



# Certificate of Registration

This certificate has been awarded to

**Prestige Diagnostics UK Ltd**

40 Ballymena Business Centre, Galgorm, County Antrim, BT42 1FL, Northern Ireland

in recognition of the organization's Quality Management System which complies with

**ISO 13485:2016**

The scope of activities covered by this certificate is defined below

**Please refer to the Appendix**

Certificate Number <b>67400/A/0001/UK/En</b>			
Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
<b>14 April 2021</b>	<b>9</b>	<b>09 April 2024</b>	<b>3</b>
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
<b>14 April 2021</b>	<b>0</b>	<b>10 April 2015</b>	<b>n/a</b>

For detailed explanation for the data fields above, refer to <http://www.urs-holdings.com/logos-and-regulations>

Issued by

*On behalf of the Schemes Manager*





# Appendix to Certificate

**Design, Manufacture and Distribution of In Vitro Diagnostic Assays in the areas of Clinical Chemistry and Latex Serology, Manufacture and Distribution of In Vitro Diagnostics Assays in the Areas of Blood Grouping, Immunturbidimetry, ELISA, Quality Controls and Calibrators, Febrile Antigens, Haemostasis, Rapid Tests, Syphilis Assays, Molecular Biology and Urine Strips**

Certificate Number **67400/A/0001/UK/En**

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
14 April 2021	9	09 April 2024	3
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
14 April 2021	0	10 April 2015	n/a

For detailed explanation for the data fields above, refer to <http://www.urs-holdings.com/logos-and-regulations>

Issued by

On behalf of the Schemes Manager



**LETTER OF AUTHORISATION**

To Whom It May Concern:

We, Prestige Diagnostics U.K. Ltd. having premises at Ballymena Business Centre, Galgorm, County Antrim, Northern Ireland, United Kingdom BT42 1FL registered with the Northern Ireland Chamber of Commerce in Belfast, represented by our Managing Director, Mr. Alan Rodgers.

Certify hereby, that the following company:

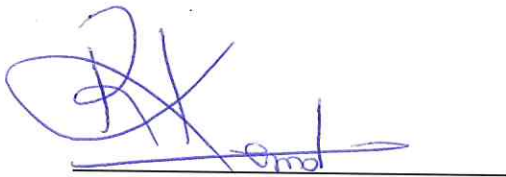
**IMUNOTEHNOMED Ltd,**  
Gh. Asachi str. 42,  
MD - 2028, Chisinau,  
Republic of Moldova,

Is authorised to import, register, sell and represent us in any matters regarding our products in order to participate in tenders organised in the territory of the Republic of Moldova.

Valid until 31st December 2021.

Date: 25<sup>th</sup> June 2021

Kind regards,



Rodney Kernohan  
On behalf of Prestige Diagnostics UK



Medicines & Healthcare products  
Regulatory Agency

10 South Colonnade  
Canary Wharf  
London E14 4PU  
United Kingdom

[mhra.gov.uk](http://mhra.gov.uk)

Certificate number: **2020110502186717/1**

Order date: **11/12/2020**

CFS Expiry date: **11/12/2025**

**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,

**Ngozi Onyeukwu**

Certificate of Free Sale Administration Team  
Signed on Behalf of MHRA

Certificate Reference: 2020110502186717/1

Ordered on: 11/12/2020

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

Manufacturer Name: Prestige Diagnostics U.K. Ltd

CFS Expiry Date: 11/12/2025

#	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 and Influenza A+B Antigen Device	Covid Rapid Test Device
4	2019-nCoV Antigen Device	Covid Rapid Test Device
5	2019-nCoV IgG/IgM Device	Covid Antibody Rapid Test Device
6	2019-nCoV IgG/IgM WB Device	Covid Antibody Rapid Test Device
7	ABO multiple blood grouping agglutination	ABO multiple blood grouping IVD, kit, agglutination
8	Activated partial thromboplastin time (APTT) Reagent	Activated partial thromboplastin time (APTT) IVD, Reagent
9	Adenovirus antigen Rapid Test Device	Adenovirus antigen IVD, kit, immunochromatographic test (ICT), rapid
10	Alanine Aminotransferase Reagent	Alanine aminotransferase (ALT) IVD, reagent
11	Albumin Reagent	Albumin IVD, Reagent
12	Alkaline phosphatase (ALP) Reagent	Total alkaline phosphatase (ALP) IVD, reagent
13	Alkaline Phosphatase (AMP) Reagent	Alkaline phosphatase (ALP)

