



Medicines & Healthcare products
Regulatory Agency



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Canary Wharf
London E14 4PU
United Kingdom

mhra.gov.uk

Certificate number: **2019100102174237/9**

Order date: **07/10/2019**

CFS Expiry date: **07/10/2024**

**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: 2019100102174237/9

Ordered on: 07/10/2019

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

Manufacturer Name: Prestige Diagnostics U.K. Ltd

CFS Expiry Date: 07/10/2024

#	Medical Device Name	Model
1	CEA Rapid Test Device	CEA immunochromatographic test
2	CMV IgG Rapid Test Device	CMV IgG immunochromatographic test
3	Hepatitis B Core Antibody Rapid Test Device	Hepatitis B core antibody immunochromatographic test
4	C-Reactive Protein Rapid Test Device	C-reactive protein immunochromatographic test
5	Mycoplasma Rapid Test Device	Mycoplasma pneumoniae immunochromatographic test
6	C-reactive Protein Control	C-reactive protein control
7	Anti HBc	Hepatitis B core antibody enzyme immunoassay
8	Malaria Rapid Test Device	Malaria antigen immunochromatographic test
9	Syphilis ELISA	Treponema pallidum immunoglobulin G (IgG)/IgM antibody enzyme immunoassay
10	Dengue Antigen/Antibody Rapid Test Device	Dengue antibody/antigen immunochromatographic test
11	TPHA Control	Treponema pallidum immunoglobulin G/immunoglobulin M control
12	HbA1c Control	Glycated haemoglobin (HbA1c) calibrator
13	Nefletron	Nephelometry/turbidimetry analyser





14	H Pylori Antibody Rapid Test Device	H Pylori Antibody immunochromatographic test
15	HIV1/HIV2 Antibody Rapid Test Device	HIV1/HIV2 antibody immunochromatographic test
16	Malaria Pan Rapid Test Device	Plasmodium antigen immunochromatographic test
17	Microalbumin Rapid Test Device	Microalbumin immunochromatographic test, rapid
18	Total Prostate Specific Antigen Rapid Test Device	PSA immunochromatographic test
19	Salmonella Rapid Test Device	Salmonella species immunochromatographic test
20	ToRCH Rapid Test Device	ToRCH screen immunochromatographic test
21	Cytomegalovirus IgM Rapid Test Device	Cytomegalovirus (CMV) immunoglobulin M immunochromatographic test
22	Chlamydia Rapid Test Device	Chlamydia trachomatis antigen immunochromatographic test
23	Hepatitis E Virus Immunoglobulin M ELISA	Hepatitis E virus immunoglobulin M (IgM) antibody enzyme immunoassay
24	Hepatitis E virus antigen ELISA	Hepatitis E virus antigen enzyme immunoassay
25	Hepatitis D virus immunoglobulin G (IgG) ELISA	Hepatitis D virus immunoglobulin G (IgG) antibody enzyme immunoassay
26	Hepatitis E virus immunoglobulin G ELISA	Hepatitis E virus immunoglobulin G enzyme immunoassay
27	Hepatitis D virus immunoglobulin M ELISA	Hepatitis D virus immunoglobulin M antibody enzyme immunoassay
28	Hepatitis D virus antigen ELISA	Hepatitis D virus antigen enzyme immunoassay
29	Antihuman globulin reagent	Antihuman globulin
30	Mycobacterium tuberculosis Rapid Test Device	Mycobacterium tuberculosis complex species immunochromatographic test
31	Gonorrhoeae antigen Rapid Test Device	Gonorrhoeae antigen immunochromatographic test



