

## DECLARATION OF CONFORMITY

AMS U.K. (NI) Ltd  
Ballymena Business Centre  
Galgorm, BT42 1FL, NI, UK

6<sup>th</sup> January 2020

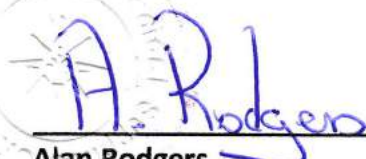
We declare the conformity of products listed in our product catalogue according to the essential requirements Annex I of the Directive 98/79/EC in the IVD directive.

The conformity was established by the manufacturer in a conformity assessment procedure according to the Annex III of the Directive 98/79/EC.

AMS U.K. (NI) Ltd  
Galgorm, County Antrim,  
United Kingdom. BT42 1FL.

CERTIFIED  
as an  
ORIGINAL DOCUMENT  
**Susan J Pinkerton**  
Notary Public  
Northern Ireland

*SJ Pinkerton*  
17 January 2020



Alan Rodgers  
Managing Director

Attached: List

**APOSTILLE**

(Convention de La Haye du 5 octobre 1961)

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<b>This public document</b> Le présent acte public / El presente documento público	
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<b>3. Acting in the capacity of</b> agissant en qualité de quien actúa en calidad de	Notary Public
<b>4. Bears the seal / stamp of</b> est revêtu du sceau / timbre de y está revestido del sello / timbre de	The Said Notary Public
<b>Certified</b> Attesté / Certificado	
<b>5. at</b> à / en	London
<b>6. the</b> le / el día	20 January 2020
<b>7. by</b> par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs
<b>8. Number</b> sous no / bajo el numero	APO-1801831
<b>9. Seal / stamp</b> Sceau / timbre Sello / timbre	
<b>10. Signature</b> Signature Firma	J. Dutta 

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CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ  
CONSULAR AUTHENTICATION

1. Quốc gia: **Việt Nam**  
Country
- Giấy tờ, tài liệu này  
This public document
2. do Ông (Bà): **J. Dutta** ký  
has been signed by
3. với chức danh: **Cán bộ lãnh sự**  
acting in the capacity of
4. và con dấu của **Bộ Ngoại giao Anh**  
bears the stamp of

được chứng nhận / hợp pháp hóa lãnh sự  
Certified

5. tại **London** 6. ngày **22/ 01/ 2020**  
at the
7. Cơ quan cấp: **Đại sứ quán Việt Nam tại VQ Anh và CH Ai-len**  
by
8. Số: **287**  
N°

Ký tên và đóng dấu  
Signature and seal/stamp  
Bí thư thứ nhất  
First Secretary



Nguyễn Diệu Hà

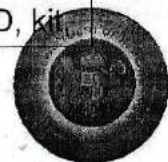
#	Medical Device
1	Activated Partial Reagent
2	Adenovirus antigen immunochromat
3	Anti Streptolysin
4	Anti Streptolysin
5	Anti Streptolysin Nephelometry/T
6	Anti Streptolysin
7	Serological Albu
8	B-type natriureti b-type natriureti Device
9	Cancer antigen
10	Cancer antigen

#	Medical Device Name	Model
1	Activated Partial Thromboplastin Time Reagent	Activated partial thromboplastin time (APTT) reagent
2	Adenovirus antigen immunochromatographic test rapid	Adenovirus antigen Rapid Test
3	Anti Streptolysin O Calibrator	Beta-haemolytic Group A Streptococcus streptolysin O antibody IVD, calibrator
4	Anti Streptolysin O Control	Beta-haemolytic Group A Streptococcus streptolysin O antibody IVD, control
5	Anti Streptolysin O Nephelometry/Turbidimetry Kit	Beta-haemolytic Group A Streptococcus streptolysin O antibody nephelometry/turbidimetry
6	Anti Streptolysin O agglutination kit	Beta-haemolytic Group A Streptococcus streptolysin O antibody IVD, kit, agglutination rapid
7	Serological Albumin	Bovine serum albumin (BSA) immunohaematology reagent
8	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 immunochromatographic test rapid
9	Cancer antigen 15-3 (CA15-3) ELISA	Cancer antigen 15-3 (CA15-3) IVD, kit, enzyme immunoassay (EIA)
10	Cancer antigen 19-9 ELISA	Cancer antigen 19-9 (CA19-9) enzyme immunoassay (EIA)



