

專案輸入新冠病毒檢驗試劑相關產品資訊清單

The imported COVID-19 IVD granted emergency use authorization by Ministry of Health and Welfare (MOHW), Taiwan

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造廠名稱 Manufacturer	檢驗標的 Target
1	2020/3/30	SARS-COV-2 Antibody Test	廣州萬孚生物技術有限公司 Guangzhou Wondffo Biotech Co., Ltd	抗體檢測 Antibody
		COVID-19 IgG/IgM Rapid Test		
2	2020/4/8	Xpert Xpress SARS-CoV-2 test	Cepheid Inc.	核酸檢測 Nucleic acid
3	2020/4/8	Abbott RealTime SARS-CoV-2 Amplification Reagent Kit	Abbott Molecular Inc.	核酸檢測 Nucleic acid
		Abbott RealTime SARS-CoV-2 Control Kit		
4	2020/4/24	2019-nCoV Ab TEST CASSETEE	英諾特(唐山)生物技術有限公司 Innovita (Tangshan) Biological Technology Co. Ltd	抗體檢測 Antibody
5	2020/4/24	cobas® SARS-CoV-2 試劑 (P/N:09175431190)	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
		cobas® SARS-CoV-2 (P/N:09175431190)		
		cobas® SARS-CoV-2 Control Kit (P/N:09175440190)"		
6	2020/5/5	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	Solgent Co., Ltd.	核酸檢測 Nucleic acid
7	2020/5/5	Novel Coronavirus (2019-nCoV) Nucleic Acid Detection Kit	上海仁度生物科技 Shanghai Rendu Biotechnology Co., Ltd	核酸檢測 Nucleic acid

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8	2020/5/8	Elecsys Anti-SARS-CoV-2	Roche Diagnostics GmbH	抗體檢測 Antibody
9	2020/5/13	TaqPath COVID-19 Combo Kit, 100 reaction	Life Technologies Corporation	核酸檢測 Nucleic acid
		TaqPath COVID-19 Combo Kit, 1000 reaction		
10	2020/5/14	BioFire COVID-19 Test Kit	Biofire Defense, LLC	核酸檢測 Nucleic acid
		BioFire COVID-19 Test Kit		
		BioFire COVID-19 Test External Control Kit(+)		
11	2020/5/19	SARS-CoV-2 Reagents for BD MAX System	Becton Dickinson And Company	核酸檢測 Nucleic acid
12	2020/5/20	Allplex 2019-nCoV Assay	Seegene Inc.	核酸檢測 Nucleic acid
13	2020/5/22	SARS-Cov-2 IgG	Abbott Laboratories Diagnostics Division	抗體檢測 Antibody
		SARS-Cov-2 IgG Calibrator Kit		
		SARS-Cov-2 IgG Control Kit		
14	2020/5/22	Biofire respiratory panel 2.1 (RP2.1)	Biofire Diagnostics, LLC	核酸檢測 Nucleic acid
15	2020/5/27	Panther Fusion Open Access RNA/DNA Enzyme cartridge	Hologic, Inc.	核酸檢測 Nucleic acid
		Panther Fusion Internal Control-S		
		Panther Fusion SARS-CoV-2 Assay Controls		
		Panther Fusion Extraction Reagent-S		
		Panther Fusion Elution Buffer		
		Panther Fusion SARS-CoV-2 Assay PPR Solution		
		Panther Fusion Oil		
		Aptima Oil Reagent		
		Panther Fusion Specimen Lysis Tubes		
		Panther Fusion Module		
Panther Fusion Open Access Pack				