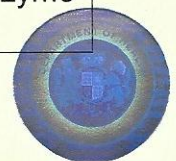


32	Group A Streptococcus antigen Rapid Test Device	Group A Streptococcus antigen immunochromatographic test
33	Group B Streptococcus antigen Rapid Test Device	Group B Streptococcus antigen immunochromatographic test
34	Serological albumin	Serological albumin
35	Fatty acid binding protein device	Fatty acid binding protein enzyme immunoassay
36	Proteus stained antigen suspension	Febrile antigens
37	6-Acetyl morphine enzyme immunoassay (EIA)	6-Acetyl morphine IVD, kit, enzyme immunoassay (EIA)
38	ABO multiple blood grouping agglutination	ABO multiple blood grouping IVD, kit, agglutination
39	Toxoplasma gondii immunoglobulin G (IgG) ELISA	Toxoplasma gondii immunoglobulin G (IgG)
40	Toxoplasma gondii immunoglobulin G (IgG) Rapid Test Device	Toxoplasma gondii immunoglobulin G (IgG)
41	Toxoplasma gondii immunoglobulin M (IgM) ELISA	Toxoplasma gondii immunoglobulin M (IgM)
42	Toxoplasma gondii immunoglobulin M (IgM) Rapid Test Device	Toxoplasma gondii immunoglobulin M (IgM)
43	Anti Streptolysin O Calibrator	Group A Streptococcus streptolysin O antibody IVD, calibrator
44	Anti streptolysin O Control	Group A Streptococcus streptolysin O antibody IVD, control
45	Group A Streptococcus streptolysin O antibody Reagent	Group A Streptococcus streptolysin O antibody IVD, reagent
46	Anti Streptolysin O Visilatex Reagent	Streptococcus streptolysin O antibody IVD, kit, agglutination, rapid
47	Calcium Arsenazo Reagent	Calcium (Ca ²⁺) IVD, reagent
48	Calcium OCPC Reagent	Calcium (Ca ²⁺) IVD, reagent
49	Calcium chloride Coagulation Reagent	Calcium chloride coagulation reagent
50	Autotron 120 Clinical Chemistry Analyser	Multichannel clinical chemistry analyser





51	Autotron 240 Clinical Chemistry Analyser	Multichannel clinical chemistry analyser
52	Autotron 420 Clinical Chemistry Analyser	Multichannel clinical chemistry analyser
53	Phototron Clinical Chemistry Analyser	Multichannel clinical chemistry analyser
54	Treponema Pallidum Haemagglutination Reagent	Treponema pallidum total antibody IVD, reagent
55	Treponema Pallidum Total Antibody Rapid Test Device	Treponema pallidum total antibody IVD, kit, immunochromatographic test (ICT), rapid
56	Uric Acid Reagent	Uric acid IVD, reagent
57	Zinc Reagent	Zinc IVD, reagent
58	Toxoplasma gondii Visilatex Reagent	Toxoplasma gondii total antibody IVD, kit, agglutination
59	Wash/cleaning Solution Automated/Semi-Automated System	Wash/cleaning solution IVD, automated/semi-automated system
60	Total thyroxine (TT4) Elisa	Total thyroxine (TT4) IVD, kit, enzyme immunoassay (EIA)
61	Urea Reagent	Urea IVD, reagent
62	Total Protein Reagent	Total protein IVD, reagent
63	Troponin T/Troponin I Rapid Test Device	Troponin T/Troponin I IVD, kit, immunochromatographic test (ICT), rapid
64	Troponin T/Troponin I Elisa	Troponin T/Troponin I IVD, kit, enzyme immunoassay (EIA)
65	Triglyceride Reagent	Triglyceride IVD, reagent
66	Tricyclic antidepressant Rapid Test Device	Tricyclic antidepressant IVD, kit, immunochromatographic test (ICT), rapid
67	Treponema Pallidum Reagin Antibody Agglutination	Treponema pallidum reagin antibody IVD, kit, agglutination
68	Total (direct) Bilirubin Reagent	Total/conjugated (direct) bilirubin IVD, kit, spectrophotometry
69	Total triiodothyronine (TT3) Elisa	Total triiodothyronine (TT3) IVD, kit, enzyme immunoassay (EIA)
70	Testosterone Elisa	Total testosterone IVD, kit, enzyme immunoassay (EIA)