		Isoenzyme IVD, Reagent
14	Alkaline phosphatase (DEA) Reagent	Alkaline phosphatase (ALP) isoenzyme IVD, reagent
15	Alpha 1 antitrypsin immunoturbidimetry	Alpha 1 antitrypsin
16	Alpha-fetoprotein (AFP) ELISA	Alpha-fetoprotein (AFP) IVD, kit, enzyme immunoassay (EIA)
17	Amphetamine / Methamphetamine Group Rapid Test Device	Amphetamine / Methamphetamine group IVD, Kit, Immunochromatographic Test (ICT), Rapid Test Device
18	Amphetamine-specific Rapid Test Device	Amphetamine-specific Rapid Device
19	Amylase Reagent	Total amylase IVD, reagent
20	Anti HBc	Hepatitis B core antibody enzyme immunoassay
21	Anti HBc Rapid Test Device	Hepatitis B virus core total antibody IVD, kit, enzyme immunoassay (EIA)
22	Anti HCV ELISA	Hepatitis C virus Antibody Enzyme Immunoassay (EIA)
23	Anti Hepatitis B surface antigen Antibody Rapid Test Device	Hepatitis B virus surface Total Antibody IVD Enzyme Immunoassay (EIA)
24	Anti Hepatitis B surface antigen ELISA	Hepatitis B virus surface Total Antibody Enzyme Immunoassay (EIA)
25	Anti Streptolysin O Calibrator	Group A Streptococcus streptolysin O antibody IVD, calibrator
26	Anti streptolysin O Control	Group A Streptococcus streptolysin O antibody IVD, control
27	Anti Streptolysin O Nephelometry/Turbidimetry Kit	Beta-haemolytic Group A Streptococcus streptolysin O antibody IVD, reagent
28	Anti Streptolysin O Visilatex Reagent	Beta-haemolytic Group A Streptococcus streptolysin O

		antibody IVD, reagent
29	Anti Streptolysin O Visilatex Reagent	Streptococcus streptolysin O antibody IVD, kit, agglutination, rapid
30	Antihuman globulin reagent	Antihuman globulin
31	Apolipoprotein A-I (Apo A1) IVD, Kit, Nephelometry / Turbidimetry	Apolipoprotein A-I (Apo A1) IVD, Kit, Nephelometry / Turbidimetry
32	Apolipoprotein A-II (Apo A2) IVD, Kit, Nephelometry / Turbidimetry	Apolipoprotein A-II (Apo A2) IVD, Kit, Nephelometry / Turbidimetry
33	Apolipoprotein B (Apo B) IVD, Kit, Nephelometry / Turbidimetry	Apolipoprotein B (Apo B) IVD, Kit, Nephelometry / Turbidimetry
34	Apolipoprotein E (Apo E) IVD, Kit, Nephelometry / Turbidimetry	Apolipoprotein E (Apo E) IVD, Kit, Nephelometry / Turbidimetry
35	Autotron 120 Clinical Chemistry Analyser	Multichannel clinical chemistry analyser
36	Autotron 240 Clinical Chemistry Analyser	Multichannel clinical chemistry analyser
37	Autotron 420 Clinical Chemistry Analyser	Multichannel clinical chemistry analyser
38	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
39	Barbiturate IVD, Kit, Rapid Test Device	Barbiturate IVD, Kit, Immunochromatographic Test (ICT), Rapid Test Device
40	Benzodiazepine Rapid Test Device	Benzodiazepine Group IVD, Kit, Immunochromatographic Test (ICT), Rapid Test Device
41	Bilirubin calibrator	Bilirubin calibrator
42	Bilirubin Control	Total bilirubin IVD, control
43	Blood Glucose Analyser	Blood glucose, point-of-care