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		Panther Fusion Tube Trays		
16	2020/6/8~ 2022/6/15	Logix Smart Coronavirus 2019 (COVID-19) Test Kit	Co-Diagnostics, Inc.	核酸檢測 Nucleic acid
17	2020/6/12	STANDARD M nCoV Real-Time Detection kit	Sd Biosensor, Inc.	核酸檢測 Nucleic acid
18	2020/6/22	72710 Platelia SARS-CoV2 Total Ab	Bio-Rad	抗體檢測 Antibody
19	2020/7/8	ADVIA Centaur SARS-CoV-2 Total (COV2T)	Siemens Healthcare Diagnostics Inc.	抗體檢測 Antibody
		ADVIA Centaur SARS-CoV-2 Total Quality Control (COV2T QC)		
20	2020/7/8	Alinity m SARS-CoV-2 AMP Kit	Abbott Molecular Inc.	核酸檢測 Nucleic acid
		Alinity m SARS-CoV-2 CTRL Kit		
		Alinity m System		
		Alinity m Sample Prep Kit 2		
		Alinity m Lysis Solution		
		Alinity m Diluent Solution		
Alinity m Vapor Barrier Solution				
21	2020/7/10	ID NOW COVID-19	Abbott Diagnostic Scarborough, Inc.	核酸檢測 Nucleic acid
22	2020/7/15	Access SARS-CoV-2 IgG	Beckman Coulter, Inc.	抗體檢測 Antibody
		Access SARS-CoV-2 IgG calibrator		
		Access SARS-CoV-2 IgG QC		
23	2020/8/5	Biocode SARS COV 2 Assay Kit	Applied Biocode, Inc	核酸檢測 Nucleic acid
24	2020/8/31	PreciControl Anti-SARS-CoV-2 品管液	Roche Diagnostics GmbH	抗體檢測 Antibody
25	2020/9/16	BD VERITOR SYSTEM FOR RAPID DETECTION OF SARS COV2	Becton, Dickinson And Company	抗原檢測 Antigen
26	2020/9/16	BD VERITOR SYSTEM FOR RAPID DETECTION OF SARS COV2	Becton, Dickinson And Company	抗原檢測 Antigen
27	2020/11/4	cobas SARS-CoV-2 & Influenza A/B	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
		cobas SARS-CoV-2 & Influenza A/B Quality Control Kit (P/N:09211128190)		
28	2020/11/9	Panbio COVID-19 Ag Rapid Test Device (Nasopharyngeal)	Abbott Rapid Diagnostics Jena GmbH	抗原檢測 Antigen

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29	2020/11/13	cobas® SARS-CoV-2 & Influenza A/B (P/N: 09233474190)	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
		Influenza A/B Quality Control Kit (P/N:09233482190)		
30	2020/11/24	APTIMA SARS-CoV2 Assay	Hologic, Inc.	核酸檢測 Nucleic acid
		APTIMA SARS-CoV 2 Controls Kit		
		Hologic Specimen Lysis Tube		
		Finisherbrand Versaclosure Tube Closures		
		Replacement Caps TCF/Selection		
		Replacement Caps Amp/Probe		
		Replacement Caps Enzyme		
		Hologic Bleach Enhancer for cleaning		
	Specimen Transport Medium			
2021/7/1	Direct Load Tube Collection Kit			
31	2020/11/30	Xpert Xpress SARS-CoV-2/Flu/RSV	Cepheid Inc.	核酸檢測 Nucleic acid
32	2020/12/14	Elecsys Anti-SARS-CoV-2 S	Roche Diagnostics GmbH	抗體檢測 Antibody
		Elecsys Anti-SARS-CoV-2 S		
		CalSet Anti-SARS-CoV-2 S		
		PreciControl Anti-SARS-CoV-2 S		
33	2020/12/28	NeuMoDx Lysis Buffer 2	Neumodx Molecular, Inc.	核酸檢測 Nucleic acid
		NeuMoDx Lysis Buffer 4		
		NeuMoDx Cartridge		
		NeuMoDx Extraction Plate		
		NeuMoDx Wash Solution, 2 L		
		NeuMoDx Release Solution, 1 L		
		NeuMoDx SARS-CoV-2 Test Strip		
		NeuMoDx Viral Lysis Buffer		
		NeuMoDx 96 Molecular System		
		Installation Kit, NMDX 96		
34	2021/1/5	Biofire respiratory panel 2.1 (RP2.1)	Biofire Diagnostics, LLC	核酸檢測 Nucleic acid
35	2021/1/6	Alinity m SARS CoV2 AMP KIT	Abbot Molecular Inc.	核酸檢測 Nucleic acid
		Alinity m SARS CoV2 CTRL KIT		
36	2021/1/7	cobas SARS-CoV-2	Roche Molecular Systems, Inc.	核酸檢測

