



Medicines & Healthcare products
Regulatory Agency



10 South Colonnade
Canary Wharf
London E14 4PU
United Kingdom

mhra.gov.uk

Certificate number: **2020031202178785/6**

Order date: **13/03/2020**

CFS Expiry date: **13/03/2025**

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, United Kingdom, have been affixed with the CE mark under 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 all member states of the European Economic Area including the United Kingdom.

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,

Lewis Kennedy

Certificate of Free Sale Administration Team
Signed on Behalf of MHRA





Certificate Reference: 2020031202178785/1

Ordered on: 13/03/2020

Directive/Regulation: In-Vitro Diagnostic Medical Devices Directive 98/79/EC

Manufacturer Name: Prestige Diagnostics U.K. Ltd

CFS Expiry Date: 13/03/2025

#	Medical Device Name	Model
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 IgG/IgM Device	Covid Antibody Rapid Test Device
4	2019-nCoV IgG/IgM WB Device	Covid Antibody Rapid Test Device
5	ABO multiple blood grouping agglutination	ABO multiple blood grouping IVD, kit, agglutination
6	Activated partial thromboplastin time (APTT) Reagent	Activated partial thromboplastin time (APTT) IVD, Reagent
7	Adenovirus antigen Rapid Test Device	Adenovirus antigen IVD, kit, immunochromatographic test (ICT), rapid
8	Alanine Aminotransferase Reagent	Alanine aminotransferase (ALT) IVD, reagent
9	Albumin Reagent	Albumin IVD, Reagent
10	Alkaline phosphatase (ALP) Reagent	Total alkaline phosphatase (ALP) IVD, reagent
11	Alkaline Phosphatase (AMP) Reagent	Alkaline phosphatase (ALP) Isoenzyme IVD, Reagent
12	Alkaline phosphatase (DEA) Reagent	Alkaline phosphatase (ALP) isoenzyme IVD, reagent
13	Alpha-fetoprotein (AFP) ELISA	Alpha-fetoprotein (AFP) IVD, kit, enzyme immunoassay (EIA)
14	Amphetamine / Methamphetamine	Amphetamine / Methamphetamine





	Group Rapid Test Device	group IVD, Kit, Immunochromatographic Test (ICT), Rapid Test Device
15	Amphetamine-specific Rapid Test Device	Amphetamine-specific Rapid Device
16	Amylase Reagent	Total amylase IVD, reagent
17	Anti HBc	Hepatitis B core antibody enzyme immunoassay
18	Anti HCV ELISA	Hepatitis C virus Antibody Enzyme Immunoassay (EIA)
19	Anti Hepatitis B surface antigen Antibody Rapid Test Device	Hepatitis B virus surface Total Antibody IVD Enzyme Immunoassay (EIA)
20	Anti Hepatitis B surface antigen ELISA	Hepatitis B virus surface Total Antibody Enzyme Immunoassay (EIA)
21	Anti Streptolysin O Calibrator	Group A Streptococcus streptolysin O antibody IVD, calibrator
22	Anti streptolysin O Control	Group A Streptococcus streptolysin O antibody IVD, control
23	Anti Streptolysin O Visilates Reagent	Streptococcus streptolysin O antibody IVD, kit, agglutination, rapid
24	Antihuman globulin reagent	Antihuman globulin
25	Apolipoprotein A-I (Apo A1) IVD, Kit, Nephelometry / Turbidimetry	Apolipoprotein A-I (Apo A1) IVD, Kit, Nephelometry / Turbidimetry
26	Apolipoprotein A-II (Apo A2) IVD, Kit, Nephelometry / Turbidimetry	Apolipoprotein A-II (Apo A2) IVD, Kit, Nephelometry / Turbidimetry
27	Apolipoprotein B (Apo B) IVD, Kit, Nephelometry / Turbidimetry	Apolipoprotein B (Apo B) IVD, Kit, Nephelometry / Turbidimetry
28	Apolipoprotein E (Apo E) IVD, Kit, Nephelometry / Turbidimetry	Apolipoprotein E (Apo E) IVD, Kit, Nephelometry / Turbidimetry
29	Autotron 120 Clinical Chemistry Analyser	Multichannel clinical chemistry analyser
30	Autotron 240 Clinical Chemistry Analyser	Multichannel clinical chemistry analyser
31	Autotron 420 Clinical Chemistry	Multichannel clinical chemistry