44	Brucella abortus Agglutination Reagent	Brucella species culture isolate antigen Agglutination Reagent
45	Brucella melitensis Agglutination Reagent	Brucella species culture isolate antigen Agglutination Reagent
46	C-Reactive Protein (CRP) Calibrator	C-reactive Protein (CRP) IVD, Calibrator
47	C-Reactive Protein (CRP) Nephelometry / Turbidimetry	C-Reactive Protein (CRP) IVD, Kit, Nephelometry / Turbidimetry
48	C-Reactive protein (CRP) Visilatex Reagent	C-Reactive Protein (CRP) IVD, Kit, Agglutination, Rapid
49	C-reactive Protein Control	C-reactive protein control
50	C-Reactive Protein Rapid Test Device	C-reactive protein immunochromatographic test
51	Calcium Arsenazo Reagent	Calcium (Ca <sup>2+</sup> ) IVD, reagent
52	Calcium chloride Coagulation Reagent	Calcium chloride coagulation reagent
53	Calcium OCPC Reagent	Calcium (Ca <sup>2+</sup> ) IVD, reagent
54	Calibration Serum	Clinical Chemistry analyte Calibrator
55	Cancer Antigen 125 (CA125) ELISA kit	Cancer Antigen 125 (CA125) IVD, kit, Enzyme Immunoassay (EIA)
56	Cancer Antigen 15-3 (CA15-3) ELISA	Cancer antigen 15-3 (CA15-3) IVD, kit, enzyme immunoassay (EIA)
57	Cancer Antigen 19-9 (CA19-9) ELISA	Cancer Antigen 19-9 (CA19-9) IVD, Kit, Enzyme Immunoassay (EIA)
58	Cannabinoid Rapid Test Device	Cannabinoid IVD, kit, Immunochromatographic Test (ICT), Rapid
59	Cardiac Control	Multiple Cardiac Marker Control
60	CEA Rapid Test Device	CEA immunochromatographic test
61	Chlamydia Rapid Test Device	Chlamydia trachomatis



		antigen immunochromatographic test
62	Chloride (Cl-) Reagent	Chloride (Cl-) IVD, reagent
63	Cholesterol Lyophilised Reagent	Total cholesterol lipid IVD, reagent
64	Cholesterol Reagent	Total cholesterol lipid IVD, reagent
65	Cholinesterase Reagent	Cholinesterase Dibucaine Number (percentage inhibition) IVD, Reagent
66	CMV IgG Rapid Test Device	CMV IgG immunochromatographic test
67	Coagulation Factor II (Prothrombin Time Reagent)	Coagulation Factor II (Prothrombin) IVD, Reagent
68	Coagulation Factor IIa Thrombin Time Reagent	Coagulation Factor IIa Thrombin) IVD, Reagent
69	Cocaine / Cocaine Metabolite Rapid Test Device	Cocaine / Cocaine Metabolite IVD, Kit, Immunochromatographic Test (ICT), Rapid
70	Complement C3/C3c	Complement C3/C3c nephelometry/turbidimetry
71	Complement C4/C4c	Complement C4/C4c nephelometry/turbidimetry
72	Copper Reagent	Copper IVD, Reagent
73	Cotinine (Nicotine Metabolite) Kit, Enzyme Immunoassay (EIA)	Cotinine (Nicotine Metabolite) IVD, Kit, Enzyme Immunoassay (EIA)
74	COVID-19 Ag ELISA	COVID ELISA
75	COVID-19 ELISA	COVID Antibody ELISA
76	COVID-19 IgG ELISA	COVID Antibody ELISA
77	COVID-19 IgM ELISA	COVID-19 Antibody ELISA
78	COVID-19 PCR Kit	COVID PCR Kit
79	Creatine Kinase (CK) Calibrator	Creatine Kinase (CK) Multiple Isoenzyme Calibrator
80	Creatine kinase (CK) Control	Creatine kinase (CK) multiple isoenzyme Control

81	Creatine kinase (CKNAC) Calibrator	Creatine kinase (CK) multiple isoenzyme Calibrator
82	Creatine Kinase (CKNAC) Reagent	Creatine Kinase (CK) Multiple Isoenzyme IVD, Reagent
83	Creatine Kinase (CKNAC) Reagent Dry	Total creatine kinase (CK) IVD, reagent
84	Creatine kinase myocardial (CKMB) Calibrator	Creatine kinase (CK) multiple isoenzyme IVD, calibrator
85	Creatine Kinase Myocardial Isoenzyme (CKMB) Control	Creatine kinase myocardial isoenzyme (CKMB) IVD, control
86	Creatine Kinase Myocardial Isoenzyme (CKMB) Rapid Test Device	Creatine Kinase Myocardial Isoenzyme (CKMB) IVD, Kit, Immunochromatographic Test (ICT) Rapid Test Device
87	Creatine kinase myocardial isoenzyme (CKMB) Reagent	Creatine kinase myocardial isoenzyme (CKMB) IVD, reagent
88	Creatine kinase myocardial isoenzyme (CKMB) Reagent Dry	Creatine kinase myocardial isoenzyme (CKMB) Reagent
89	Creatinine Reagent	Creatinine IVD, reagent
90	Cystatin C	Cystatin C nephelometry/turbidimetry
91	Cytomegalovirus (CMV) Immunoglobulin G (IgG) ELISA	Cytomegalovirus (CMV) Immunoglobulin G (IgG) Antibody IVD, Kit, Enzyme Immunoassay (EIA)
92	Cytomegalovirus (CMV) Immunoglobulin M (IgM) ELISA	Cytomegalovirus (CMV) Immunoglobulin M (IgM) Antibody IVD, Kit, Enzyme Immunoassay (EIA)
93	Cytomegalovirus IgM Rapid Test Device	Cytomegalovirus (CMV) immunoglobulin M immunochromatographic test
94	D-dimer	D-dimer nephelometry/turbidimetry
95	D-dimer Rapid Test Device	D-dimer IVD, Kit, Immunochromatographic Test (ICT), Rapid Test