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		cobas SARS-CoV-2 Control Kit		Nucleic acid
37	2021/1/19	Virokey SARS CoV-2 RT PCR Test v2.0	Vela Operations Singapore Pte Ltd	核酸檢測 Nucleic acid
38	2021/1/28	TaqPath COVID-19 RT-PCR Kit Advanced	Life Technologies Corporation	核酸檢測 Nucleic acid
		TaqPath RT-PCR COVID-19 Kit		
		TaqPath COVID-19 Control		
		TaqPath COVID-19 Control Dilution Buffer		
39	2021/2/4	Elecsys Anti-SARS-CoV-2	Roche Diagnostics GmbH	抗體檢測 Antibody
40	2021/2/9	ACCESS SARS-CoV-2 IgG	Beckman Coulter, Inc.	抗體檢測 Antibody
		ACCESS SARS-CoV-2 IgG CALIBRATOR		
		ACCESS SARS-CoV-2 IgG QC		
		ACCESS SARS-CoV-2 IgM		
		ACCESS SARS-CoV-2 IgM CALIBRATOR		
		ACCESS SARS-CoV-2 IgM QC		
41	2021/2/9	cobas SARS-CoV-2 試劑	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
		cobas SARS-CoV-2 Control Kit		
42	2021/2/23	Xpert Xpress SARS-CoV-2	Cepheid Inc.	核酸檢測 Nucleic acid
43	2021/4/9	AdviseDx SARS-CoV-2 IgG II (for Alinity)	Abbott Ireland Diagnostics Division	抗體檢測 Antibody
		AdviseDx SARS-CoV-2 IgG II Calibrator Kit (for Alinity)		
		AdviseDx SARS-CoV-2 IgG II Control Kit (for Alinity)		
		AdviseDx SARS-CoV-2 IgG II (for Architect)		
		AdviseDx SARS-CoV-2 IgG II Calibrator Kit (for Architect)		
		AdviseDx SARS-CoV-2 IgG II Control Kit (for Architect)		

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44	2021/4/21	Alinity m Resp-4-Plex AMP Kit	Abbott Molecular Inc.	核酸檢測 Nucleic acid
		Alinity m Resp-4-Plex CTRL Kit		
45	2021/4/21	BioFire Respiratory Panel 2.1 (RP2.1)	Biofire Diagnostics, LLC	核酸檢測 Nucleic acid
46	2021/4/30	QIAstat-Dx Operational Module	QIAGEN Gmbh	核酸檢測 Nucleic acid
		QIAstat-Dx Analytical Module		
		QIAstat-Dx Respiratory SARS-CoV-2 Panel		
47	2021/5/10	Panbio COVID-19 Ag Rapid Test Device (NASAL)	Abbott Rapid Diagnostics Jena Gmbh	抗原檢測 Antigen
48	2021/5/17	cPass SARS-CoV-2 Neutralization Antibody Detection Kit	Genscript USA, Inc.	抗體檢測 Antibody
49	2021/5/25	BD Veritor System for Rapid Detection of SARS-Cov-2	Becton, Dickinson And Company	抗原檢測 Antigen
50	2021/5/25	ID NOW COVID-19	Abbott Diagnostic Scarborough, Inc.	核酸檢測 Nucleic acid
51	2021/5/25	Panbio COVID-19 Ag Rapid Test Device (Nasopharyngeal)	Abbott Rapid Diagnostics Jena Gmbh	抗原檢測 Antigen
52	2021/5/25	Panbio COVID-19 Ag Rapid Test Device (NASAL)	Abbott Rapid Diagnostics Jena Gmbh	抗原檢測 Antigen
53	2021/5/25	TaqPath RT-PCR COVID-19 Kit, 1,000 reactions	Life Technologies Corporation	核酸檢測 Nucleic acid
		TaqPath COVID-19 Control		
	TaqPath COVID-19 Control Dilution Buffer			
	2021/6/24	MAGMAX Viral/Pathogen II Nucleic Acid Isolation Kit	Thermo Fisher Scientific Baltics Uab	核酸檢測 Nucleic acid
54	2021/5/25	Alinity m SARS CoV2 AMP KIT	Abbott Molecular Inc.	核酸檢測 Nucleic acid

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		Alinity m SARS CoV2 CTRL KIT		
55	2021/5/25	Xpert Xpress SARS-CoV2	Cepheid Inc.	核酸檢測 Nucleic acid
56	2021/5/26	SARS-CoV-2 Reagents for BD MAX System	Becton Dickinson And Company	核酸檢測 Nucleic acid
57	2021/5/26	cobas SARS-CoV-2	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
		cobas SARS-CoV-2		
		cobas SARS-CoV-2 Control Kit		
		cobas SARS-CoV-2 & Influenza A/B		
		cobas SARS-CoV-2 & Influenza A/B Quality Control Kit		
58	2021/5/28	Xpert Xpress SARS-CoV-2	Cepheid Inc.	核酸檢測 Nucleic acid
59	2021/6/7	ADVIA Centaur SARS-CoV-2 Total (COV2T)	Siemens Healthcare Diagnostics Inc.	抗體檢測 Antibody
		ADVIA Centaur SARS-CoV-2 Total (COV2T)		
		ADVIA Centaur SARS-CoV-2 Total Quality Control (COV2T QC)		
60	2021/6/7	SARS-CoV-2 Rapid Antigen Test	Sd Biosensor, Inc.	抗原檢測 Antigen
61	2021/6/10	GenBody COVID-19 Ag	Genbody Inc.	抗原檢測 Antigen
62	2021/6/10	ACCESS SARS-CoV-2 IgM	Beckman Coulter Inc.	抗體檢測 Antibody
		ACCESS SARS-CoV-2 IgM QC		
		ACCESS SARS-CoV-2 IgM Calibrator		
		ACCESS SARS-CoV-2 IgG		
		ACCESS SARS-CoV-2 IgG Calibrator		
		ACCESS SARS-CoV-2 IgG QC		
		ACCESS SARS-CoV-2 IgG II		
		ACCESS SARS-CoV-2 IgG II Calibrator		
ACCESS SARS-CoV-2 IgG II QC				
63	2021/6/11	APTIMA SARS-CoV-2 Assay Kit	Hologic Inc.	核酸檢測 Nucleic acid
		APTIMA SARS-CoV-2 Control Kit		
		Hologic Specimen Lysis Tubes		
		Hologic Specimen Lysis Tubes		