	Analyser	analyser
32	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
33	Barbiturate IVD, Kit, Rapid Test Device	Barbiturate IVD, Kit, Immunochromatographic Test (ICT), Rapid Test Device
34	Benzodiazepine Rapid Test Device	Benzodiazepine Group IVD, Kit, Immunochromatographic Test (ICT), Rapid Test Device
35	Bilirubin calibrator	Bilirubin calibrator
36	Bilirubin Control	Total bilirubin IVD, control
37	Brucella abortus Agglutination Reagent	Brucella species culture isolate antigen Agglutination Reagent
38	Brucella melitensis Agglutination Reagent	Brucella species culture isolate antigen Agglutination Reagent
39	C-Reactive Protein (CRP) Calibrator	C-reactive Protein (CRP) IVD, Calibrator
40	C-Reactive Protein (CRP) Nephelometry / Turbidimetry	C-Reactive Protein (CRP) IVD, Kit, Nephelometry / Turbidimetry
41	C-Reactive protein (CRP) Visilatem Reagent	C-Reactive Protein (CRP) IVD, Kit, Agglutination, Rapid
42	C-reactive Protein Control	C-reactive protein control
43	C-Reactive Protein Rapid Test Device	C-reactive protein immunochromatographic test
44	Calcium Arsenazo Reagent	Calcium (Ca ²⁺) IVD, reagent
45	Calcium chloride Coagulation Reagent	Calcium chloride coagulation reagent
46	Calcium OCPC Reagent	Calcium (Ca ²⁺) IVD, reagent
47	Calibration Serum	Clinical Chemistry analyte Calibrator
48	Cancer Antigen 125 (CA125) ELISA kit	Cancer Antigen 125 (CA125) IVD, kit, Enzyme Immunoassay (EIA)
49	Cancer Antigen 15-3 (CA15-3) ELISA	Cancer antigen 15-3 (CA15-3) IVD, kit, enzyme immunoassay (EIA)
50	Cancer Antigen 19-9 (CA19-9) ELISA	Cancer Antigen 19-9 (CA19-9)





		IVD, Kit, Enzyme Immunoassay (EIA)
51	Cannabinoid Rapid Test Device	Cannabinoid IVD, kit, Immunochromatographic Test (ICT), Rapid
52	Cardiac Control	Multiple Cardiac Marker Control
53	CEA Rapid Test Device	CEA immunochromatographic test
54	Chlamydia Rapid Test Device	Chlamydia trachomatis antigen immunochromatographic test
55	Chloride (Cl-) Reagent	Chloride (Cl-) IVD, reagent
56	Cholesterol Reagent	Total cholesterol lipid IVD, reagent
57	Cholinesterase Reagent	Cholinesterase Dibucaine Number (percentage inhibition) IVD, Reagent
58	CMV IgG Rapid Test Device	CMV IgG immunochromatographic test
59	Coagulation Factor II (Prothrombin Time Reagent)	Coagulation Factor II (Prothrombin) IVD, Reagent
60	Coagulation Factor IIa Thrombin Time Reagent	Coagulation Factor IIa Thrombin) IVD, Reagent
61	Cocaine / Cocaine Metabolite Rapid Test Device	Cocaine / Cocaine Metabolite IVD, Kit, Immunochromatographic Test (ICT), Rapid
62	Complement C3/C3c	Complement C3/C3c nephelometry/turbidimetry
63	Complement C4/C4c	Complement C4/C4c nephelometry/turbidimetry
64	Copper Reagent	Copper IVD, Reagent
65	Cotinine (Nicotine Metabolite) Kit, Enzyme Immunoassay (EIA)	Cotinine (Nicotine Metabolite) IVD, Kit, Enzyme Immunoassay (EIA)
66	COVID-19 ELISA	COVID Antibody ELISA
67	COVID-19 PCR Kit	COVID PCR Kit
68	Creatine Kinase (CK) Calibrator	Creatine Kinase (CK) Multiple Isoenzyme Calibrator
69	Creatine kinase (CK) Control	Creatine kinase (CK) multiple isoenzyme Control
70	Creatine kinase (CKNAC) Calibrator	Creatine kinase (CK) multiple isoenzyme Calibrator