		Device
96	Dengue Antigen/Antibody Rapid Test Device	Dengue antibody/antigen immunochromatographic test
97	Dengue Virus Immunoglobulin A (IgA)/IgG/IgM Antibody Enzyme Immunoassay (EIA)	Dengue virus immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, enzyme immunoassay (EIA)
98	Direct Bilirubin Reagent	Total/conjugated (direct) bilirubin Reagent
99	DNA/RNA Detection Cartridge	Nucleic acid extraction and amplification kit
100	DNA/RNA Detection Cartridge COVID-19	Nucleic acid extraction and amplification kit
101	DNA/RNA Detection Cartridge Influenza A/B/RSV	DNA/RNA extraction and amplification kit
102	DNA/RNA Extraction Kit	Nucleic acid extraction/purification kit
103	Enzyme Immunoassay (EIA) Analyser Semi-automated	Enzyme immunoassay (EIA) analyser IVD, semi-automated
104	Erythrocyte Sedimentation Rate (ESR) Control	Erythrocyte sedimentation rate (ESR) IVD, control
105	Estradiol ELISA	Estradiol (oestradiol) (E2) IVD, kit, enzyme immunoassay (EIA)
106	Faecal Occult Blood IVD, Control	Faecal occult blood IVD, control
107	Faecal Occult Blood Rapid Test Kit	Faecal occult blood IVD, kit, immunochromatographic test (ICT), Rapid Test Kit
108	Fastep 1000	Haemoglobin analyser IVD, point-of-care
109	Fastep Hb	Haemoglobin point-of-care analyser
110	Fastep Hb Hemometer Strips	Total Haemoglobin Hemometer Strips
111	Fatty acid binding protein device	Fatty acid binding protein enzyme immunoassay

112	Febrile Antigen Reagent	Multiple Salmonella species antigen IVD, reagent
113	Febrile Negative Control	Multiple febrile infection-associated bacteria antigen IVD, control
114	Febrile Positive Control	Multiple febrile infection-associated bacteria antigen IVD, control
115	Ferritin ELISA	Ferritin IVD, kit, enzyme immunoassay (EIA)
116	Ferritin immunoassay	Ferritin enzyme immunoassay
117	FLIA	Fluorescence Immunoassay Point of Care Analyser
118	FOB Control	Faecal occult blood control
119	Follicle stimulating hormone (FSH) ELISA	Follicle stimulating hormone (FSH) IVD, Kit, Enzyme Immunoassay (EIA)
120	Follicle stimulating hormone (FSH) Rapid Test Device	Follicle stimulating hormone (FSH) IVD, kit, immunochromatographic test (ICT), rapid
121	Free (unbound) prostate specific antigen (PSA) ELISA	Free (unbound) prostate specific antigen (PSA) IVD, kit, enzyme immunoassay (EIA)
122	Free Thyroxine (FT4) ELISA	Free thyroxine (FT4) IVD, kit, enzyme immunoassay (EIA)
123	Free Triiodothyronine ELISA	Free triiodothyronine (FT3) IVD, kit, enzyme immunoassay (EIA)
124	Full Blood Count Control	Full blood count IVD, control
125	Full Blood Count Kit, Cell Count	Full blood count IVD, kit, cell count
126	Gamma-glutamyltransferase (GGT) Reagent	Gamma-glutamyltransferase (GGT) IVD, reagent
127	Glucose Reagent	Glucose Reagent Single Liquid
128	Glucose Reagent Lyophilised	Glucose Reagent Lyo