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64	2021/6/11	Lucira CHECK-IT COVID-19 Test Kit	Lucira Health, Inc.	核酸檢測 Nucleic acid
65	2021/6/11	Lucira CHECK- IT COVID-19 Test Kit	Lucira Health, Inc.	核酸檢測 Nucleic acid
66	2021/6/11	ViroKey SARS-CoV-2 RT-PCR Test v2.0	Vela Operations Singapore Pte Ltd	核酸檢測 Nucleic acid
67	2021/6/11	SARS-CoV-2 Antigen Self Test Nasal	Sd Biosensor	抗原檢測 Antigen
68	2021/6/18	STANDARD Q COVID-19 Ag	Sd Biosensor, Inc.	抗原檢測 Antigen
		STANDARD F COVID-19 Ag FIA		
69	2021/6/18	Elecsys Anti-SARS-CoV-2	Roche Diagnostics Gmbh	抗體檢測 Antibody
70	2021/6/21	BD Veritor System for Rapid Detection of SARS-CoV-2	Bd Rapid Diagnostic Suzhou Co Ltd	抗原檢測 Antigen
71	2021/6/21	SARS-CoV-2 IgG Kit	Abbott Laboratories	抗體檢測 Antibody
		SARS-CoV-2 IgG Calibrator Kit		
		SARS-CoV-2 IgG Control Kit		
72	2021/6/22	QuickVue AT-Home OTC COVID-19 Test	Quidel Corporation	抗原檢測 Antigen
		QuickVue AT-Home OTC COVID-19 Test		
		QuickVue AT-Home OTC COVID-19 Test		
73	2021/6/22	Biocode SARS-CoV-2 Assay Kit	Applied Biocode, Inc	核酸檢測 Nucleic acid
74	2021/6/22	AdviseDx SARS-CoV-2 IgG II (for Alinity)	Abbott Ireland Diagnostics Division	抗體檢測 Antibody
		AdviseDx SARS-CoV-2 IgG II Calibrator (for Alinity)		
		AdviseDx SARS-CoV-2 IgG II Control (for Alinity)		
		AdviseDx SARS-CoV-2 IgG II (for Architect)		
		AdviseDx SARS-CoV-2 IgG II Calibrator Kit(for Architect)		

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		AdviseDx SARS-CoV-2 IgG II Control Kit(for Architect)		
75	2021/6/22	INNOSCREEN covid-19 Antigen Rapid Test Device	Abbott Ireland Diagnostics Division	抗原檢測 Antigen
76	2021/6/23	Humasis COVID-19 Ag Test	Humasis Co., Ltd.	抗原檢測 Antigen
77	2021/6/25	GenBody COVID-19 Ag	Genbody Inc.	抗原檢測 Antigen
78	2021/6/28	EUORealTime SARS-CoV-2	Euroimmun Medizinische Labordiagnostika Ag	核酸檢測 Nucleic acid
79	2021/6/29	MassARRAY SARS-CoV-2 Panel 試劑	Agena Bioscience, Inc.	核酸檢測 Nucleic acid
80	2021/6/29	TaqPath COVID-19 Pooling Assay Kit TaqPath COVID-19 Control Kit TaqPath COVID-19 Control Dilution Buffer TaqPath COVID-19 Module1/MS2 Phage Control TaqPath COVID-19 Module2 Assay Kit COVID-19 Control COVID-19 Module 2 Control Dilution Buffer	Life Technologies Corporation	核酸檢測 Nucleic acid
81	2021/6/29	GenBody COVID-19 Ag	Genbody Inc.	抗原檢測 Antigen
82	2021/7/1	InteliSwab COVID-19 Rapid Test	Orasure Technologies, Inc.	抗原檢測 Antigen
83	2021/7/1	AdviseDx SARS-CoV-2 IgM with Architect Reagent kit	Abbott Ireland Diagnostics Division	抗體檢測 Antibody

