



Medicines & Healthcare products
Regulatory Agency



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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,

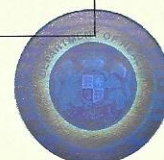
Lewis Kennedy

Certificate of Free Sale Administration Team
Signed on Behalf of MHRA



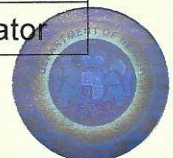


32	Group A Streptococcus antigen Rapid Test Device	Group A Streptococcus antigen immunochromatographic test
33	Group B Streptococcus antigen Rapid Test Device	Group B Streptococcus antigen immunochromatographic test
34	Serological albumin	Serological albumin
35	Fatty acid binding protein device	Fatty 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 Visilates 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





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





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)





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