71	Creatine Kinase (CKNAC) Reagent	Creatine Kinase (CK) Multiple Isoenzyme IVD, Reagent
72	Creatine kinase myocardial (CKMB) Calibrator	Creatine kinase (CK) multiple isoenzyme IVD, calibrator
73	Creatine Kinase Myocardial Isoenzyme (CKMB) Control	Creatine kinase myocardial isoenzyme (CKMB) IVD, control
74	Creatine Kinase Myocardial Isoenzyme (CKMB) Rapid Test Device	Creatine Kinase Myocardial Isoenzyme (CKMB) IVD, Kit, Immunochromatographic Test (ICT) Rapid Test Device
75	Creatine kinase myocardial isoenzyme (CKMB) Reagent	Creatine kinase myocardial isoenzyme (CKMB) IVD, reagent
76	Creatine kinase myocardial isoenzyme (CKMB) Reagent Dry	Creatine kinase myocardial isoenzyme (CKMB) Reagent
77	Creatinine Reagent	Creatinine IVD, reagent
78	Cystatin C	Cystatin C nephelometry/turbidimetry
79	Cytomegalovirus (CMV) Immunoglobulin G (IgG) ELISA	Cytomegalovirus (CMV) Immunoglobulin G (IgG) Antibody IVD, Kit, Enzyme Immunoassay (EIA)
80	Cytomegalovirus (CMV) Immunoglobulin M (IgM) ELISA	Cytomegalovirus (CMV) Immunoglobulin M (IgM) Antibody IVD, Kit, Enzyme Immunoassay (EIA)
81	Cytomegalovirus IgM Rapid Test Device	Cytomegalovirus (CMV) immunoglobulin M immunochromatographic test
82	D-dimer	D-dimer nephelometry/turbidimetry
83	D-dimer Rapid Test Device	D-dimer IVD, Kit, Immunochromatographic Test (ICT), Rapid Test Device
84	Dengue Antigen/Antibody Rapid Test Device	Dengue antibody/antigen immunochromatographic test
85	Dengue Virus Immunoglobulin A (IgA)/IgG/IgM Antibody Enzyme Immunoassay (EIA)	Dengue virus immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, enzyme immunoassay (EIA)
86	Direct Bilirubin Reagent	Total/conjugated (direct) bilirubin Reagent





87	Enzyme Immunoassay (EIA) Analyser Semi-automated	Enzyme immunoassay (EIA) analyser IVD, semi-automated
88	Erythrocyte Sedimentation Rate (ESR) Control	Erythrocyte sedimentation rate (ESR) IVD, control
89	Estradiol ELISA	Estradiol (oestradiol) (E2) IVD, kit, enzyme immunoassay (EIA)
90	Faecal Occult Blood IVD, Control	Faecal occult blood IVD, control
91	Faecal Occult Blood Rapid Test Kit	Faecal occult blood IVD, kit, immunochromatographic test (ICT), Rapid Test Kit
92	Fastep Hb	Haemoglobin point-of-care analyser
93	Fastep Hb Hemometer Strips	Total Haemoglobin Hemometer Strips
94	Fatty acid binding protein device	Fatty acid binding protein enzyme immunoassay
95	Febrile Antigen Reagent	Multiple Salmonella species antigen IVD, reagent
96	Febrile Negative Control	Multiple febrile infection-associated bacteria antigen IVD, control
97	Febrile Positive Control	Multiple febrile infection-associated bacteria antigen IVD, control
98	Ferritin ELISA	Ferritin IVD, kit, enzyme immunoassay (EIA)
99	Ferritin immunoassay	Ferritin enzyme immunoassay
100	FLIA	Fluorescence Immunoassay Point of Care Analyser
101	FOB Control	Faecal occult blood control
102	Follicle stimulating hormone (FSH) ELISA	Follicle stimulating hormone (FSH) IVD, Kit, Enzyme Immunoassay (EIA)
103	Follicle stimulating hormone (FSH) Rapid Test Device	Follicle stimulating hormone (FSH) IVD, kit, immunochromatographic test (ICT), rapid
104	Free (unbound) prostate specific antigen (PSA) ELISA	Free (unbound) prostate specific antigen (PSA) IVD, kit, enzyme immunoassay (EIA)
105	Free Thyroxine (FT4) ELISA	Free thyroxine (FT4) IVD, kit, enzyme immunoassay (EIA)