11	Cotinine (nicotine metabolite) enzyme immunoassay (EIA)	Cotinine (nicotine metabolite) IVD, kit, enzyme immunoassay (EIA)
12	Creatine kinase (CKNAC) Reagent	Creatine kinase (CK) multiple isoenzyme IVD, reagent
13	Amphetamine-specific immunochromatographic test rapid	Amphetamine-specific Rapid Test
14	Creatine kinase myocardial isoenzyme (CKMB) Control	Creatine kinase myocardial isoenzyme (CKMB) IVD, control
15	Cytomegalovirus (IgG) ELISA	Cytomegalovirus (CMV) immunoglobulin G (IgG) antibody enzyme immunoassay
16	Dengue virus Dual antigen/antibody Rapid Test Device	Dengue virus antigen/antibody IVD, kit, immunochromatographic test (ICT), rapid
17	Dengue virus Antibody enzyme immunoassay	Dengue virus immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, enzyme immunoassay
18	Erythrocyte Sedimentation Rate Control	Erythrocyte sedimentation rate (ESR) IVD, control
19	Amylase isoenzyme IVD, reagent	Amylase isoenzyme Reagent
20	ABO/Rh(D) multiple blood grouping kit	ABO/Rh(D) multiple blood grouping IVD, kit, agglutination
21	Group A Streptococcus antigen Rapid Test Device	Beta-haemolytic Group A Streptococcus antigen immunochromatographic test
22	Group B Streptococcus antigen Rapid Test Device	Beta-haemolytic Group B Streptococcus antigen IVD, kit, immunochromatographic test (ICT), rapid
23	Carcinoembryonic antigen Rapid Test Device	Carcinoembryonic antigen (CEA) IVD, kit, immunochromatographic test (ICT)
24	Chlamydia antigen Rapid Test Device	Chlamydia trachomatis antigen IVD, kit, immunochromatographic test (ICT), rapid
25	Cytomegalovirus (CMV) immunoglobulin M (IgM) ELISA	Cytomegalovirus (CMV) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay
26	Cytomegalovirus (CMV) immunoglobulin G Rapid Test Device	Cytomegalovirus (CMV) immunoglobulin G (IgG) antibody

		IVD, kit, immunochromatographic test
27	Cytomegalovirus (CMV) Immunoglobulin M Rapid Test Device	Cytomegalovirus (CMV) immunoglobulin M (IgM) antibody IVD, kit, immunochromatographic test (ICT), rapid
28	C-reactive protein Calibrator	C-reactive protein (CRP) IVD, calibrator
29	C-reactive Protein Control	C-reactive protein (CRP) IVD, control
30	C-reactive Protein (CRP) Rapid Test Device	C-reactive protein (CRP) IVD, kit, immunochromatographic test (ICT)
31	C-reactive protein (CRP) IVD, kit, nephelometry/turbidimetry	C-reactive protein (CRP) IVD, kit, nephelometry/turbidimetry
32	Creatine kinase myocardial isoenzyme (CKMB) Rapid Test Device	Creatine kinase myocardial isoenzyme (CKMB) IVD, kit, immunochromatographic test (ICT) rapid
33	Faecal Occult Blood Control	Faecal occult blood IVD, control
34	Fatty acid binding protein (FABP) IVD, kit, enzyme immunoassay	Fatty acid binding protein (FABP) IVD, kit, enzyme immunoassay (EIA)
35	Differential Haematology Analyser	Haematological cell analyser IVD, automated
36	Helicobacter pylori immunoglobulin G (IgG) Rapid Test Device	Helicobacter pylori immunoglobulin G (IgG) antibody IVD, kit, immunochromatographic test (ICT), rapid
37	Hepatitis B virus core immunoglobulin M (IgM) ELISA	Hepatitis B virus core immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
38	Anti Hepatitis B virus core ELISA	Hepatitis B virus core total antibody IVD, kit, enzyme immunoassay (EIA)
39	Anti Hepatitis B virus core antibody Rapid Test Device	Hepatitis B virus core total antibody IVD, kit, immunochromatographic test (ICT), rapid
40	Hepatitis B virus e-antigen IVD, kit,	Hepatitis B virus e-antigen IVD, kit,