129	Glycated Haemoglobin (HbA1C) Analyser	Glycated haemoglobin (HbA1C) analyser IVD
130	Glycated Haemoglobin (HbA1c) Calibrator	Glycated Haemoglobin (HbA1c) Calibrator
131	Glycated haemoglobin (HbA1c) Control	Glycated haemoglobin (HbA1c) IVD, control
132	Glycated Haemoglobin (HbA1c) IVD, Reagent	Glycated haemoglobin (HbA1c) IVD, reagent
133	Gonorrhoeae antigen Rapid Test Device	Gonorrhoeae antigen immunochromatographic test
134	Group A Streptococcus antigen Rapid Test Device	Group A Streptococcus antigen immunochromatographic test
135	Group A Streptococcus streptolysin O antibody Reagent	Group A Streptococcus streptolysin O antibody IVD, reagent
136	Group B Streptococcus antigen Rapid Test Device	Group B Streptococcus antigen immunochromatographic test
137	H Pylori Antibody Rapid Test Device	H Pylori Antibody immunochromatographic test
138	Haemoglobin (totHb) Control	Total haemoglobin (totHb) IVD, control
139	Haemoglobin (totHb) Reagent	Total haemoglobin (totHb) IVD, reagent
140	HCV Rapid Test Device	Hepatitis C virus Antibody Enzyme Immunoassay
141	Helicobacter Pylori Antigen Rapid Test Device	Helicobacter pylori antigen IVD, kit, immunochromatographic test (ICT), rapid
142	Hematron 3	Haematological cell analyser IVD, automated
143	Hematron 5	Haematological cell analyser IVD, automated
144	Hepatitis A Virus Immunoglobulin G (IgG) Antibody Reagent	Hepatitis A virus immunoglobulin G (IgG) antibody IVD, reagent
145	Hepatitis A virus Immunoglobulin M (IgM)	Hepatitis A virus

	Antibody, Enzyme Immunoassay (EIA)	immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
146	Hepatitis B Core Antibody Rapid Test Device	Hepatitis B core antibody immunochromatographic test
147	Hepatitis B Virus Core Immunoglobulin M (IgM) Antibody, Enzyme Immunoassay (EIA)	Hepatitis B virus core immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
148	Hepatitis B Virus e-antigen Enzyme Immunoassay (EIA)	Hepatitis B virus e-antigen IVD, kit, enzyme immunoassay (EIA)
149	Hepatitis B Virus e-antigen Total Antibody, Enzyme Immunoassay (EIA)	Hepatitis B virus e-antigen total antibody IVD, kit, enzyme immunoassay (EIA)
150	Hepatitis B virus surface antigen ELISA	Hepatitis B virus surface antigen enzyme immunoassay (EIA)
151	Hepatitis B Virus surface antigen Rapid Test Device	Hepatitis B virus surface antigen IVD, kit, enzyme immunoassay (EIA)
152	Hepatitis D virus antigen ELISA	Hepatitis D virus antigen enzyme immunoassay
153	Hepatitis D virus immunoglobulin G (IgG) ELISA	Hepatitis D virus immunoglobulin G (IgG) antibody enzyme immunoassay
154	Hepatitis D virus immunoglobulin M ELISA	Hepatitis D virus immunoglobulin M antibody enzyme immunoassay
155	Hepatitis E virus antigen ELISA	Hepatitis E virus antigen enzyme immunoassay
156	Hepatitis E virus immunoglobulin G ELISA	Hepatitis E virus immunoglobulin G enzyme immunoassay
157	Hepatitis E Virus Immunoglobulin M ELISA	Hepatitis E virus immunoglobulin M (IgM) antibody enzyme immunoassay
158	Hepatitis G virus immunoglobulin G ELISA	Hepatitis G virus immunoglobulin G (IgG)

		antibody enzyme immunoassay
159	Herpes Simplex Virus 1 (HSV1) Immunoglobulin G (IgG) ELISA	Herpes simplex virus 1 (HSV1) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
160	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)
161	Herpes Simplex Virus 1 (HSV1) Immunoglobulin M (IgM) ELISA	Herpes simplex virus 1 (HSV1) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
162	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)
163	Herpes simplex virus 2 (HSV2) immunoglobulin G (IgG) ELISA	Herpes simplex virus 2 (HSV2) immunoglobulin G (IgG)
164	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)
165	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) ELISA	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
166	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)
167	High density lipoprotein (HDL) cholesterol Reagent	High density lipoprotein (HDL) cholesterol IVD, Reagent
168	High-density lipoprotein (HDL) Calibrator	High-density lipoprotein (HDL) cholesterol IVD, calibrator
169	HIV1/HIV2 Antibody Rapid Test Device	HIV1/HIV2 antibody immunochromatographic test