106	Free Triiodothyronine ELISA	Free triiodothyronine (FT3) IVD, kit, enzyme immunoassay (EIA)
107	Full Blood Count Control	Full blood count IVD, control
108	Full Blood Count Kit, Cell Count	Full blood count IVD, kit, cell count
109	Gamma-glutamyltransferase (GGT) Reagent	Gamma-glutamyltransferase (GGT) IVD, reagent
110	Glucose Reagent	Glucose Reagent Single Liquid
111	Glucose Reagent Lyophilised	Glucose Reagent Lyo
112	Glycated Haemoglobin (HbA1C) Analyser	Glycated haemoglobin (HbA1C) analyser IVD
113	Glycated Haemoglobin (HbA1c) Calibrator	Glycated Haemoglobin (HbA1c) Calibrator
114	Glycated haemoglobin (HbA1c) Control	Glycated haemoglobin (HbA1c) IVD, control
115	Glycated Haemoglobin (HbA1c) IVD, Reagent	Glycated haemoglobin (HbA1c) IVD, reagent
116	Gonorrhoeae antigen Rapid Test Device	Gonorrhoeae antigen immunochromatographic test
117	Group A Streptococcus antigen Rapid Test Device	Group A Streptococcus antigen immunochromatographic test
118	Group A Streptococcus streptolysin O antibody Reagent	Group A Streptococcus streptolysin O antibody IVD, reagent
119	Group B Streptococcus antigen Rapid Test Device	Group B Streptococcus antigen immunochromatographic test
120	H Pylori Antibody Rapid Test Device	H Pylori Antibody immunochromatographic test
121	Haemoglobin (totHb) Control	Total haemoglobin (totHb) IVD, control
122	Haemoglobin (totHb) Reagent	Total haemoglobin (totHb) IVD, reagent
123	HCV Rapid Test Device	Hepatitis C virus Antibody Enzyme Immunoassay
124	Helicobacter Pylori Antigen Rapid Test Device	Helicobacter pylori antigen IVD, kit, immunochromatographic test (ICT), rapid
125	Hematron 3	Haematological cell analyser IVD, automated





126	Hematron 5	Haematological cell analyser IVD, automated
127	Hepatitis A Virus Immunoglobulin G (IgG) Antibody Reagent	Hepatitis A virus immunoglobulin G (IgG) antibody IVD, reagent
128	Hepatitis A virus Immunoglobulin M (IgM) Antibody, Enzyme Immunoassay (EIA)	Hepatitis A virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
129	Hepatitis B Core Antibody Rapid Test Device	Hepatitis B core antibody immunochromatographic test
130	Hepatitis B Virus Core Immunoglobulin M (IgM) Antibody, Enzyme Immunoassay (EIA)	Hepatitis B virus core immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
131	Hepatitis B Virus e-antigen Enzyme Immunoassay (EIA)	Hepatitis B virus e-antigen IVD, kit, enzyme immunoassay (EIA)
132	Hepatitis B Virus e-antigen Total Antibody, Enzyme Immunoassay (EIA)	Hepatitis B virus e-antigen total antibody IVD, kit, enzyme immunoassay (EIA)
133	Hepatitis B virus surface antigen ELISA	Hepatitis B virus surface antigen enzyme immunoassay (EIA)
134	Hepatitis B Virus surface antigen Rapid Test Device	Hepatitis B virus surface antigen IVD, kit, enzyme immunoassay (EIA)
135	Hepatitis D virus antigen ELISA	Hepatitis D virus antigen enzyme immunoassay
136	Hepatitis D virus immunoglobulin G (IgG) ELISA	Hepatitis D virus immunoglobulin G (IgG) antibody enzyme immunoassay
137	Hepatitis D virus immunoglobulin M ELISA	Hepatitis D virus immunoglobulin M antibody enzyme immunoassay
138	Hepatitis E virus antigen ELISA	Hepatitis E virus antigen enzyme immunoassay
139	Hepatitis E virus immunoglobulin G ELISA	Hepatitis E virus immunoglobulin G enzyme immunoassay
140	Hepatitis E Virus Immunoglobulin M ELISA	Hepatitis E virus immunoglobulin M (IgM) antibody enzyme immunoassay
141	Hepatitis G virus immunoglobulin G ELISA	Hepatitis G virus immunoglobulin G (IgG) antibody enzyme immunoassay