	ELISA	enzyme immunoassay (EIA)
41	Hepatitis B virus e-antigen Rapid Test Device	Hepatitis B virus e-antigen IVD, kit, immunochromatographic test (ICT), rapid
42	Anti Hepatitis B virus e-antigen antibody ELISA	Hepatitis B virus e-antigen total antibody IVD, kit, enzyme immunoassay (EIA)
43	Anti Hepatitis B virus e-antigen total antibody Rapid Test Device	Hepatitis B virus e-antigen total antibody IVD, kit, immunochromatographic test (ICT), rapid
44	Hepatitis B virus surface antigen ELISA	Hepatitis B virus surface antigen IVD, kit, enzyme immunoassay (EIA)
45	Hepatitis B virus surface Antigen Rapid Test Device	Hepatitis B virus surface antigen IVD, kit, immunochromatographic test (ICT), rapid
46	Anti Hepatitis B virus surface antibody ELISA	Hepatitis B virus surface total antibody IVD, kit, enzyme immunoassay (EIA)
47	Anti Hepatitis B virus surface Rapid Test Device	Hepatitis B virus surface total antibody IVD, kit, immunochromatographic test (ICT), rapid
48	Anti Hepatitis C virus antibody ELISA	Hepatitis C virus immunoglobulin G (IgG) antibody IVD, kit, chemiluminescent immunoassay
49	Hepatitis C virus antibody Rapid Test Device	Hepatitis C virus total antibody IVD, kit, immunochromatographic test (ICT), rapid
50	Hepatitis D virus antigen ELISA	Hepatitis D virus antigen IVD, kit, enzyme immunoassay (EIA)
51	Hepatitis D virus immunoglobulin G (IgG) ELISA	Hepatitis D virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
52	Hepatitis D virus immunoglobulin M (IgM) antibody ELISA	Hepatitis D virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
53	Hepatitis E virus antigen ELISA	Hepatitis E virus antigen IVD, kit, enzyme immunoassay (EIA)



54	Hepatitis E virus immunoglobulin G (IgG) antibody ELISA	Hepatitis E virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
55	Herpes simplex virus 1 (HSV1) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)	Herpes simplex virus 1 (HSV1) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
56	Herpes simplex virus 1 (HSV1) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)	Herpes simplex virus 1 (HSV1) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
57	Herpes simplex virus 2 (HSV2) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)	Herpes simplex virus 2 (HSV2) immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
58	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)	Herpes simplex virus 2 (HSV2) immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
59	High-density lipoprotein (HDL) Calibrator	High-density lipoprotein (HDL) cholesterol IVD, calibrator
60	Anti HIV1/HIV2 antibody ELISA	HIV1/HIV2 antibody IVD, kit, enzyme immunoassay (EIA)
61	HIV1/HIV2 antibody Rapid Test Device	HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid
62	Anti HIV1/HIV2 antigen/antibody 4th Generation ELISA	HIV1/HIV2 antigen/antibody IVD, kit, enzyme immunoassay (EIA)
63	Free Prostate Specific Antigen (PSA) ELISA	Free (unbound) prostate specific antigen (PSA) IVD, kit, enzyme immunoassay (EIA)
64	HIV1/HIV2 antigen/antibody 4th Generation Rapid Test Device	HIV1/HIV2 antigen/antibody IVD, kit, immunochromatographic test (ICT), rapid
65	Human chorionic gonadotropin beta-subunit (beta-HCG) Rapid Test Device	Human chorionic gonadotropin beta-subunit (beta-HCG) IVD, kit, immunochromatographic test (ICT), rapid
66	Lipase Reagent	Lipase IVD, reagent
67	Low density lipoprotein (LDL) cholesterol Calibrator	Low density lipoprotein (LDL) cholesterol IVD, calibrator