71	Total Prostate Specific Antigen (PSA) Elisa	Total prostate specific antigen (PSA) IVD, kit, enzyme immunoassay (EIA)
72	Lactate Dehydrogenase (LDH) Reagent	Total lactate dehydrogenase (LDH) IVD, reagent
73	Amylase Reagent	Total amylase IVD, reagent
74	Haemoglobin (totHb) Reagent	Total haemoglobin (totHb) IVD, reagent
75	Total creatine kinase (CK) IVD, reagent	Creatine kinase (CK) Reagent
76	Cholesterol Reagent	Total cholesterol lipid IVD, reagent
77	Total Aspartate Aminotransferase (AST) Reagent	Total aspartate aminotransferase (AST) IVD, reagent
78	Alkaline phosphatase (ALP) Reagent	Total alkaline phosphatase (ALP) IVD, reagent
79	Thyroid stimulating hormone (TSH) Elisa	Thyroid stimulating hormone (TSH) IVD, kit, enzyme immunoassay (EIA)
80	Thrombin time (TT) Reagent	Thrombin time (TT) IVD, reagent
81	Sodium Reagent	Sodium (Na ⁺) IVD, reagent
82	Rubella Virus Immunoglobulin M (IgM) Antibody Enzyme Immunoassay (EIA)	Rubella virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
83	Rubella Virus Immunoglobulin G (IgG) Antibody Enzyme immunoassay (EIA)	Rubella virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
84	Rotavirus Antigen Rapid Test Device	Rotavirus antigen IVD, kit, immunochromatographic test (ICT), rapid
85	Activated partial thromboplastin time (APTT) Reagent	Activated partial thromboplastin time (APTT) IVD, Reagent
86	Rheumatoid Factor Nephelometry / Turbidimetry	Rheumatoid factor IVD, kit, nephelometry/turbidimetry
87	Prothrombin time Clotting Reagent	Prothrombin time (PT) IVD, kit, clotting
88	Rheumatoid Factor Visilatex Reagent	Rheumatoid factor IVD, kit, agglutination
89	Rheumatoid Factor Control	Rheumatoid factor IVD, control
90	Rheumatoid Factor Calibrator	Rheumatoid factor IVD, calibrator





91	Propoxyphene / Propoxyphene Rapid Test Device	Propoxyphene/propoxyphene metabolite IVD, kit, immunochromatographic test (ICT), rapid
92	Prolactin Elisa	Prolactin IVD, kit, enzyme immunoassay (EIA)
93	Microalbumin Reagent	Microalbumin IVD, reagent
94	Progesterone Elisa	Progesterone IVD, kit, enzyme immunoassay (EIA)
95	Potassium Reagent	Potassium (K ⁺) IVD, reagent
96	Methadone Rapid Test Device	Methadone IVD, kit, immunochromatographic test (ICT), rapid
97	Phencyclidine (PCP) Rapid Test Device	Phencyclidine (PCP) IVD, kit, immunochromatographic test (ICT)
98	Luteinizing hormone (LH) ELISA	Luteinizing hormone (LH) IVD, kit, enzyme immunoassay (EIA)
99	Opiate/opiate metabolite Rapid Test Device	Opiate/opiate metabolite IVD, kit, immunochromatographic test (ICT)
100	Methamphetamine-specific Rapid Test Device	Methamphetamine-specific IVD, kit, immunochromatographic test (ICT) assay, rapid
101	Neonatal Thyroid Stimulating Hormone (Neonatal TSH) Elisa	Neonatal thyroid stimulating hormone (neonatal TSH) IVD, kit, enzyme immunoassay (EIA)
102	Myoglobin Rapid Test Device	Myoglobin IVD, kit, immunochromatographic test (ICT), rapid
103	Low Ionic-Strength Salt Solution (LISS) Reagent	Low ionic-strength salt solution (LISS) immunohaematology reagent IVD
104	Morphine/morphine Metabolite Rapid Test Device	Morphine/morphine metabolite IVD, kit, immunochromatographic test (ICT), rapid
105	Inorganic Phosphate Reagent	Inorganic phosphate (PO ₄ ³⁻) IVD, reagent
106	Magnesium Reagent	Magnesium (Mg ²⁺) IVD, reagent
107	Lysergic Acid Diethylamide (LSD)/LSD Metabolite Reagent	Lysergic acid diethylamide (LSD)/LSD metabolite IVD, reagent