170	HIV1/HIV2 Antibody/Antigen Rapid Test Device	HIV1/HIV2 IVD, kit, immunochromatographic test (ICT), rapid
171	Human Assayed control	Clinical Chemistry analyte Control
172	Human chorionic gonadotropin beta-subunit (beta-HCG) ELISA	Human chorionic gonadotropin beta-subunit (beta-HCG) IVD, kit, enzyme immunoassay (EIA)
173	Human Chorionic Gonadotropin beta-subunit (beta-HCG) Rapid Test Device	Human Chorionic Gonadotropin beta-subunit (beta-HCG) IVD, kit, Immunochromatographic rapid
174	Immunoglobulin A (IgA total) Reagent	Total immunoglobulin A (IgA total) IVD, reagent
175	Immunoglobulin G (IgG total) Reagent	Total immunoglobulin G (IgG total) IVD, reagent
176	Immunoglobulin M (IgM total) Reagent	Total immunoglobulin M (IgM total) IVD, reagent
177	Influenza A/B virus antigen ELISA	Influenza A/B virus antigen IVD, kit, enzyme immunoassay (EIA)
178	Influenza A/B virus Rapid Test Device	Influenza A/B virus enzyme immunoassay
179	Inorganic Phosphate Reagent	Inorganic phosphate (PO <sub>4</sub> <sup>3-</sup> ) IVD, reagent
180	Iron Reagent	Iron IVD, reagent
181	Lactate Dehydrogenase (LDH) (L - P) Reagent	Total lactate dehydrogenase (LDH) IVD, reagent
182	Lactate Dehydrogenase (LDH) (P - L) Reagent	Total lactate dehydrogenase (LDH) IVD, reagent
183	Lactate Dehydrogenase (LDH) Multiple Isoenzyme Reagent	Lactate dehydrogenase (LDH) multiple isoenzyme IVD, reagent
184	Lactate Dehydrogenase (LDH) Reagent	Total lactate dehydrogenase (LDH) IVD, reagent
185	Lactate Reagent	Lactate IVD, reagent
186	Lipase Reagent	Lipase IVD, reagent



187	Lipoprotein A Reagent	Lipoprotein A IVD, reagent
188	Low Density Lipoprotein (LDL) Cholesterol Calibrator	Low density lipoprotein (LDL) cholesterol IVD, calibrator
189	Low Density Lipoprotein (LDL) Cholesterol Reagent	Low density lipoprotein (LDL) cholesterol IVD, reagent
190	Low Ionic-Strength Salt Solution (LISS) Reagent	Low ionic-strength salt solution (LISS) immunohaematology reagent IVD
191	Luteinizing hormone (LH) ELISA	Luteinizing hormone (LH) IVD, kit, enzyme immunoassay (EIA)
192	Luteinizing hormone (LH) Rapid Test Device	Luteinizing hormone (LH) IVD, kit, immunochromatographic test
193	Lysergic Acid Diethylamide (LSD)/LSD Metabolite Reagent	Lysergic acid diethylamide (LSD)/LSD metabolite IVD, reagent
194	Magnesium Reagent	Magnesium (Mg <sup>2+</sup> ) IVD, reagent
195	Malaria ELISA	Multiple Plasmodium species antigen IVD, reagent
196	Malaria Pan Rapid Test Device	Plasmodium antigen immunochromatographic test
197	Malaria Rapid Test Device	Malaria antigen immunochromatographic test
198	Measles Virus Immunoglobulin G (IgG) Antibody Enzyme Immunoassay (EIA)	Measles virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
199	Methadone Rapid Test Device	Methadone IVD, kit, immunochromatographic test (ICT), rapid
200	Methamphetamine-specific Rapid Test Device	Methamphetamine-specific IVD, kit, immunochromatographic test (ICT) assay, rapid
201	Microalbumin Control	Microalbumin IVD, control
202	Microalbumin Rapid Test Device	Microalbumin immunochromagraphic test,

