



Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
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

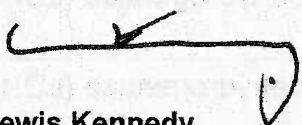
CERTIFICATE OF FREE SALE FOR EXPORTATION OF MEDICAL PRODUCTS

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



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