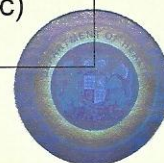


108	Human chorionic gonadotropin beta-subunit (beta-HCG) ELISA	Human chorionic gonadotropin beta-subunit (beta-HCG) IVD, kit, immunochromatographic test (ICT), rapid
109	Low Density Lipoprotein (LDL) Cholesterol Reagent	Low density lipoprotein (LDL) cholesterol IVD, reagent
110	Low Density Lipoprotein (LDL) Cholesterol Calibrator	Low density lipoprotein (LDL) cholesterol IVD, calibrator
111	High-density lipoprotein (HDL) Calibrator	High-density lipoprotein (HDL) cholesterol IVD, calibrator
112	Lipase Reagent	Lipase IVD, reagent
113	Lactate Reagent	Lactate IVD, reagent
114	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)
115	Herpes simplex virus 2 (HSV2) immunoglobulin G (IgG) ELISA	Herpes simplex virus 2 (HSV2) immunoglobulin G (IgG)
116	Lactate Dehydrogenase (LDH) Multiple Isoenzyme Reagent	Lactate dehydrogenase (LDH) multiple isoenzyme IVD, reagent
117	Iron Reagent	Iron IVD, reagent
118	Influenza A/B virus antigen ELISA	Influenza A/B virus antigen IVD, kit, enzyme immunoassay (EIA)
119	Human chorionic gonadotropin beta-subunit (beta-HCG) ELISA	Human chorionic gonadotropin beta-subunit (beta-HCG) IVD, kit, enzyme immunoassay (EIA)
120	High density lipoprotein (HDL) cholesterol Reagent	High density lipoprotein (HDL) cholesterol IVD, Reagent
121	Hepatitis B Virus surface antigen Rapid Test Device	Hepatitis B virus surface antigen IVD, kit, enzyme immunoassay (EIA)
122	Hepatitis B virus surface antigen ELISA	Hepatitis B virus surface antigen enzyme immunoassay (EIA)
123	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) ELISA	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
124	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) Rapid Test	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) antibody



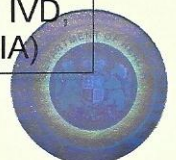


	Device	IVD, kit, enzyme immunoassay (EIA)
125	Herpes Simplex Virus 1 (HSV1) Immunoglobulin M (IgM) ELISA	Herpes simplex virus 1 (HSV1) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
126	Herpes simplex virus 1 (HSV1) immunoglobulin M (IgM) Rapid Test Device	Herpes simplex virus 1 (HSV1) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
127	Herpes Simplex Virus 1 (HSV1) Immunoglobulin G (IgG) ELISA	Herpes simplex virus 1 (HSV1) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
128	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)
129	Hematron 3	Haematological cell analyser IVD, automated
130	Hematron 5	Haematological cell analyser IVD, automated
131	Hepatitis B Virus e-antigen Total Antibody, Enzyme Immunoassay (EIA)	Hepatitis B virus e-antigen total antibody IVD, kit, enzyme immunoassay (EIA)
132	Hepatitis B Virus e-antigen Enzyme Immunoassay (EIA)	Hepatitis B virus e-antigen IVD, kit, enzyme immunoassay (EIA)
133	Hepatitis B Virus Core Immunoglobulin M (IgM) Antibody, Enzyme Immunoassay (EIA)	Hepatitis B virus core immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
134	Hepatitis A virus Immunoglobulin M (IgM) Antibody, Enzyme Immunoassay (EIA)	Hepatitis A virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
135	Hepatitis A Virus Immunoglobulin G (IgG) Antibody Reagent	Hepatitis A virus immunoglobulin G (IgG) antibody IVD, reagent
136	Helicobacter Pylori Antigen Rapid Test Device	Helicobacter pylori antigen IVD, kit, immunochromatographic test (ICT), rapid
137	Glycated Haemoglobin (HbA1c) IVD, Reagent	Glycated haemoglobin (HbA1c) IVD, reagent





