimetry	Alpha 1 antitrypsin
19	Alpha-fetoprotein (AFP) ELISA	Alpha-fetoprotein (AFP) IVD, kit, enzyme immunoassay (EIA)
20	Amphetamine-specific Rapid Test Device	Amphetamine-specific Rapid Device
21	Amylase Isoenzyme Reagent	Amylase Isoenzyme IVD, Reagent
22	Amylase Reagent	Total amylase IVD, reagent
23	Anti Streptolysin O Calibrator	Group A Streptococcus streptolysin O antibody IVD, calibrator
24	Anti streptolysin O Control	Group A Streptococcus streptolysin O antibody IVD, control
25	Anti Streptolysin O Nephelometry/Turbidimetry Kit	Beta-haemolytic Group A Streptococcus streptolysin O antibody IVD, reagent
26	Anti Streptolysin O Visilatem Reagent	Beta-haemolytic Group A Streptococcus streptolysin O antibody IVD, reagent
27	Anti Streptolysin O Visilatem Reagent	Streptococcus streptolysin O antibody IVD, kit, agglutination, rapid
28	Antihuman globulin reagent	Antihuman globulin
29	Apolipoprotein A-I (Apo A1) IVD, Kit, Nephelometry / Turbidimetry	Apolipoprotein A-I (Apo A1) IVD, Kit, Nephelometry / Turbidimetry
30	Apolipoprotein B (Apo B) IVD, Kit, Nephelometry / Turbidimetry	Apolipoprotein B (Apo B) IVD, Kit, Nephelometry / Turbidimetry
31	B-type Natriuretic Protein/N-Terminal Pro B-Type Natriuretic Peptide Rapid Test Device	B-type Natriuretic Protein/N-Terminal Pro B-Type Natriuretic Peptide IVD, kit, immunochromatographic Test (ICT), Rapid Device
32	Barbiturate IVD, Kit, Rapid Test Device	Barbiturate IVD, Kit, Immunochromatographic

		Test (ICT), Rapid Test Device
33	Benzodiazepine Rapid Test Device	Benzodiazepine Group IVD, Kit, Immunochromatographic Test (ICT), Rapid Test Device
34	Bilirubin calibrator	Bilirubin calibrator
35	Brucella abortus Agglutination Reagent	Brucella species culture isolate antigen Agglutination Reagent
36	Brucella melitensis Agglutination Reagent	Brucella species culture isolate antigen Agglutination Reagent
37	C-Reactive Protein (CRP) Calibrator	C-reactive Protein (CRP) IVD, Calibrator
38	C-Reactive Protein (CRP) Nephelometry / Turbidimetry	C-Reactive Protein (CRP) IVD, Kit, Nephelometry / Turbidimetry
39	C-Reactive protein (CRP) Visilates Reagent	C-Reactive Protein (CRP) IVD, Kit, Agglutination, Rapid
40	C-reactive Protein Control	C-reactive protein control
41	C-Reactive Protein Rapid Test Device	C-reactive protein immunochromatographic test
42	Calcium Arsenazo Reagent	Calcium (Ca ²⁺) IVD, reagent
43	Calcium chloride Coagulation Reagent	Calcium chloride coagulation reagent
44	Calcium OCPC Reagent	Calcium (Ca ²⁺) IVD, reagent
45	Calibration Serum	Clinical Chemistry analyte Calibrator
46	Cancer Antigen 125 (CA125) ELISA kit	Cancer Antigen 125 (CA125) IVD, kit, Enzyme Immunoassay (EIA)
47	Cancer Antigen 15-3 (CA15-3) ELISA	Cancer antigen 15-3 (CA15-3) IVD, kit, enzyme immunoassay (EIA)
48	Cancer Antigen 19-9 (CA19-9) ELISA	Cancer Antigen 19-9 (CA19-9) IVD, Kit, Enzyme Immunoassay (EIA)
49	Cannabinoid Rapid Test Device	Cannabinoid IVD, kit, Immunochromatographic Test (ICT), Rapid
50	CEA Rapid Test Device	CEA immunochromatographic test