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		AdviseDx SARS-CoV-2 IgM with Architect Calibrator kit		
		AdviseDx SARS-CoV-2 IgM with Architect Control kit		
		AdviseDx SARS-CoV-2 IgM with Alinity Reagent kit		
		AdviseDx SARS-CoV-2 IgM with Alinity Calibrator kit		
		AdviseDx SARS-CoV-2 IgM with Alinity Control kit		
84	2021/7/2	cPass SARS-CoV-2 Neutralization Antibody Detection Kit	Genscript USA Inc.	抗體檢驗 Antibody
85	2021/7/5	ADVIA Centaur SARS-CoV-2 IgG (sCOVG)	Siemens Healthcare Diagnostics Inc.	抗體檢測 Antibody
		ADVIA Centaur SARS-CoV-2 IgG Quality Control (sCOVG QC)		
86	2021/7/5	CareStart COVID-19 Antigen	Access Bio	抗原檢測 Antigen
87	2021/7/7	Anti-SARS-CoV-2 ELISA (IgG)	Euroimmun Medizinische Labordiagnostika Ag	抗體檢測 Antibody
88	2021/7/8	Panbio COVID-19 Antigen SELF-TEST	Abbott Rapid Diagnostics Jena Gmbh	抗原檢測 Antigen
89	2021/7/8	INNOSCREEN COVID-19 IgG/IgM Rapid Test Device	Innovation Scientific Pty Ltd	抗體檢測 Antibody
90	2021/7/8~ 2022/8/22	QuickVue SARS Antigen Test	Quidel Corporation	抗原檢測 Antigen

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91	2021/7/8	COVID-19 IgG/IgM Rapid Test Cassette	Hangzhou Clongene Biotech Co., Ltd.	抗體檢測 Antibody
92	2021/7/13~ 2022/6/17	STANDARD Q COVID-19 Ag Home Test	SD Biosensor Inc.	抗原檢測 Antigen
93	2021/7/14	SARS-CoV-2 IgM Reagent for Alinity	Abbot Ireland Diagnostics Division	抗體檢測 Antibody
		SARS-CoV-2 IgM Calibrator for Alinity		
		SARS-CoV-2 IgM Control for Alinity		
		SARS-CoV-2 IgM Reagent for ARCHITECT		
		SARS-CoV-2 IgM Calibrator for ARCHITECT		
		SARS-CoV-2 IgM Control for ARCHITECT		
94	2021/7/14	SARS-CoV-2 IgG reagent kit for Alinity	Abbott Ireland Diagnostics Division	抗體檢測 Antibody
		SARS-CoV-2 IgG Calibrator kit for Alinity		
		SARS-CoV-2 IgG Control kit for Alinity		
		SARS-CoV-2 IgG reagent kit for Architect		
		SARS-CoV-2 IgG Calibrator kit for Architect		
		SARS-CoV-2 IgG Control kit for Architect		
95	2021/7/14	Biocredit COVID-19 Ag	RapiGEN Inc	抗原檢測 Antigen
96	2021/7/19	Humasis COVID-19 Ag Home test	Humasis Co., Ltd.	抗原檢測 Antigen

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97	2021/7/22	DiaPlexQ Novel coronavirus (2019-nCoV) Detection Kit	Solgent Co.,Ltd	核酸檢測 Nucleic acid
98	2021/7/26	Sofia SARS Antigen FIA	QUIDEL CORPORATION	抗原檢測 Antigen
99	2021/7/27	Humasis COVID-19 Ag Test	Humasis Co., Ltd.	抗原檢測 Antigen
100	2021/7/28	BIOCREDIT COVID-19 Ag Home Test Nasal	RapiGEN INC	抗原檢測 Antigen
101	2021/7/28	SGTi-flex COVID-19 IgM/IgG	Sugentech, Inc.	抗體檢測 Antibody
102	2021/7/28	BioPlex 2200 SARS-CoV IgG Reagent	BIO-RAD LABORATORIES INC.	抗體檢測 Antibody
		BioPlex 2200 SARS-CoV IgG Calibrator Set		
		BioPlex 2200 SARS-CoV IgG Control Set		
103	2021/7/29	Humasis COVID-19 Ag Home test	Humasis Co.,Ltd	抗原檢測 Antigen
104	2021/7/30	QuantiVirus SARS-CoV-2 Test Kit	DiaCarta, Inc.	核酸檢測 Nucleic acid
105	2021/8/2	SARS-CoV-2 IgG II Reagent for ARCHITECT	Abbott Ireland Diagnostics Division	抗體檢測 Antibody
		SARS-CoV-2 IgG II Calibrator for ARCHITECT		