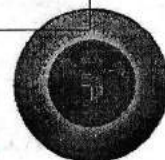


68	Low density lipoprotein (LDL) cholesterol Reagent	Low density lipoprotein (LDL) cholesterol IVD, reagent
69	Lysergic acid diethylamide (LSD)/LSD metabolite Reagent	Lysergic acid diethylamide (LSD)/LSD metabolite IVD, reagent
70	Methaqualone Reagent	Methaqualone IVD, reagent
71	Full Blood Count Control	Full blood count IVD, control
72	Methamphetamine-specific Rapid Test Device	Methamphetamine-specific IVD, kit, immunochromatographic test (ICT) assay, rapid
73	Microalbumin Rapid Test Device	Microalbumin IVD, kit, immunochromatographic test (ICT), rapid
74	Microalbumin Reagent	Microalbumin IVD, reagent
75	Morphine/morphine metabolite Rapid Test Device	Morphine/morphine metabolite IVD, kit, immunochromatographic test (ICT), rapid
76	Multiple cardiac marker IVD, kit, immunochromatographic test (ICT), rapid	Multiple cardiac marker IVD, kit, immunochromatographic test (ICT), rapid
77	Glycated haemoglobin (HbA1c) Calibrator	Glycated haemoglobin (HbA1c) IVD, calibrator
78	Glycated haemoglobin (HbA1c) Control	Glycated haemoglobin (HbA1c) IVD, control
79	Chlamydia antigen Rapid Test Device	Multiple Chlamydia species antigen IVD, kit, immunochromatographic test (ICT), rapid
80	Chlamydia trachomatis immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)	Chlamydia trachomatis immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
81	Salmonella Rapid Test Device	Multiple Salmonella species antigen IVD, kit, immunochromatographic test (ICT), rapid
82	Multiple Salmonella species antibody Reagent	Multiple Salmonella species total antibody IVD, reagent
83	Mycobacterium tuberculosis complex species total antibody IVD, kit, enzyme immunoassay (EIA)	Mycobacterium tuberculosis complex species total antibody IVD, kit, enzyme immunoassay



		(EIA)
84	Mycobacterium tuberculosis complex species antigen IVD, kit, immunochromatographic test (ICT), rapid	Mycobacterium tuberculosis complex species antigen IVD, kit, immunochromatographic test (ICT), rapid
85	Mycoplasma pneumoniae immunoglobulin M (IgM) antibody IVD, kit, immunochromatographic test (ICT), rapid	Mycoplasma pneumoniae immunoglobulin M (IgM) antibody IVD, kit, immunochromatographic test (ICT), rapid
86	Chlamydia trachomatis immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)	Chlamydia trachomatis immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
87	Mycoplasma pneumoniae total antibody IVD, kit, enzyme immunoassay (EIA)	Mycoplasma pneumoniae total antibody IVD, kit, enzyme immunoassay (EIA)
88	Myoglobin Rapid Test Device	Myoglobin IVD, kit, immunochromatographic test (ICT), rapid
89	Neisseria gonorrhoeae antigen IVD, kit, immunochromatographic test (ICT), rapid	Neisseria gonorrhoeae antigen IVD, kit, immunochromatographic test (ICT), rapid
90	Nephelometry/turbidimetry analyser IVD, manual	Nephelometry/turbidimetry analyser IVD, manual
91	Propoxyphene/propoxyphene metabolite Rapid Test Device	Propoxyphene/propoxyphene metabolite IVD, kit, immunochromatographic test (ICT), rapid
92	Prothrombin time (PT) IVD, kit, clotting	Prothrombin time (PT) IVD, kit, clotting
93	Febrile Positive control	Multiple febrile infection-associated bacteria antibody IVD, control
94	Rheumatoid factor Control	Rheumatoid factor IVD, control
95	Rheumatoid factor IVD, kit, nephelometry/turbidimetry	Rheumatoid factor IVD, kit, nephelometry/turbidimetry
96	Rotavirus antigen Rapid Test Device	Rotavirus antigen IVD, kit, immunochromatographic test (ICT), rapid
97	Rubella virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay	Rubella virus immunoglobulin G (IgG) antibody IVD, kit, enzyme