51	Chlamydia trachomatis Nucleic Acid Kit	Chlamydia trachomatis nucleic acid IVD, kit, nucleic acid technique (NAT)
52	Chloride (Cl-) Reagent	Chloride (Cl-) IVD, reagent
53	Cholesterol Lyophilised Reagent	Total cholesterol lipid IVD, reagent
54	Cholesterol Reagent	Total cholesterol lipid IVD, reagent
55	Cholinesterase Reagent	Cholinesterase Dibucaine Number (percentage inhibition) IVD, Reagent
56	Cocaine / Cocaine Metabolite Rapid Test Device	Cocaine / Cocaine Metabolite IVD, Kit, Immunochromatographic Test (ICT), Rapid
57	Complement C3/C3c	Complement C3/C3c nephelometry/turbidimetry
58	Complement C4/C4c	Complement C4/C4c nephelometry/turbidimetry
59	Copper Reagent	Copper IVD, Reagent
60	Cotinine Device	Cotinine (nicotine metabolite) IVD, kit, enzyme immunoassay
61	COVID-19 Antigen ELISA	SARS-CoV-2 antigen IVD, kit, enzyme immunoassay (EIA)
62	COVID-19 ELISA	SARS-CoV-2 immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, enzyme immunoassay (EIA)
63	COVID-19 IgG ELISA	SARS-CoV-2 immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
64	COVID-19 IgM ELISA	SARS-CoV-2 immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
65	COVID-19 Lyophilised Nucleic Acid Kit	SARS-CoV-2 nucleic acid IVD, kit, nucleic acid technique (NAT)
66	Creatine Kinase (CKNAC) Reagent	Creatine Kinase (CK) Multiple Isoenzyme IVD, Reagent

67	Creatine Kinase (CKNAC) Reagent Dry	Total creatine kinase (CK) IVD, reagent
68	Creatine Kinase Myocardial Isoenzyme (CKMB) Rapid Test Device	Creatine Kinase Myocardial Isoenzyme (CKMB) IVD, Kit, Immunochromatographic Test (ICT) Rapid Test Device
69	Creatine kinase myocardial isoenzyme (CKMB) Reagent	Creatine kinase myocardial isoenzyme (CKMB) IVD, reagent
70	Creatine kinase myocardial isoenzyme (CKMB) Reagent Dry	Creatine kinase myocardial isoenzyme (CKMB) Reagent
71	Creatinine Reagent	Creatinine IVD, reagent
72	Cystatin C	Cystatin C nephelometry/turbidimetry
73	D-dimer Rapid Test Device	D-dimer IVD, Kit, Immunochromatographic Test (ICT), Rapid Test Device
74	Dengue Antibody Device	Dengue virus antibody IVD, kit, immunochromatographic test (ICT), rapid
75	Dengue Antigen/Antibody Rapid Test Device	Dengue antibody/antigen immunochromatographic test
76	Dengue Virus Immunoglobulin A (IgA)/IgG/IgM Antibody Enzyme Immunoassay (EIA)	Dengue virus immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, enzyme immunoassay (EIA)
77	Dengue Virus Nucleic Acid Kit	Dengue virus nucleic acid IVD, kit, nucleic acid technique (NAT)
78	Direct Bilirubin Reagent	Total/conjugated (direct) bilirubin Reagent
79	DNA/RNA Detection Cartridge	Nucleic acid extraction and amplification kit
80	DNA/RNA Detection Cartridge COVID-19	Nucleic acid extraction and amplification kit
81	DNA/RNA Detection Cartridge Influenza A/B/RSV	DNA/RNA extraction and amplification kit
82	DNA/RNA Extraction Kit	Nucleic acid extraction/purification kit
83	Erythrocyte Sedimentation Rate (ESR) Control	Erythrocyte sedimentation rate (ESR) IVD, control