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		SARS-CoV-2 IgG II Control for ARCHITECT		
		SARS-CoV-2 IgG II Reagent for Alinity		
		SARS-CoV-2 IgG II Calibrator for Alinity		
		SARS-CoV-2 IgG II Control for Alinity		
106	2021/8/3	BIOCREDIT COVID-19 Ag Home Test Nasal	RapiGEN INC	抗原檢測 Antigen
107	2021/8/4	DiaPlexQ Novel Coronavirus (2019 nCoV) Detection Kit	Solgent Co.,Ltd	核酸檢測 Nucleic acid
108	2021/8/4	STANDARD Q COVID-19 IgM/IgG Plus	SD BIOSENSOR, INC.	抗體檢測 Antibody
		STANDARD F COVID-19 IgM/IgG Combo FIA		
109	2021/8/5	Celltrion DiaTrust COVID-19 Ag Home Test	Humasis Co., Ltd.	抗原檢測 Antigen
110	2021/8/9~ 2022/6/17	STANDARD Q COVID-19 Ag Test	SD Biosensor,Inc.	抗原檢測 Antigen
111	2021/8/10	Celltrion DiaTrust COVID-19 Ag Home Test	Humasis Co., Ltd.	抗原檢測 Antigen
112	2021/8/30~ 2022/12/6	BIOCREDIT COVID-19 Ag Home Test Nasal	RapiGEN INC	抗原檢測 Antigen

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113	2021/8/30	SARS-CoV-2 Rapid Antigen Test Nasal	SD BIOSENSOR, INC.	抗原檢測 Antigen
114	2021/8/30	Humasis COVID-19 Ag Test	Humasis Co., Ltd.	抗原檢測 Antigen
115	2021/9/14	Advanta Dx SARS-CoV-2 RT-PCR Assay	Fluidigm Corporation	核酸檢測 Nucleic acid
116	2021/9/14	TaqPath COVID-19 Fast PCR Combo Kit 2.0	Life Technologies Corporation	核酸檢測 Nucleic acid
117	2021/9/14	BD Veritor System for Rapid Detection of SARS-CoV-2& Flu A+B	BECTON, DICKINSON AND COMPANY (BD) (OFFICE)	抗原檢測 Antigen
118	2021/9/15	BD SARS-CoV-2/Flu for BD MAX System	BECTON,DICKINSON AND COMPANY	核酸檢測 Nucleic acid
119	2021/9/23	CareStart COVID-19 Antigen	Access Bio, Inc.	抗原檢測 Antigen
120	2021/9/23	TaqPath COVID-19 RNase P Kit 2.0	Life Technologies Corporation	核酸檢測 Nucleic acid
		TaqPath COVID-19 Plus Control		
		TaqPath COVID-19 Control Dilution Buffer		
		TaqPath RT-PCR COVID-19,FluA,FluB Kit		
		TaqPath RT-PCR COVID-19,FluA,FluB Control		

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121	2021/10/7	SARS-CoV-2 NGS ASSAY	Twist Bioscience Corporation	核酸檢測 Nucleic acid
122	2021/10/7	VERI-Q Covid-19 Ag Rapid Test	MiCoBioMed Co.,Ltd	抗原檢測 Antigen
123	2021/10/25	cPASS™ SARS-CoV-2 Neutralization Antibody Detection Kit	GenScript USA,Inc	抗體檢測 Antibody
124	2021/10/26	CovAb SARS-CoV-2 Ab Test	Diabetomics, Inc.	抗體檢測 Antibody
125	2021/11/2~ 2022/6/10	Flowflex COVID-19 Antigen Home Test	ACON Laboratories, Inc.	抗原檢測 Antigen
126	2021/11/3	GenBody COVID-19 Ag Home Test	GenBody Inc.	抗原檢測 Antigen
127	2021/11/4	“ASAN”Easy Test COVID-19 Ag	Asan Pharmaceutical CO.,LTD.	抗原檢測 Antigen
128	2021/11/9	VERI-Q COVID-19 Ag Rapid Test	ERA BIOTEQ ENTERPRISE CO., LTD.	抗原檢測 Antigen
129	2021/11/12	Elecsys Anti-SARS-CoV-2 (cobas e 411/601/602)	Roche Diagnostics GmbH	抗體檢測 Antibody
		Elecsys Anti-SARS-CoV-2 (for cobas e 801)		
		Precicontrol Anti-SARS-CoV-2		
		Elecsys Anti-SARS-CoV-2 S (cobas e 411/601/602)		
		Elecsys Anti-SARS-CoV-2 S (cobas e 801)		
		CalSet Anti-SARS-CoV-2 S		
		Precicontrol Anti-SARS-CoV-2 S		
130	2021/12/06	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack	Ortho Clinical Diagnostics	抗體檢測 Antibody
		VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrators		
		VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls		
131	2021/12/30	Alinity m SARS-CoV-2 AMP kit	Abbot Molecular Inc.	核酸檢測