142	Herpes Simplex Virus 1 (HSV1) Immunoglobulin G (IgG) ELISA	Herpes simplex virus 1 (HSV1) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
143	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)
144	Herpes Simplex Virus 1 (HSV1) Immunoglobulin M (IgM) ELISA	Herpes simplex virus 1 (HSV1) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
145	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)
146	Herpes simplex virus 2 (HSV2) immunoglobulin G (IgG) ELISA	Herpes simplex virus 2 (HSV2) immunoglobulin G (IgG)
147	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)
148	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) ELISA	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
149	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)
150	High density lipoprotein (HDL) cholesterol Reagent	High density lipoprotein (HDL) cholesterol IVD, Reagent
151	High-density lipoprotein (HDL) Calibrator	High-density lipoprotein (HDL) cholesterol IVD, calibrator
152	HIV1/HIV2 Antibody Rapid Test Device	HIV1/HIV2 antibody immunochromatographic test
153	Human Assayed control	Clinical Chemistry analyte Control
154	Human chorionic gonadotropin beta- subunit (beta-HCG) ELISA	Human chorionic gonadotropin beta-subunit (beta-HCG) IVD, kit, enzyme immunoassay (EIA)
155	Human Chorionic Gonadotropin beta-	Human Chorionic Gonadotropin





	subunit (beta-HCG) Rapid Test Device	beta-subunit (beta-HCG) IVD, kit, Immunochromatographic rapid
156	Immunoglobulin A (IgA total) Reagent	Total immunoglobulin A (IgA total) IVD, reagent
157	Immunoglobulin G (IgG total) Reagent	Total immunoglobulin G (IgG total) IVD, reagent
158	Immunoglobulin M (IgM total) Reagent	Total immunoglobulin M (IgM total) IVD, reagent
159	Influenza A/B virus Rapid Test Device	Influenza A/B virus enzyme immunoassay
160	Inorganic Phosphate Reagent	Inorganic phosphate (PO ₄ ³⁻) IVD, reagent
161	Iron Reagent	Iron IVD, reagent
162	Lactate Dehydrogenase (LDH) (L - P) Reagent	Total lactate dehydrogenase (LDH) IVD, reagent
163	Lactate Dehydrogenase (LDH) (P - L) Reagent	Total lactate dehydrogenase (LDH) IVD, reagent
164	Lactate Dehydrogenase (LDH) Multiple Isoenzyme Reagent	Lactate dehydrogenase (LDH) multiple isoenzyme IVD, reagent
165	Lactate Dehydrogenase (LDH) Reagent	Total lactate dehydrogenase (LDH) IVD, reagent
166	Lactate Reagent	Lactate IVD, reagent
167	Lipase Reagent	Lipase IVD, reagent
168	Lipoprotein A Reagent	Lipoprotein A IVD, reagent
169	Low Density Lipoprotein (LDL) Cholesterol Calibrator	Low density lipoprotein (LDL) cholesterol IVD, calibrator
170	Low Density Lipoprotein (LDL) Cholesterol Reagent	Low density lipoprotein (LDL) cholesterol IVD, reagent
171	Low Ionic-Strength Salt Solution (LISS) Reagent	Low ionic-strength salt solution (LISS) immunohaematology reagent IVD
172	Luteinizing hormone (LH) ELISA	Luteinizing hormone (LH) IVD, kit, enzyme immunoassay (EIA)
173	Luteinizing hormone (LH) Reagent Testing Device	Luteinizing hormone (LH) IVD, kit, immunochromatographic test (ICT), rapid
174	Magnesium Reagent	Magnesium (Mg ²⁺) IVD, reagent
175	Malaria ELISA	Multiple Plasmodium species