84	Estradiol ELISA	Estradiol (oestradiol) (E2) IVD, kit, enzyme immunoassay (EIA)
85	Faecal Occult Blood Rapid Test Kit	Faecal occult blood IVD, kit, immunochromatographic test (ICT), Rapid Test Kit
86	Fastep 1000	Haemoglobin analyser IVD, point-of-care
87	Fastep Hb	Haemoglobin point-of-care analyser
88	Fastep Hb Hemometer Strips	Total Haemoglobin Hemometer Strips
89	Fatty acid binding protein device	Fatty acid binding protein enzyme immunoassay
90	Febrile Antigen Reagent	Multiple Salmonella species antigen IVD, reagent
91	Febrile Negative Control	Multiple febrile infection-associated bacteria antigen IVD, control
92	Febrile Positive Control	Multiple febrile infection-associated bacteria antigen IVD, control
93	Ferritin ELISA	Ferritin IVD, kit, enzyme immunoassay (EIA)
94	FLIA	Fluorescence Immunoassay Point of Care Analyser
95	Follicle stimulating hormone (FSH) ELISA	Follicle stimulating hormone (FSH) IVD, Kit, Enzyme Immunoassay (EIA)
96	Free Thyroxine (FT4) ELISA	Free thyroxine (FT4) IVD, kit, enzyme immunoassay (EIA)
97	Free Triiodothyronine ELISA	Free triiodothyronine (FT3) IVD, kit, enzyme immunoassay (EIA)
98	Full Blood Count Kit, Cell Count	Full blood count IVD, kit, cell count
99	Gamma-glutamyltransferase (GGT) Reagent	Gamma-glutamyltransferase (GGT) IVD, reagent
100	Glucose Reagent	Glucose Reagent Single Liquid
101	Glucose Reagent Lyophilised	Glucose Reagent Lyo
102	Glycated Haemoglobin (HbA1c) Calibrator	Glycated Haemoglobin (HbA1c) Calibrator
103	Glycated haemoglobin (HbA1c) Control	Glycated haemoglobin (HbA1c) IVD, control

104	Glycated Haemoglobin (HbA1c) IVD, Reagent	Glycated haemoglobin (HbA1c) IVD, reagent
105	Gonorrhoeae antigen Rapid Test Device	Gonorrhoeae antigen immunochromatographic test
106	Group A Streptococcus antigen Rapid Test Device	Group A Streptococcus antigen immunochromatographic test
107	Group A Streptococcus streptolysin O antibody Reagent	Group A Streptococcus streptolysin O antibody IVD, reagent
108	Group B Streptococcus antigen Rapid Test Device	Group B Streptococcus antigen immunochromatographic test
109	H Pylori Antibody Rapid Test Device	H Pylori Antibody immunochromatographic test
110	Haemoglobin (totHb) Reagent	Total haemoglobin (totHb) IVD, reagent
111	HAV IgG ELISA	Hepatitis A virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
112	HAV IgM Device	Hepatitis A virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay device
113	Helicobacter Pylori Antigen Rapid Test Device	Helicobacter pylori antigen IVD, kit, immunochromatographic test (ICT), rapid
114	Hepatitis A virus Immunoglobulin M (IgM) Antibody, Enzyme Immunoassay (EIA)	Hepatitis A virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
115	Hepatitis E virus immunoglobulin G ELISA	Hepatitis E virus immunoglobulin G enzyme immunoassay
116	Herpes Simplex Virus 1 (HSV1) Immunoglobulin G (IgG) ELISA	Herpes simplex virus 1 (HSV1) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
117	Herpes simplex virus 1 (HSV1) immunoglobulin G (IgG) Rapid Test Device	Herpes simplex virus 1 (HSV1) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
118	Herpes Simplex Virus 1 (HSV1) Immunoglobulin M (IgM) ELISA	Herpes simplex virus 1 (HSV1) immunoglobulin M