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		Alinity m SARS-CoV-2 CTRL kit		Nucleic acid
132	2022/2/9	Xpert Xpress SARS-CoV-2	Cepheid Inc.	核酸檢測 Nucleic acid
133	2022/2/15	GenBody COVID-19 Ag Home Test	GENBODY INC.	抗原檢測 Antigen
134	2022/2/25	ACCESS SARS-CoV-2 IgM Calibrator	BECKMAN COULTER, INC.	抗體檢測 Antibody
		ACCESS SARS-CoV-2 IgG II Calibrator		
		ACCESS SARS-CoV-2 IgG II QC		
135	2022/3/4	Humasis COVID-19 Ag Test	Humasis Co., Ltd.	抗原檢測 Antigen
136	2022/3/28	BioCode CoV-2 Flu Plus assay	Applied Biocode, Inc.	核酸檢測 Nucleic acid
137	2022/3/28	Aptima SARS-CoV-2 Assay Kit	Hologic, Inc.	核酸檢測 Nucleic acid
138	2022/4/18	Virokey SARS CoV-2 RT PCR Test v2.0	Vela Operations Singapore Pte Ltd	核酸檢測 Nucleic acid
139	2022/4/19	Allplex 2019-nCoV Assay	Seegene Inc.	核酸檢測 Nucleic acid
140	2022/4/21	GenBody COVID-19 Ag Home Test	GENBODY INC.	抗原檢測 Antigen
141	2022/4/28	GenBody COVID-19 Ag	GenBody Inc.	抗原檢測 Antigen
142	2022/4/29	Gmate COVID-19 Ag Saliva	Philosys Co., Ltd	抗原檢測 Antigen
143	2022/5/3	BD kit for rapid detection of SARS-CoV-2	BD Rapid Diagnostics (Suzhou) Co., Ltd.	抗原檢測 Antigen
144	2022/5/6	Humasis COVID-19 Ag Test	Humasis Co., Ltd.	抗原檢測 Antigen
145	2022/5/9~ 2022/7/28	BIOCREDIT COVID-19 Ag Home Test Nasal	RapiGEN INC.	抗原檢測 Antigen
146	2022/5/10~ 2022/6/15	Flowflex COVID-19 Antigen Home Test	ACON Laboratories, Inc.	抗原檢測 Antigen
147	2022/5/10	Humasis COVID-19 Ag Home Test	Humasis Co., Ltd.	抗原檢測 Antigen
148	2022/5/12	Panbio COVID-19 Ag Rapid Test Device (NASAL)	Abbott Rapid Diagnostics Jena GmbH	抗原檢測 Antigen

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149	2022/5/13	InnoScreen COVID-19 Antigen Rapid Test Device (Self-Test)	INNOVATION SCIENTIFIC PTY LTD	抗原檢測 Antigen
150	2022/5/13	Indicaid covid-19 rapid antigen at-home test	Phase Scientific International Limited	抗原檢測 Antigen
151	2022/5/13	Panbio COVID-19 Ag Rapid Test Device(Nasopharyngeal)	Abbott Rapid Diagnostics Jena GmbH	抗原檢測 Antigen
152	2022/5/16	Xpert Xpress SARS-CoV-2	CEPHEID	核酸檢測 Nucleic acid
153	2022/5/20	Humasis COVID-19 Ag Home test	Humasis Co.,Ltd	抗原檢測 Antigen
154	2022/5/20	STANDARD Q COVID-19 Ag Home Test	SD BIOSENSOR, INC.	抗原檢測 Antigen
155	2022/5/20	STANDARD Q COVID-19 Ag Home Test	SD Biosensor, Inc.	抗原檢測 Antigen
156	2022/5/20	InnoScreen COVID-19 Antigen Rapid Test Device	Innovation Scientific Pty Ltd	抗原檢測 Antigen
157	2022/5/20	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	SolGent Co., Ltd	核酸檢測 Nucleic acid
158	2022/5/23	PCL SELF TEST-COVID19 Ag	PCL, Inc	抗原檢測 Antigen
159	2022/5/23	INDICAID COVID-19 Rapid Antigen At-home test	PHASE Scientific International Ltd.	抗原檢測 Antigen
160	2022/5/25	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	SolGent Co., Ltd.	核酸檢測 Nucleic acid
161	2022/6/6	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Reagent Pack	Ortho-Clinical Diagnostics, Inc.	抗體檢測 Antibody
		VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators		
		VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Controls		
162	2022/6/6	PCL SELF TEST-COVID19 Ag	PCL,Inc.	抗原檢測 Antigen
163	2022/6/8	VERI-Q COVID-19 Ag Rapid Test	MiCo BioMed Co., Ltd	抗原檢測 Antigen