138	Free Triiodothyronine ELISA	Free triiodothyronine (FT3) IVD, kit, enzyme immunoassay (EIA)
139	Glycated haemoglobin (HbA1c) Control	Glycated haemoglobin (HbA1c) IVD, control
140	Glycated Haemoglobin (HbA1C) Analyser	Glycated haemoglobin (HbA1C) analyser IVD
141	Follicle stimulating hormone (FSH) ELISA	Follicle stimulating hormone (FSH) IVD, Kit, Enzyme Immunoassay (EIA)
142	Gamma-glutamyltransferase (GGT) Reagent	Gamma-glutamyltransferase (GGT) IVD, reagent
143	Fibrinogen Assay (factor I) Reagent	Fibrinogen assay (factor I) IVD, reagent
144	Full Blood Count Kit, Cell Count	Full blood count IVD, kit, cell count
145	Full Blood Count Control	Full blood count IVD, control
146	Estradiol ELISA	Estradiol (oestradiol) (E2) IVD, kit, enzyme immunoassay (EIA)
147	Free Thyroxine (FT4) ELISA	Free thyroxine (FT4) IVD, kit, enzyme immunoassay (EIA)
148	Free (unbound) prostate specific antigen (PSA) ELISA	Free (unbound) prostate specific antigen (PSA) IVD, kit, enzyme immunoassay (EIA)
149	D-dimer Rapid Test Device	D-dimer IVD, Kit, Immunochromatographic Test (ICT), Rapid Test Device
150	Creatinine Reagent	Creatinine IVD, reagent
151	Creatine Kinase Myocardial Isoenzyme (CKMB) Control	Creatine kinase myocardial isoenzyme (CKMB) IVD, control
152	Erythrocyte Sedimentation Rate (ESR) Control	Erythrocyte sedimentation rate (ESR) IVD, control
153	Enzyme Immunoassay (EIA) Analyser Semi-automated	Enzyme immunoassay (EIA) analyser IVD, semi-automated
154	Creatine Kinase (CK) Calibrator	Creatine Kinase (CK) Multiple Isoenzyme Calibrator
155	Dengue Virus Immunoglobulin A (IgA)/IgG/IgM Antibody Enzyme Immunoassay (EIA)	Dengue virus immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, enzyme immunoassay (EIA)
156	Cotinine (Nicotine Metabolite) Kit, Enzyme Immunoassay (EIA)	Cotinine (Nicotine Metabolite) IVD, Kit, Enzyme Immunoassay (EIA)





157	Cytomegalovirus (CMV) Immunoglobulin M (IgM) ELISA	Cytomegalovirus (CMV) Immunoglobulin M (IgM) Antibody IVD, Kit, Enzyme Immunoassay (EIA)
158	Cytomegalovirus (CMV) Immunoglobulin G (IgG) ELISA	Cytomegalovirus (CMV) Immunoglobulin G (IgG) Antibody IVD, Kit, Enzyme Immunoassay (EIA)
159	Creatine Kinase Myocardial Isoenzyme (CKMB) Rapid Test Device	Creatine Kinase Myocardial Isoenzyme (CKMB) IVD, Kit, Immunochromatographic Test (ICT) Rapid Test Device
160	Creatine Kinase (CKNAC) Reagent	Creatine Kinase (CK) Multiple Isoenzyme IVD, Reagent
161	C-Reactive Protein (CRP) Nephelometry / Turbidimetry	C-Reactive Protein (CRP) IVD, Kit, Nephelometry / Turbidimetry
162	C-Reactive protein (CRP) Visilatex Reagent	C-Reactive Protein (CRP) IVD, Kit, Agglutination, Rapid
163	C-Reactive Protein (CRP) Calibrator	C-reactive Protein (CRP) IVD, Calibrator
164	Copper Reagent	Copper IVD, Reagent
165	Cocaine / Cocaine Metabolite Rapid Test Device	Cocaine / Cocaine Metabolite IVD, Kit, Immunochromatographic Test (ICT), Rapid
166	Coagulation Factor IIa Thrombin Time Reagent	Coagulation Factor IIa Thrombin) IVD, Reagent
167	Coagulation Factor II (Prothrombin Time Reagent)	Coagulation Factor II (Prothrombin) IVD, Reagent
168	Turboclot	Coagulation Analyser IVD, Laboratory, Semi-Automated
169	Turbolyte	Coagulation analyser IVD, laboratory, semi-automated
170	Chloride (Cl-) Reagent	Chloride (Cl-) IVD, reagent
171	Cholinesterase Reagent	Cholinesterase Dibucaine Number (percentage inhibition) IVD, Reagent
172	Carcinoembryonic Antigen (CEA) ELISA	Carcinoembryonic Antigen (CEA) IVD, Kit, Enzyme Immunoassay (EIA)