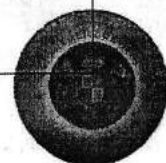
	(EIA)	immunoassay (EIA)
98	Rubella virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)	Rubella virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
99	Thrombin time (TT) Reagent	Thrombin time (TT) IVD, reagent
100	Total lactate dehydrogenase (LDH) Reagent	Total lactate dehydrogenase (LDH) IVD, reagent
101	Malaria Pan Rapid Test Device	Multiple Plasmodium species antigen IVD, kit, immunochromatographic test (ICT), rapid
102	Total prostate specific antigen (PSA) ELISA	Total prostate specific antigen (PSA) IVD, kit, enzyme immunoassay (EIA)
103	Total prostate specific antigen (PSA) Rapid Test Device	Total prostate specific antigen (PSA) IVD, kit, immunochromatographic test (ICT), rapid
104	Total thyroxine (TT4) ELISA	Total thyroxine (TT4) IVD, kit, enzyme immunoassay (EIA)
105	Toxoplasma gondii immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)	Toxoplasma gondii immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
106	Toxoplasma gondii immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)	Toxoplasma gondii immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
107	Treponema pallidum Control	Treponema pallidum immunoglobulin G (IgG)/IgM antibody IVD, control
108	Syphilis (Treponema pallidum) ELISA	Treponema pallidum immunoglobulin G (IgG)/IgM antibody IVD, kit, enzyme immunoassay (EIA)
109	Treponema pallidum reagin antibody IVD, kit, agglutination	Treponema pallidum reagin antibody IVD, kit, agglutination
110	Plasmodium falciparum Rapid Test Device	Plasmodium falciparum antigen IVD, kit, immunochromatographic test (ICT), rapid



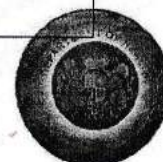
111	Syphilis ( <i>Treponema pallidum</i> ) Rapid Test Device	<i>Treponema pallidum</i> total antibody IVD, kit, immunochromatographic test (ICT), rapid
112	Troponin I ELISA	Troponin I IVD, kit, enzyme immunoassay (EIA)
113	Troponin I Rapid Test Device	Troponin I IVD, kit, immunochromatographic test (ICT), rapid
114	Wash/cleaning solution IVD, automated/semi-automated system	Wash/cleaning solution IVD, automated/semi-automated system
115	Multiple <i>Plasmodium</i> species antigen Reagent	Multiple <i>Plasmodium</i> species antigen IVD, reagent
116	Multiple <i>Rickettsia</i> species (typhus group) antigen IVD, kit, agglutination	Multiple <i>Rickettsia</i> species (typhus group) antigen IVD, kit, agglutination
117	Multiple <i>Plasmodium</i> species total antibody ELISA	Multiple <i>Plasmodium</i> species total antibody IVD, kit, enzyme immunoassay (EIA)
118	Hepatitis A virus immunoglobulin M (IgM) antibody Rapid Test Device	Hepatitis A virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA), rapid
119	Multiple blood group genotyping Control	Multiple blood group genotyping IVD, control
120	Alanine aminotransferase Reagent	Alanine aminotransferase (ALT) IVD, reagent
121	Low ionic-strength salt solution (LISS) Reagent	Low ionic-strength salt solution (LISS) immunohaematology reagent IVD
122	Lactate Reagent	Lactate IVD, reagent
123	Lactate dehydrogenase (LDH, L-P) Reagent	Lactate dehydrogenase (LDH) multiple isoenzyme IVD, reagent
124	Lactate dehydrogenase (LDH, P-L) Reagent	Lactate dehydrogenase (LDH) multiple isoenzyme IVD, reagent
125	Iron Reagent	Iron IVD, reagent
126	Inorganic Phosphate Reagent	Inorganic phosphate (PO <sub>4</sub> <sup>3-</sup> ) IVD, reagent
127	Human chorionic gonadotropin beta-subunit (beta-HCG) ELISA	Human chorionic gonadotropin beta-subunit (beta-HCG) IVD, kit, enzyme immunoassay (EIA)