		(IgM) antibody IVD, kit, enzyme immunoassay (EIA)
119	Herpes simplex virus 1 (HSV1) immunoglobulin M (IgM) Rapid Test Device	Herpes simplex virus 1 (HSV1) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
120	Herpes simplex virus 2 (HSV2) immunoglobulin G (IgG) ELISA	Herpes simplex virus 2 (HSV2) immunoglobulin G (IgG)
121	Herpes Simplex Virus 2 (HSV2) Immunoglobulin G (IgG) Rapid Test Device	Herpes simplex virus 2 (HSV2) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
122	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) ELISA	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
123	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) Rapid Test Device	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
124	HEV IgM Device	Hepatitis E virus immunoglobulin M (IgM) antibody IVD, kit
125	High density lipoprotein (HDL) cholesterol Reagent	High density lipoprotein (HDL) cholesterol IVD, Reagent
126	High-density lipoprotein (HDL) Calibrator	High-density lipoprotein (HDL) cholesterol IVD, calibrator
127	HSV 1/2 IgG/IgM Device	Herpes simplex virus 1 & 2 (HSV1 & 2) immunoglobulin G (IgG)/IgM antibody IVD, kit
128	Human Assayed control	Clinical Chemistry analyte Control
129	Human chorionic gonadotropin beta-subunit (beta-HCG) ELISA	Human chorionic gonadotropin beta-subunit (beta-HCG) IVD, kit, enzyme immunoassay (EIA)
130	Human Chorionic Gonadotropin beta-subunit (beta-HCG) Rapid Test Device	Human Chorionic Gonadotropin beta-subunit (beta-HCG) IVD, kit, Immunochromatographic rapid
131	Inorganic Phosphate Reagent	Inorganic phosphate (PO ₄ ³⁻) IVD, reagent
132	Iron Reagent	Iron IVD, reagent

133	Lactate Dehydrogenase (LDH) (L - P) Reagent	Total lactate dehydrogenase (LDH) IVD, reagent
134	Lactate Dehydrogenase (LDH) (P - L) Reagent	Total lactate dehydrogenase (LDH) IVD, reagent
135	Lactate Dehydrogenase (LDH) Multiple Isoenzyme Reagent	Lactate dehydrogenase (LDH) multiple isoenzyme IVD, reagent
136	Lactate Dehydrogenase (LDH) Reagent	Total lactate dehydrogenase (LDH) IVD, reagent
137	Lactate Reagent	Lactate IVD, reagent
138	Lipase Reagent	Lipase IVD, reagent
139	Low Density Lipoprotein (LDL) Cholesterol Calibrator	Low density lipoprotein (LDL) cholesterol IVD, calibrator
140	Low Density Lipoprotein (LDL) Cholesterol Reagent	Low density lipoprotein (LDL) cholesterol IVD, reagent
141	Low Ionic-Strength Salt Solution (LISS) Reagent	Low ionic-strength salt solution (LISS) immunohaematology reagent IVD
142	Luteinizing hormone (LH) ELISA	Luteinizing hormone (LH) IVD, kit, enzyme immunoassay (EIA)
143	Magnesium Reagent	Magnesium (Mg ²⁺) IVD, reagent
144	MagXtractor MX48	DNA RNA Extraction Analyser, Automated
145	MagXtractor MX96	DNA RNA Extraction Analyser, Automated
146	Malaria Pan Rapid Test Device	Plasmodium antigen immunochromatographic test
147	Malaria Rapid Test Device	Malaria antigen immunochromatographic test
148	Methadone Rapid Test Device	Methadone IVD, kit, immunochromatographic test (ICT), rapid
149	Methamphetamine-specific Rapid Test Device	Methamphetamine-specific IVD, kit, immunochromatographic test (ICT) assay, rapid
150	Microalbumin Rapid Test Device	Microalbumin immunochromatographic test, rapid
151	Microalbumin Reagent	Microalbumin IVD, reagent