		rapid
203	Microalbumin Reagent	Microalbumin IVD, reagent
204	Morphine/morphine Metabolite Rapid Test Device	Morphine/morphine metabolite IVD, kit, immunochromatographic test (ICT), rapid
205	Multiple Drugs of Abuse Rapid Test Device	Multiple drugs of abuse IVD, kit, immunochromatographic test (ICT), rapid
206	Mumps Virus Immunoglobulin G (IgG) Antibody Enzyme Immunoassay (EIA)	Mumps virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
207	Mycobacterium tuberculosis Rapid Test Device	Mycobacterium tuberculosis complex species immunochromatographic test
208	Mycoplasma Rapid Test Device	Mycoplasma pneumoniae immunochromatographic test
209	Myoglobin Rapid Test Device	Myoglobin IVD, kit, immunochromatographic test (ICT), rapid
210	Nefletron	Nephelometry/turbidimetry analyser
211	Neonatal Thyroid Stimulating Hormone (Neonatal TSH) Elisa	Neonatal thyroid stimulating hormone (neonatal TSH) IVD, kit, enzyme immunoassay (EIA)
212	Opiate/opiate metabolite Rapid Test Device	Opiate/opiate metabolite IVD, kit, immunochromatographic test (ICT)
213	PCR Duo	PCR POCT Analyser
214	Phencyclidine (PCP) Rapid Test Device	Phencyclidine (PCP) IVD, kit, immunochromatographic test (ICT)
215	Phototron Clinical Chemistry Analyser	Multichannel clinical chemistry analyser
216	Plasma Calibrator	Multiple coagulation factor IVD, calibrator
217	Plasma Control	Multiple coagulation factor IVD, control

218	Potassium Reagent	Potassium (K+) IVD, reagent
219	Progesterone Elisa	Progesterone IVD, kit, enzyme immunoassay (EIA)
220	Prolactin Elisa	Prolactin IVD, kit, enzyme immunoassay (EIA)
221	Propoxyphene / Propoxyphene Rapid Test Device	Propoxyphene/propoxyphene metabolite IVD, kit, immunochromatographic test (ICT), rapid
222	Proteus stained antigen suspension	Febrile antigens
223	Prothrombin time Clotting Reagent	Prothrombin time (PT) IVD, kit, clotting
224	Respiratory Syncytial Virus (RSV) Antigen Reagent	Respiratory syncytial virus (RSV) antigen IVD, reagent
225	Rh(D)/Kell Multiple Blood Grouping Agglutination	Rh(D)/Kell multiple blood grouping IVD, kit, agglutination
226	Rheumatoid Factor Calibrator	Rheumatoid factor IVD, calibrator
227	Rheumatoid Factor Control	Rheumatoid factor IVD, control
228	Rheumatoid Factor Nephelometry / Turbidimetry	Rheumatoid factor IVD, kit, nephelometry/turbidimetry
229	Rheumatoid Factor Visilatex Reagent	Rheumatoid factor IVD, kit, agglutination
230	Rotavirus Antigen Rapid Test Device	Rotavirus antigen IVD, kit, immunochromatographic test (ICT), rapid
231	RPR Reagent	Treponema pallidum reagin antibody IVD, kit, agglutination
232	Rubella Virus Immunoglobulin G (IgG) Antibody Enzyme immunoassay (EIA)	Rubella virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
233	Rubella Virus Immunoglobulin M (IgM) Antibody Enzyme Immunoassay (EIA)	Rubella virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
234	Salmonella Rapid Test Device	Salmonella species immunochromatographic test

235	Salmonella species Reagent	Multiple Salmonella species total antibody IVD, reagent
236	Serological albumin	Serological albumin
237	Single Use Specimen Container	General specimen container, preservation solution, non-sterile
238	Sodium Reagent	Sodium (Na+) IVD, reagent
239	Syphilis ELISA	Treponema pallidum immunoglobulin G (IgG)/IgM antibody enzyme immunoassay
240	Testosterone Elisa	Total testosterone IVD, kit, enzyme immunoassay (EIA)
241	Thrombin time (TT) Reagent	Thrombin time (TT) IVD, reagent
242	Thyroid stimulating hormone (TSH) Elisa	Thyroid stimulating hormone (TSH) IVD, kit, enzyme immunoassay (EIA)
243	ToRCH Rapid Test Device	ToRCH screen immunochromatographic test
244	Total (direct) Bilirubin Reagent	Total/conjugated (direct) bilirubin IVD, kit, spectrophotometry
245	Total Aspartate Aminotransferase (AST) Reagent	Total aspartate aminotransferase (AST) IVD, reagent
246	Total Bilirubin / Direct Bilirubin Combo	Total/conjugated (direct) bilirubin Reagent
247	Total Bilirubin Reagent	Total/conjugated (direct) bilirubin Reagent
248	Total creatine kinase (CK) IVD, reagent	Creatine kinase (CK) Reagent
249	Total Prostate Specific Antigen (PSA) Elisa	Total prostate specific antigen (PSA) IVD, kit, enzyme immunoassay (EIA)
250	Total Prostate Specific Antigen Rapid Test Device	PSA immunochromatographic test
251	Total Protein Reagent	Total protein IVD, reagent
252	Total thyroxine (TT4) Elisa	Total thyroxine (TT4) IVD, kit,