128	High density lipoprotein (HDL) Reagent	High density lipoprotein (HDL) cholesterol IVD, reagent
129	Hepatitis E virus immunoglobulin M (IgM) ELISA	Hepatitis E virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
130	Hepatitis E virus immunoglobulin M (IgM) Rapid Test Device	Hepatitis E virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
131	Hepatitis E virus immunoglobulin G (IgG) ELISA	Hepatitis E virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
132	Hepatitis A virus total antibody Rapid Test Device	Hepatitis A virus total antibody IVD, kit, enzyme immunoassay (EIA)
133	Hepatitis A virus immunoglobulin M (IgM) ELISA	Hepatitis A virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
134	Hepatitis A virus immunoglobulin G (IgG) ELISA	Hepatitis A virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
135	Helicobacter pylori Antigen Rapid Test Device	Helicobacter pylori antigen IVD, kit, immunochromatographic test (ICT), rapid
136	Glycated haemoglobin (HbA1c) Reagent	Glycated haemoglobin (HbA1c) IVD, reagent
137	H-20 Glycated haemoglobin (HbA1C) Analyser	Glycated haemoglobin (HbA1C) analyser IVD
138	Glucose Reagent	Glucose IVD, reagent
139	Gamma-glutamyltransferase (GGT) Reagent	Gamma-glutamyltransferase (GGT) IVD, reagent
140	Full blood cell count kit	Full blood count IVD, kit, cell count
141	Free triiodothyronine (FT3) ELISA	Free triiodothyronine (FT3) IVD, kit, enzyme immunoassay (EIA)
142	Free thyroxine (FT4) ELISA	Free thyroxine (FT4) IVD, kit, enzyme immunoassay (EIA)
143	Follicle stimulating hormone (FSH) ELISA	Follicle stimulating hormone (FSH) IVD, kit, enzyme immunoassay (EIA)
144	Fibrinogen Reagent	Fibrinogen assay (factor I) IVD,

		reagent
145	Ferritin ELISA	Ferritin IVD, kit, enzyme immunoassay (EIA)
146	Faecal occult blood Rapid Test Device	Faecal occult blood IVD, kit, immunochromatographic test (ICT), rapid
147	Estradiol ELISA	Estradiol (oestradiol) (E2) IVD, kit, enzyme immunoassay (EIA)
148	Microread ELISA Reader	Enzyme immunoassay (EIA) analyser IVD, semi-automated
149	Microwash ELISA Plate Washer	Enzyme immunoassay (EIA) analyser IVD, semi-automated
150	D-dimer Rapid Test Device	D-dimer IVD, kit, immunochromatographic test (ICT), rapid
151	Creatinine Reagent	Creatinine IVD, reagent
152	Creatine kinase myocardial isoenzyme (CKMB) Reagent	Creatine kinase myocardial isoenzyme (CKMB) IVD, reagent
153	Creatine kinase (CK) multiple isoenzyme Reagent	Creatine kinase (CK) multiple isoenzyme IVD, reagent
154	Creatine kinase (CK) Control	Creatine kinase (CK) multiple isoenzyme IVD, control
155	Creatine kinase (CK) Calibrator	Creatine kinase (CK) multiple isoenzyme IVD, calibrator
156	C-reactive protein (CRP) Visilatex Agglutination	C-reactive protein (CRP) IVD, kit, agglutination, rapid
157	Copper Reagent	Copper IVD, reagent
158	Cocaine/cocaine metabolite Rapid Test Device	Cocaine/cocaine metabolite IVD, kit, immunochromatographic test (ICT), rapid
159	Thrombin Time Reagent	Coagulation factor IIa (thrombin) IVD, reagent
160	Prothrombin Time Reagent	Coagulation factor II (prothrombin) IVD, reagent
161	Haemostasis Coagulation Analyser, semi-automated	Coagulation analyser IVD, laboratory, semi-automated
162	Cholinesterase Reagent	Cholinesterase dibucaine number (percentage inhibition) IVD, reagent