		antigen IVD, reagent
176	Malaria Pan Rapid Test Device	Plasmodium antigen immunochromatographic test
177	Malaria Rapid Test Device	Malaria antigen immunochromatographic test
178	Measles Virus Immunoglobulin G (IgG) Antibody Enzyme Immunoassay (EIA)	Measles virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
179	Methadone Rapid Test Device	Methadone IVD, kit, immunochromatographic test (ICT), rapid
180	Methamphetamine-specific Rapid Test Device	Methamphetamine-specific IVD, kit, immunochromatographic test (ICT) assay, rapid
181	Microalbumin Control	Microalbumin IVD, control
182	Microalbumin Rapid Test Device	Microalbumin immunochromatographic test, rapid
183	Microalbumin Reagent	Microalbumin IVD, reagent
184	Morphine/morphine Metabolite Rapid Test Device	Morphine/morphine metabolite IVD, kit, immunochromatographic test (ICT), rapid
185	Multiple Drugs of Abuse Rapid Test Device	Multiple drugs of abuse IVD, kit, immunochromatographic test (ICT), rapid
186	Mumps Virus Immunoglobulin G (IgG) Antibody Enzyme Immunoassay (EIA)	Mumps virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
187	Mycobacterium tuberculosis Rapid Test Device	Mycobacterium tuberculosis complex species immunochromatographic test
188	Mycoplasma Rapid Test Device	Mycoplasma pneumoniae immunochromatographic test
189	Myoglobin Rapid Test Device	Myoglobin IVD, kit, immunochromatographic test (ICT), rapid
190	Nefletron	Nephelometry/turbidimetry analyser
191	Neonatal Thyroid Stimulating Hormone (Neonatal TSH) Elisa	Neonatal thyroid stimulating hormone (neonatal TSH) IVD, kit,





		enzyme immunoassay (EIA)
192	Opiate/opiate metabolite Rapid Test Device	Opiate/opiate metabolite IVD, kit, immunochromatographic test (ICT)
193	PCR Duo	PCR POCT Analyser
194	Phencyclidine (PCP) Rapid Test Device	Phencyclidine (PCP) IVD, kit, immunochromatographic test (ICT)
195	Phototron Clinical Chemistry Analyser	Multichannel clinical chemistry analyser
196	Plasma Calibrator	Multiple coagulation factor IVD, calibrator
197	Plasma Control	Multiple coagulation factor IVD, control
198	Potassium Reagent	Potassium (K+) IVD, reagent
199	Progesterone Elisa	Progesterone IVD, kit, enzyme immunoassay (EIA)
200	Prolactin Elisa	Prolactin IVD, kit, enzyme immunoassay (EIA)
201	Propoxyphene / Propoxyphene Rapid Test Device	Propoxyphene/propoxyphene metabolite IVD, kit, immunochromatographic test (ICT), rapid
202	Proteus stained antigen suspension	Febrile antigens
203	Prothrombin time Clotting Reagent	Prothrombin time (PT) IVD, kit, clotting
204	Rh(D)/Kell Multiple Blood Grouping Agglutination	Rh(D)/Kell multiple blood grouping IVD, kit, agglutination
205	Rheumatoid Factor Calibrator	Rheumatoid factor IVD, calibrator
206	Rheumatoid Factor Control	Rheumatoid factor IVD, control
207	Rheumatoid Factor Nephelometry / Turbidimetry	Rheumatoid factor IVD, kit, nephelometry/turbidimetry
208	Rheumatoid Factor Visilatex Reagent	Rheumatoid factor IVD, kit, agglutination
209	Rotavirus Antigen Rapid Test Device	Rotavirus antigen IVD, kit, immunochromatographic test (ICT), rapid
210	RPR Reagent	Treponema pallidum reagin antibody IVD, kit, agglutination
211	Rubella Virus Immunoglobulin G (IgG)	Rubella virus immunoglobulin G