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164	2022/6/10	Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home	BTNX, INC.	抗原檢測 Antigen
165	2022/6/10	NeuMoDx Lysis Buffer 2	NeuMoDx Molecular, Inc.	核酸檢測 Nucleic acid
		NeuMoDx Lysis Buffer 3		
		NeuMoDx Cartridge		
		NeuMoDx Extraction Plate		
		NeuMoDx Wash Solution, 2 L		
		NeuMoDx Release Solution, 1 L		
		NeuMoDx SARS-CoV-2 Test Strip		
		NeuMoDx Viral Lysis Buffer		
		NeuMoDx Saliva Collection Kit		
		NeuMoDx 96 Molecular System		
NeuMoDx 288 Molecular System				
166	2022/6/10	BIOCREDIT COVID-19 Ag Home Test Nasal	RapiGEN, Inc.	抗原檢測 Antigen
167	2022/8/9	PCL SELF TEST COVID19 Ag	PCL Inc.	抗原檢測 Antigen
168	2022/8/11	TaqPath COVID-19 RNase P Kit 2.0	Life Technologies Corporation	核酸檢測 Nucleic acid
		TaqPath COVID-19 Plus Control	Microgenics Corporation	
		TaqPath COVID-19 Control Dilution Buffer	Life Technologies Corporation	
169	2022/8/17	TaqPath COVID-19 Module1/MS2 Phage Control	Life Technologies Corporation	核酸檢測 Nucleic acid
		TaqPath COVID-19 Module2 Assay Kit	Microgenics Corporation	
		COVID-19 Control		
		COVID-19 Module 2 Control Dilution Buffer	Life Technologies Corporation	
170	2022/8/18	cobas SARS-CoV-2 Duo	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
		cobas SARS-CoV-2 Duo Control Kit		
171	2022/8/18	Xpert Xpress CoV-2 plus	Cepheid	核酸檢測 Nucleic acid
172	2022/8/18	cobas SARS-CoV-2	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
		cobas SARS-CoV-2 Control Kit		
173	2022/8/19	TaqPath RT-PCR COVID-19 Kit	Life Technologies Corporation	核酸檢測 Nucleic acid
		TaqPath RT-PCR COVID-19 Control	Microgenics Corporation	

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		TaqPath RT-PCR COVID-19 Control Dilution Buffer	Life Technologies Corporation	
174	2022/8/19	PCL SELF TEST-COVID19 Ag	PCL,Inc.	抗原檢測 Antigen
175	2022/8/19	PCL SELF TEST COVID19 Ag	PCL,Inc.	抗原檢測 Antigen
176	2022/8/23	PCL SELF TEST COVID19 Ag	PCL,Inc.	抗原檢測 Antigen
177	2022/8/24	ID NOW COVID-19 2.0	Abbott Diagnostics Scarborough, Inc.	核酸檢測 Nucleic acid
178	2022/8/30	PCL SELF TEST COVID 19 Ag	PCL,Inc.	抗原檢測 Antigen
179	2022/9/13	BioFire Respiratory Panel 2.1 (RP2.1)	BioFire Diagnostic, LLC	核酸檢測 Nucleic acid
180	2022/9/16	Xpert Xpress SARS-CoV-2 /Flu/RSV plus	Cepheid	核酸檢測 Nucleic acid
181	2022/10/5	STANDARD M10 SARS-CoV-2	SD Biosensor, Inc.	核酸檢測 Nucleic acid
		STANDARD M10		
182	2022/10/18	Alinity m SARS-CoV-2 AMP Kit	ABBOTT MOLECULAR, INC	核酸檢測 Nucleic acid
		Alinity m SARS-CoV-2 CTRL Kit		
183	2022/10/21	Celltrion DiaTrust COVID-19 Ag Home Test	Humasis Co., Ltd	抗原檢測 Antigen
184	2022/10/31	Indicaid covid-19 rapid antigen at-home test	Phase Scientific International Ltd	抗原檢測 Antigen
185	2022/11/7	CareStart COVID-19 Antigen Home Test	Access Bio, Inc.	抗原檢測 Antigen
186	2022/12/5	ACCESS SARS-CoV-2 IgG II Calibrator	BECKMAN COULTER, INC.	抗體檢測 Antibody