152	Multiple Drugs of Abuse Rapid Test Device	Multiple drugs of abuse IVD, kit, immunochromatographic test (ICT), rapid
153	Mycobacterium tuberculosis Rapid Test Device	Mycobacterium tuberculosis complex species immunochromatographic test
154	Mycoplasma Rapid Test Device	Mycoplasma pneumoniae immunochromatographic test
155	Myoglobin Rapid Test Device	Myoglobin IVD, kit, immunochromatographic test (ICT), rapid
156	Nefletron Apolipoprotein A1	Apolipoprotein A-I (Apo A1) IVD, kit, nephelometry/turbidimetry
157	Nefletron Apolipoprotein B	Apolipoprotein B (Apo B) IVD, kit, nephelometry/turbidimetry
158	Nefletron Cyclic Citrullinated Peptide	Cyclic citrullinated peptide antibody (anti-CCP) IVD, kit, immunoassay
159	Nefletron D-Dimer	D-dimer IVD, kit, nephelometry/turbidimetry
160	Nefletron HbA1c	Glycated haemoglobin (HbA1c) IVD, kit, nephelometry/turbidimetry
161	Nefletron Immunoglobulin A (IgA)	Total immunoglobulin A (IgA total) IVD, kit, nephelometry/turbidimetry
162	Nefletron Immunoglobulin G (IgG)	Immunoglobulin G (IgG total) IVD, kit, nephelometry/turbidimetry
163	Nefletron Immunoglobulin M (IgM)	Immunoglobulin M (IgM total) IVD, kit, nephelometry/turbidimetry
164	Nefletron Microalbumin (MAU)	Microalbumin IVD, kit, nephelometry/turbidimetry
165	Nefletron Serum Amyloid A	Serum amyloid A IVD, kit, nephelometry/turbidimetry
166	Neisseria gonorrhoeae Nucleic Acid Kit	Neisseria gonorrhoeae nucleic acid IVD, kit, nucleic acid technique (NAT)
167	Neonatal Thyroid Stimulating Hormone (Neonatal TSH) Elisa	Neonatal thyroid stimulating hormone (neonatal TSH) IVD, kit, enzyme immunoassay (EIA)

168	Neutralising Antibody ELISA	SARS-CoV-2 neutralizing antibody IVD, kit, enzyme immunoassay (EIA)
169	PCR Duo	PCR POCT Analyser
170	Phencyclidine (PCP) Rapid Test Device	Phencyclidine (PCP) IVD, kit, immunochromatographic test (ICT)
171	Plasma Calibrator	Multiple coagulation factor IVD, calibrator
172	Plasma Control	Multiple coagulation factor IVD, control
173	Potassium Reagent	Potassium (K+) IVD, reagent
174	Progesterone Elisa	Progesterone IVD, kit, enzyme immunoassay (EIA)
175	Prolactin Elisa	Prolactin IVD, kit, enzyme immunoassay (EIA)
176	Proteus stained antigen suspension	Febrile antigens
177	Prothrombin time Clotting Reagent	Prothrombin time (PT) IVD, kit, clotting
178	Real Time PCR Analyser	Thermal cycler nucleic acid amplification analyser
179	Rheumatoid Factor Calibrator	Rheumatoid factor IVD, calibrator
180	Rheumatoid Factor Control	Rheumatoid factor IVD, control
181	Rheumatoid Factor Nephelometry / Turbidimetry	Rheumatoid factor IVD, kit, nephelometry/turbidimetry
182	Rheumatoid Factor Visilatelx Reagent	Rheumatoid factor IVD, kit, agglutination
183	Rotavirus Antigen Rapid Test Device	Rotavirus antigen IVD, kit, immunochromatographic test (ICT), rapid
184	RPR Reagent	Treponema pallidum reagin antibody IVD, kit, agglutination
185	Salmonella Nucleic Acid Kit	Multiple Salmonella species nucleic acid IVD, kit, nucleic acid technique (NAT)
186	Salmonella Rapid Test Device	Salmonella species immunochromatographic test
187	Serological albumin	Serological albumin