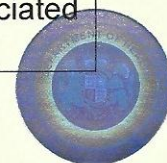


173	Cannabinoid Rapid Test Device	Cannabinoid IVD, kit, Immunochromatographic Test (ICT), Rapid
174	Cancer Antigen 15-3 (CA15-3) ELISA	Cancer antigen 15-3 (CA15-3) IVD, kit, enzyme immunoassay (EIA)
175	Cancer Antigen 19-9 (CA19-9) ELISA	Cancer Antigen 19-9 (CA19-9) IVD, Kit, Enzyme Immunoassay (EIA)
176	Cancer Antigen 125 (CA125) ELISA kit	Cancer Antigen 125 (CA125) IVD, kit, Enzyme Immunoassay (EIA)
177	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
178	Amphetamine-specific Rapid Test Device	Amphetamine-specific Rapid Device
179	Benzodiazepine Rapid Test Device	Benzodiazepine Group IVD, Kit, Immunochromatographic Test (ICT), Rapid Test Device
180	Amphetamine / Methamphetamine Group Rapid Test Device	Amphetamine / Methamphetamine group IVD, Kit, Immunochromatographic Test (ICT), Rapid Test Device
181	Barbiturate IVD, Kit, Rapid Test Device	Barbiturate IVD, Kit, Immunochromatographic Test (ICT), Rapid Test Device
182	Alpha-fetoprotein (AFP) ELISA	Alpha-fetoprotein (AFP) IVD, kit, enzyme immunoassay (EIA)
183	Albumin Reagent	Albumin IVD, Reagent
184	Amylase Isoenzyme Reagent	Amylase Isoenzyme IVD, Reagent
185	Adenovirus antigen Rapid Test Device	Adenovirus antigen IVD, kit, immunochromatographic test (ICT), rapid
186	Alanine Aminotransferase Reagent	Alanine aminotransferase (ALT) IVD, reagent
187	Alkaline Phosphatase (AMP) Reagent	Alkaline phosphatase (ALP) Isoenzyme IVD, Reagent
188	Alkaline phosphatase (DEA) Reagent	Alkaline phosphatase (ALP) isoenzyme IVD, reagent





189	Creatine kinase myocardial isoenzyme (CKMB) Reagent	Creatine kinase myocardial isoenzyme (CKMB) IVD, reagent
190	Creatine kinase myocardial isoenzyme (CKMB) Reagent Dry	Creatine kinase myocardial isoenzyme (CKMB) Reagent
191	Creatine kinase (CK) Control	Creatine kinase (CK) multiple isoenzyme Control
192	Ferritin ELISA	Ferritin IVD, kit, enzyme immunoassay (EIA)
193	Glucose Reagent	Glucose Reagent Single Liquid
194	Glucose Reagent Lyophilised	Glucose Reagent Lyo
195	Brucella abortus Agglutination Reagent	Brucella species culture isolate antigen Agglutination Reagent
196	Brucella melitensis Agglutination Reagent	Brucella species culture isolate antigen Agglutination Reagent
197	Urea UV Reagent	Urea IVD, reagent
198	Urea Colour Reagent	Urea IVD, reagent
199	Total Bilirubin Reagent	Total/conjugated (direct) bilirubin Reagent
200	Direct Bilirubin Reagent	Total/conjugated (direct) bilirubin Reagent
201	Total Bilirubin / Direct Bilirubin Combo	Total/conjugated (direct) bilirubin Reagent
202	Urine Strips	Multiple urine analyte IVD, kit, colorimetric dipstick, rapid
203	Treponema pallidum reagin antibody kit, agglutination	Treponema pallidum reagin antibody IVD, kit, agglutination
204	RPR Reagent	Treponema pallidum reagin antibody IVD, kit, agglutination
205	Lactate Dehydrogenase (LDH) (L - P) Reagent	Total lactate dehydrogenase (LDH) IVD, reagent
206	Lactate Dehydrogenase (LDH) (P - L) Reagent	Total lactate dehydrogenase (LDH) IVD, reagent
207	Febrile Antigen Reagent	Multiple Salmonella species antigen IVD, reagent
208	Febrile Positive Control	Multiple febrile infection-associated bacteria antigen IVD, control
209	Febrile Negative Control	Multiple febrile infection-associated bacteria antigen IVD, control





210	Plasma Control	Multiple coagulation factor IVD, control
211	Plasma Calibrator	Multiple coagulation factor IVD, calibrator
212	Multiple Drugs of Abuse Rapid Test Device	Multiple drugs of abuse IVD, kit, immunochromatographic test (ICT), rapid
213	Salmonella species Reagent	Multiple Salmonella species total antibody IVD, reagent
214	Human Assayed control	Clinical Chemistry analyte Control
215	Calibration Serum	Clinical Chemistry analyte Calibrator
216	Creatine kinase (CKNAC) Calibrator	Creatine kinase (CK) multiple isoenzyme Calibrator
217	Creatine kinase myocardial (CKMB) Calibrator	Creatine kinase (CK) multiple isoenzyme IVD, calibrator

End of Schedule. No additional information past this point.