		enzyme immunoassay (EIA)
253	Total triiodothyronine (TT3) Elisa	Total triiodothyronine (TT3) IVD, kit, enzyme immunoassay (EIA)
254	Toxoplasma gondii immunoglobulin G (IgG) ELISA	Toxoplasma gondii immunoglobulin G (IgG)
255	Toxoplasma gondii immunoglobulin G (IgG) Rapid Test Device	Toxoplasma gondii immunoglobulin G (IgG)
256	Toxoplasma gondii immunoglobulin M (IgM) ELISA	Toxoplasma gondii immunoglobulin M (IgM)
257	Toxoplasma gondii immunoglobulin M (IgM) Rapid Test Device	Toxoplasma gondii immunoglobulin M (IgM)
258	Toxoplasma gondii Visilatex Reagent	Toxoplasma gondii total antibody IVD, kit, agglutination
259	TPHA Control	Treponema pallidum immunoglobulin G/immunoglobulin M control
260	Treponema Pallidum Haemagglutination Reagent	Treponema pallidum total antibody IVD, reagent
261	Treponema Pallidum Reagin Antibody Agglutination	Treponema pallidum reagin antibody IVD, kit, agglutination
262	Treponema Pallidum Total Antibody Rapid Test Device	Treponema pallidum total antibody IVD, kit, immunochromatographic test (ICT), rapid
263	Tricyclic antidepressant Rapid Test Device	Tricyclic antidepressant IVD, kit, immunochromatographic test (ICT), rapid
264	Triglyceride Reagent	Triglyceride IVD, reagent
265	Troponin T/Troponin I Elisa	Troponin T/Troponin I IVD, kit, enzyme immunoassay (EIA)
266	Troponin T/Troponin I Rapid Test Device	Troponin T/Troponin I IVD, kit, immunochromatographic test (ICT), rapid
267	Turboclot	Coagulation Analyser IVD, Laboratory, Semi-Automated

268	Turbolyte	Coagulation analyser IVD, laboratory, semi-automated
269	Urea Colour Reagent	Urea IVD, reagent
270	Urea Reagent	Urea IVD, reagent
271	Urea UV Reagent	Urea IVD, reagent
272	Uric Acid Reagent	Uric acid IVD, reagent
273	Urine Strips	Multiple urine analyte IVD, kit, colorimetric dipstick, rapid
274	Varicella-zoster Virus (VZV) Antigen Reagent	Varicella-zoster virus (VZV) antigen IVD, reagent
275	Vitamin Calibrator	Multiple vitamin IVD, calibrator
276	Vitamin D Control	25-Hydroxy vitamin D3 control
277	Vitamin D ELISA	Vitamin D enzyme immunoassay
278	Wash/cleaning Solution Automated/Semi-Automated System	Wash/cleaning solution IVD, automated/semi-automated system
279	Zinc Reagent	Zinc IVD, reagent

End of Schedule. No additional information past this point.



11<sup>th</sup> January 2021

**Statement regarding the non-requirement for an EU Representative.**

TO WHOM IT MAY CONCERN:

Despite the departure of the United Kingdom from the European Union via the Brexit process, the province of Northern Ireland is under a different set of rules from the rest of the UK. This is known as the Northern Ireland Protocol.

Owing to the unique circumstances of Northern Ireland (NI), being part of the UK but also having a land border with an EU Member State, special conditions for NI were signed upon in the EU-UK trade deal. It was agreed that no physical or trade border would exist between NI and the Republic of Ireland and furthermore, that Northern Ireland would remain *de facto* part of the EU's single market.

This means that Prestige Diagnostics Ltd, having a registered address in Northern Ireland, **does not require** an EU Representative. '

Signed on behalf of Prestige Diagnostics Ltd



Alan Rodgers  
Managing Director