188	Single Use Specimen Container	General specimen container, preservation solution, non-sterile
189	Sodium Reagent	Sodium (Na+) IVD, reagent
190	Staphylococcus aureus Nucleic Acid Kit	Multiple Staphylococcus species nucleic acid IVD, kit, nucleic acid technique (NAT)
191	Syphilis ELISA	Treponema pallidum immunoglobulin G (IgG)/IgM antibody enzyme immunoassay
192	Testosterone Elisa	Total testosterone IVD, kit, enzyme immunoassay (EIA)
193	Thrombin time (TT) Reagent	Thrombin time (TT) IVD, reagent
194	Thyroid stimulating hormone (TSH) Elisa	Thyroid stimulating hormone (TSH) IVD, kit, enzyme immunoassay (EIA)
195	Total (direct) Bilirubin Reagent	Total/conjugated (direct) bilirubin IVD, kit, spectrophotometry
196	Total Aspartate Aminotransferase (AST) Reagent	Total aspartate aminotransferase (AST) IVD, reagent
197	Total Bilirubin / Direct Bilirubin Combo	Total/conjugated (direct) bilirubin Reagent
198	Total Bilirubin Reagent	Total/conjugated (direct) bilirubin Reagent
199	Total creatine kinase (CK) IVD, reagent	Creatine kinase (CK) Reagent
200	Total Protein Reagent	Total protein IVD, reagent
201	Total thyroxine (TT4) Elisa	Total thyroxine (TT4) IVD, kit, enzyme immunoassay (EIA)
202	Total triiodothyronine (TT3) Elisa	Total triiodothyronine (TT3) IVD, kit, enzyme immunoassay (EIA)
203	TPHA Control	Treponema pallidum immunoglobulin G/immunoglobulin M control
204	Treponema Pallidum Haemagglutination Reagent	Treponema pallidum total antibody IVD, reagent
205	Treponema Pallidum Reagin Antibody Agglutination	Treponema pallidum reagin antibody IVD, kit, agglutination

206	Treponema pallidum reagin antibody kit, agglutination	Treponema pallidum reagin antibody IVD, kit, agglutination
207	Treponema Pallidum Total Antibody Rapid Test Device	Treponema pallidum total antibody IVD, kit, immunochromatographic test (ICT), rapid
208	Tricyclic antidepressant Rapid Test Device	Tricyclic antidepressant IVD, kit, immunochromatographic test (ICT), rapid
209	Triglyceride Reagent	Triglyceride IVD, reagent
210	Troponin T/Troponin I Elisa	Troponin T/Troponin I IVD, kit, enzyme immunoassay (EIA)
211	Troponin T/Troponin I Rapid Test Device	Troponin T/Troponin I IVD, kit, immunochromatographic test (ICT), rapid
212	Tuberculosis Nucleic Acid Kit	Mycobacterium tuberculosis nucleic acid IVD, kit, nucleic acid technique (NAT)
213	Typhoid Device	Multiple Salmonella species IVD, kit, immunochromatographic test (ICT), rapid
214	Urea Colour Reagent	Urea IVD, reagent
215	Urea Reagent	Urea IVD, reagent
216	Urea UV Reagent	Urea IVD, reagent
217	Uric Acid Reagent	Uric acid IVD, reagent
218	Vitamin D ELISA	Vitamin D enzyme immunoassay
219	Wash/cleaning Solution Automated/Semi-Automated System	Wash/cleaning solution IVD, automated/semi-automated system
220	Zinc Reagent	Zinc IVD, reagent

End of Schedule. No additional information past this point.