163	Chloride Reagent	Chloride (Cl-) IVD, reagent
164	Carcinoembryonic antigen (CEA) ELISA	Carcinoembryonic antigen (CEA) IVD, kit, enzyme immunoassay (EIA)
165	Cannabinoid Rapid Test Device	Cannabinoid IVD, kit, immunochromatographic test (ICT), rapid
166	Cancer antigen 125 (CA125) ELISA	Cancer antigen 125 (CA125) IVD, kit, enzyme immunoassay (EIA)
167	Calcium Chloride Reagent	Calcium chloride coagulation reagent
168	Calcium Arsenazo Reagent	Calcium (Ca <sup>2+</sup> ) IVD, reagent
169	Calcium OCPC Reagent	Calcium (Ca <sup>2+</sup> ) IVD, reagent
170	Blood glucose analyser	Blood glucose, point-of-care
171	Group A Streptococcus total antibody agglutination	Group A Streptococcus total antibody IVD, kit, agglutination
172	Group A Streptococcus multiple enzyme antibody Reagent	Beta-haemolytic Group A Streptococcus multiple enzyme antibody IVD, reagent
173	Benzodiazepine group Rapid Test Device	Benzodiazepine group IVD, kit, immunochromatographic test (ICT), rapid
174	Barbiturate Rapid Test Device	Barbiturate IVD, kit, immunochromatographic test (ICT), rapid
175	Amphetamine/methamphetamine group Rapid Test Device	Amphetamine/methamphetamine group IVD, kit, immunochromatographic test (ICT), rapid
176	Albumin Reagent	Albumin IVD, reagent
177	Alpha-fetoprotein (AFP) ELISA	Alpha-fetoprotein (AFP) IVD, kit, enzyme immunoassay (EIA)
178	Alkaline phosphatase (ALP) Reagent	Alkaline phosphatase (ALP) isoenzyme IVD, reagent
179	Magnesium Reagent	Magnesium (Mg <sup>2+</sup> ) IVD, reagent
180	Rheumatoid Factor Calibrator	Rheumatoid factor IVD, calibrator
181	Prolactin ELISA	Prolactin IVD, kit, enzyme immunoassay (EIA)



182	Progesterone ELISA	Progesterone IVD, kit, enzyme immunoassay (EIA)
183	Potassium Reagent	Potassium (K+) IVD, reagent
184	Phencyclidine (PCP) Rapid Test Device	Phencyclidine (PCP) IVD, kit, immunochromatographic test (ICT)
185	Opiate/opiate metabolite Rapid Test Device	Opiate/opiate metabolite IVD, kit, immunochromatographic test (ICT)
186	Neonatal thyroid stimulating hormone (neonatal TSH) ELISA	Neonatal thyroid stimulating hormone (neonatal TSH) IVD, kit, enzyme immunoassay (EIA)
187	Multiple Urine Analyte Strips	Multiple urine analyte IVD, kit, colorimetric dipstick, rapid
188	Salmonella Antigen Reagent	Multiple Salmonella species antigen reagent
189	High Density Lipoprotein / Low Density Lipoprotein Control	High Density Lipoprotein / Low Density Lipoprotein Control
190	High Density Lipoprotein / Low Density Lipoprotein Calibrator	High Density Lipoprotein / Low Density Lipoprotein Calibrator
191	TORCH 5 in 1 IgG Rapid Test Device	TORCH 5 in 1 IgG Rapid Test Device
192	TORCH 5 in 1 IgM Rapid Test Device	TORCH 5 in 1 IgM Rapid Test Device
193	Febrile Negative Control	Febrile Negative Control
194	Febrile Positive Control	Febrile Positive Control
195	Febrile Negative Control	Febrile Negative Control
196	Multiple Drugs of Abuse Rapid Test Device	Multiple drugs of abuse IVD, kit, immunochromatographic test (ICT), rapid
197	Plasma Control	Plasma Control
198	Plasma Calibrator	Plasma calibrator
199	Multiple Clinical Chemistry Analyte Control	Multiple Clinical Chemistry Analyte Control
200	Clinical Chemistry Calibration Serum	Multiple Clinical Chemistry Analyte Calibrator
201	Brucella abortus antigen Agglutination Reagent	Brucella abortus antigen Agglutination Reagent
202	Brucella melitensis Antigen Agglutination Reagent	Brucella melitensis Antigen Agglutination Reagent