	Antibody Enzyme immunoassay (EIA)	(IgG) antibody IVD, kit, enzyme immunoassay (EIA)
212	Rubella Virus Immunoglobulin M (IgM) Antibody Enzyme Immunoassay (EIA)	Rubella virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
213	Salmonella Rapid Test Device	Salmonella species immunochromatographic test
214	Salmonella species Reagent	Multiple Salmonella species total antibody IVD, reagent
215	Serological albumin	Serological albumin
216	Sodium Reagent	Sodium (Na+) IVD, reagent
217	Syphilis ELISA	Treponema pallidum immunoglobulin G (IgG)/IgM antibody enzyme immunoassay
218	Testosterone Elisa	Total testosterone IVD, kit, enzyme immunoassay (EIA)
219	Thrombin time (TT) Reagent	Thrombin time (TT) IVD, reagent
220	Thyroid stimulating hormone (TSH) Elisa	Thyroid stimulating hormone (TSH) IVD, kit, enzyme immunoassay (EIA)
221	ToRCH Rapid Test Device	ToRCH screen immunochromatographic test
222	Total (direct) Bilirubin Reagent	Total/conjugated (direct) bilirubin IVD, kit, spectrophotometry
223	Total Aspartate Aminotransferase (AST) Reagent	Total aspartate aminotransferase (AST) IVD, reagent
224	Total Bilirubin / Direct Bilirubin Combo	Total/conjugated (direct) bilirubin Reagent
225	Total Bilirubin Reagent	Total/conjugated (direct) bilirubin Reagent
226	Total creatine kinase (CK) IVD, reagent	Creatine kinase (CK) Reagent
227	Total Prostate Specific Antigen (PSA) Elisa	Total prostate specific antigen (PSA) IVD, kit, enzyme immunoassay (EIA)
228	Total Prostate Specific Antigen Rapid Test Device	PSA immunochromatographic test
229	Total Protein Reagent	Total protein IVD, reagent
230	Total thyroxine (TT4) Elisa	Total thyroxine (TT4) IVD, kit,





		enzyme immunoassay (EIA)
231	Total triiodothyronine (TT3) Elisa	Total triiodothyronine (TT3) IVD, kit, enzyme immunoassay (EIA)
232	Toxoplasma gondii immunoglobulin G (IgG) ELISA	Toxoplasma gondii immunoglobulin G (IgG)
233	Toxoplasma gondii immunoglobulin G (IgG) Rapid Test Device	Toxoplasma gondii immunoglobulin G (IgG)
234	Toxoplasma gondii immunoglobulin M (IgM) ELISA	Toxoplasma gondii immunoglobulin M (IgM)
235	Toxoplasma gondii immunoglobulin M (IgM) Rapid Test Device	Toxoplasma gondii immunoglobulin M (IgM)
236	Toxoplasma gondii Visilatest Reagent	Toxoplasma gondii total antibody IVD, kit, agglutination
237	TPHA Control	Treponema pallidum immunoglobulin G/immunoglobulin M control
238	Treponema Pallidum Haemagglutination Reagent	Treponema pallidum total antibody IVD, reagent
239	Treponema Pallidum Reagin Antibody Agglutination	Treponema pallidum reagin antibody IVD, kit, agglutination
240	Treponema pallidum reagin antibody kit, agglutination	Treponema pallidum reagin antibody IVD, kit, agglutination
241	Treponema Pallidum Total Antibody Rapid Test Device	Treponema pallidum total antibody IVD, kit, immunochromatographic test (ICT), rapid
242	Tricyclic antidepressant Rapid Test Device	Tricyclic antidepressant IVD, kit, immunochromatographic test (ICT), rapid
243	Triglyceride Reagent	Triglyceride IVD, reagent
244	Troponin T/Troponin I Elisa	Troponin T/Troponin I IVD, kit, enzyme immunoassay (EIA)
245	Troponin T/Troponin I Rapid Test Device	Troponin T/Troponin I IVD, kit, immunochromatographic test (ICT), rapid
246	Turboclot	Coagulation Analyser IVD, Laboratory, Semi-Automated
247	Turbolyte	Coagulation analyser IVD, laboratory, semi-automated
248	Urea Colour Reagent	Urea IVD, reagent





249	Urea Reagent	Urea IVD, reagent
250	Urea UV Reagent	Urea IVD, reagent
251	Uric Acid Reagent	Uric acid IVD, reagent
252	Urine Strips	Multiple urine analyte IVD, kit, colorimetric dipstick, rapid
253	Varicella-zoster Virus (VZV) Antigen Reagent	Varicella-zoster virus (VZV) antigen IVD, reagent
254	Vitamin D Control	25-Hydroxy vitamin D3 control
255	Vitamin D ELISA	Vitamin D enzyme immunoassay
256	Wash/cleaning Solution Automated/Semi-Automated System	Wash/cleaning solution IVD, automated/semi-automated system
257	Zinc Reagent	Zinc IVD, reagent

End of Schedule. No additional information past this point.