203	Autotron 120 Clinical Chemistry Analyser	Autotron 120
204	Autotron 240 Clinical Chemistry Analyser	Autotron 240 Clinical Chemistry Analyser
205	Autotron 420 Clinical Chemistry Analyser	Autotron 420 Clinical Chemistry Analyser
206	Phototron Clinical Chemistry Analyser	Phototron Clinical Chemistry Analyser
207	Methadone Rapid Test Device	Methadone IVD, kit, immunochromatographic test (ICT), rapid
208	Luteinizing hormone (LH) ELISA	Luteinizing hormone (LH) IVD, kit, enzyme immunoassay (EIA)
209	Rheumatoid Factor Visilatex Reagent	Rheumatoid factor IVD, kit, agglutination
210	Zinc Reagent	Zinc IVD, reagent
211	Uric acid Reagent	Uric acid IVD, reagent
212	Urea Reagent	Urea IVD, reagent
213	Troponin T/Troponin I Rapid Test Device	Troponin T/Troponin I IVD, kit, immunochromatographic test (ICT), rapid
214	Triglyceride Reagent	Triglyceride IVD, reagent
215	Tricyclic antidepressant Rapid Test Device	Tricyclic antidepressant IVD, kit, immunochromatographic test (ICT), rapid
216	Treponema pallidum Haemagglutination Reagent	Treponema pallidum total antibody IVD, reagent
217	Syphilis Rapid Test Device	Treponema pallidum antigen IVD, kit, immunochromatographic test (ICT), rapid
218	Toxoplasma gondii Visilatex Reagent	Toxoplasma gondii total antibody IVD, kit, agglutination
219	Testosterone ELISA	Testosterone IVD, kit, enzyme immunoassay (EIA)
220	Total Protein Reagent	Total protein IVD, reagent
221	Haemoglobin Reagent	haemoglobin (totHb) IVD, reagent
222	Creatine Kinase (CKNAC) Reagent	creatine kinase (CK) IVD, reagent
223	Creatine Kinase (CKNAC) Dry Reagent	creatine kinase (CK) Dry reagent



224	Cholesterol Reagent	cholesterol lipid IVD, reagent
225	Aspartate Aminotransferase (AST) Reagent	Total aspartate aminotransferase (AST) IVD, reagent
226	Amylase Reagent	amylase IVD, reagent
227	Alkaline Phosphatase (ALP) Reagent	alkaline phosphatase (ALP) IVD, reagent
228	Thyroxine (TT4) antibody ELISA	Thyroxine antibody IVD, kit, enzyme immunoassay (EIA)
229	Thyroid stimulating hormone (TSH) ELISA	Thyroid stimulating hormone (TSH) IVD, kit, enzyme immunoassay (EIA)
230	Sodium Reagent	Sodium (Na+) IVD, reagent
231	Toxoplasma gondii immunoglobulin G (IgG) ELISA	Toxoplasma gondii immunoglobulin G (IgG) antibody enzyme immunoassay (EIA)
232	Toxoplasma gondii immunoglobulin G (IgG) Rapid Test Device	Toxoplasma gondii immunoglobulin G (IgG) antibody enzyme immunoassay (EIA)
233	Toxoplasma gondii immunoglobulin M (IgM) ELISA	Toxoplasma gondii immunoglobulin M (IgM) antibody enzyme immunoassay (EIA)
234	Toxoplasma gondii immunoglobulin M (IgM) Rapid Test Device	Toxoplasma gondii immunoglobulin M (IgM) antibody enzyme immunoassay (EIA)
235	Total/direct bilirubin Reagent	Total/conjugated (direct) bilirubin IVD, kit,
236	Total triiodothyronine (TT3) ELISA	Total triiodothyronine (TT3) IVD, kit, enzyme immunoassay (EIA)
237	Uric acid Reagent Lyophilised	Uric acid IVD, reagent
238	Cholesterol Reagent	Total cholesterol lipid IVD, reagent
239	Cholesterol Lyophilised Reagent	Total cholesterol lipid IVD, reagent

End of Schedule. No additional information past this point.

