

現在位置：[首頁](#) > [其他](#) > [認識COVID-19](#) > [核准疫苗及檢驗試劑清單](#)

## 核准疫苗及檢驗試劑清單

### 衛生福利部已核准專案輸入/製造之COVID-19疫苗

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

序號 No.	中/英文品名 Vaccine name	核准日期 Approval date
1	阿斯特捷利康COVID-19疫苗 AstraZeneca COVID-19 Vaccine (Vaxzevri a)	2021/02/20
2	莫德納 COVID-19 疫苗 Moderna COVID-19 Vaccine (Spikevax)	2021/04/22
3	高端新冠肺炎疫苗 MVC COVID-19 Vaccine	2021/07/30
4	BNT162b2 COVID-19疫苗 BNT162b2 COVID-19 Vaccine	2021/08/03
5	Novavax COVID-19 疫苗 (Novavax)	2022/06/22

上述疫苗相關中文說明書，請參考本部食品藥物管理署官網

<https://www.fda.gov.tw/TC/siteList.aspx?sid=11845>

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For the Chinese instructions of the above vaccines, please refer to the official website of Taiwan Food and Drug Administration : <http://www.fda.gov.tw/TC/siteList.aspx?sid=11845>。

### 專案製造新冠病毒檢驗試劑相關產品資訊清單

### The domestic 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	製造商名稱 Manufacturer	檢驗類型 Target
1	2020/4/30	瑞基新型冠狀病毒 (orf 1ab) 檢測試劑 POCKIT Central SARS-CoV-2 (orf 1ab) Premix Kit 瑞基自動化核酸分析儀 POCKIT Central Nucleic Acid Analyzer 瑞基萃取耗材組 POCKIT Central Cartridge Set (B) 瑞基新型冠狀病毒(orf 1ab)檢 測試劑陽性對照組 POCKIT Central SARS-CoV-2 (orf 1ab) P(+) Control Reagent	瑞基海洋生物科技股份有限公司 GeneReach Biotechnology Corporation	核酸檢測 Nucleic acid
2	2020/5/11	列特博新型冠狀病毒RNA檢測 試劑組 LabTurbo AIO COVID- 19 RNA Testing Kit 列特博AIO核酸萃取試劑組 LabTurbo Viral DNA/RNA AI O extraction Kit 列特博AIO全自動核酸偵測系 統 LabTurbo AIO SP-qPCR Aut omation System	諾貝爾生物有限公司 Taigen Bioscience Corporation	核酸檢測 Nucleic acid
3	2020/5/25	"高端"新型冠狀病毒核酸檢驗 組 MVC SARS-CoV-2 qPCR Kit	高端疫苗生物製劑股份有限 公司委託台塑生醫科技股份 有限公司（宜蘭廠）製造 Ma nufactured by (FORMOSA BIOMEDICAL TECHNOLOG	核酸檢測 Nucleic acid

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
			Y CORPORATION) for (MEDIGEN VACCINE BIOLOGICS CORPORATION)	
4	2020/5/29	凌越新型冠狀病毒抗體快速檢測試劑 ALERT SARS-CoV-2 Antibody Rapid Test	凌越生醫股份有限公司台北廠 EXCELSIOR BIO-SYSTEM INCORPORATION Taipei Factory	抗體檢測 Antibody
5	2020/6/10	普生新冠肺炎核酸檢測試劑盒 GB SARS-CoV-2 Real-time RT-PCR	普生股份有限公司 GENERAL BIOLOGICALS CORPORATION	核酸檢測 Nucleic acid
6	2020/6/30	金萬林SARS-CoV-2核酸檢測試劑套組第一代 KimForest SARS-CoV-2 Detection Kit v1	金萬林企業股份有限公司委託世基生物醫學股份有限公司台北廠製造 Manufactured by Pharmigene Inc. for KimForest Enterprise Co., Ltd.	核酸檢測 Nucleic acid
7	2020/7/1	泉沂醫學新冠病毒核酸檢測試劑組 GENEONE COVID-19 Nucleic Acid Diagnostic Kit	泉沂醫學科技股份有限公司 GeneOne Diagnostics Corporation	核酸檢測 Nucleic acid
8	2020/7/1	"克雷多微特"新型冠狀病毒-19檢驗試劑 VitaPCR SARS-CoV-2 Assay "克雷多微特" PCR分析儀 VitaPCR Instrument "克雷多微特"新型冠狀病毒-19品管套組	泉創生醫有限公司 TRENTON BIOMEDICAL LTD.	核酸檢測 Nucleic acid

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		VitaPCR SARS-CoV-2 External Control Set		
9	2020/7/6	SARS-CoV-2 iPMx分子快速檢驗系統-SARS-CoV-2 試劑套組 SARS-CoV-2 Reagent Kit SARS-CoV-2 iPMx分子快速檢驗系統-SARS-CoV-2 品管物套組 SARS-CoV-2 Control Kit SARS-CoV-2 iPMx分子快速檢驗系統-SARS-CoV-2 iPMx檢測儀 SARS-CoV-2 iPMx Molecular Rapid Test System	工業技術研究院醫療器材GM P工廠 Industrial Technology Research Institute, Medical Device GMP Manufacturer	核酸檢測 Nucleic acid
10	2020/7/24	昕創生醫新型冠狀病毒核酸檢測套組 Innocreate SARS-CoV-2 QD Kit	昕創生醫技術股份有限公司 Innocreate Bioscience Co., Ltd.	核酸檢測 Nucleic acid
11	2020/7/24	德必碁新型冠狀病毒核酸檢驗組 ExProbe SARS-CoV-2 Testing Kit	德必碁生物科技股份有限公司 TBG BIOTECHNOLOGY CORP.	核酸檢測 Nucleic acid
12	2020/7/27	新型冠狀病毒抗體快篩試劑 COVID-19 Antibody Rapid Test	鼎群科技股份有限公司 TRISON TECHNOLOGY INTEGRATION CORPORATION	抗體檢測 Antibody
13	2020/8/12	長興COVIDual COVID-19 抗體檢測試劑 COVIDual COVID-19 antibody Rapid Test	長興材料工業股份有限公司 ETERNAL MATERIALS CO., LTD.	抗體檢測 Antibody

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
14	2020/8/20 2022/2/23	博鍊新型冠狀病毒核酸檢測試劑 IntelliPlex SARS-CoV-2 Detection Kit	博鍊生技股份有限公司 PLEXBIO CO., LTD.	核酸檢測 Nucleic acid
15	2020/8/24	東耀新型冠狀病毒抗體快速檢 驗試劑 ASK COVID-19 Antibody Rapid Test	東耀生物科技有限公司 TONYAR BIOTECH. INC.	抗體檢測 Antibody
16	2020/8/27	飛確 新型冠狀病毒抗原快速 檢驗試劑 Vstrip COVID-19 Antigen Rapid Test	寶齡富錦生技股份有限公司 汐止廠 Panion & BF Biotech Inc. Xi zhi Factory	抗原檢測 Antigen
17	2020/9/1	COVID19 IgG & IgM 快篩檢測 試劑 COVID19 IgG & IgM Antibody Detection Kit (Colloidal Gold Method) For in vitro diagnosis	百歐生命科技股份有限公司 委託龍騰生技股份有限公司 新市廠製造 Manufactured by LOMG TERM BIORESEARCH INC. for AllBio Science, Inc.	抗體檢測 Antibody
18	2020/9/16	普生新冠肺炎核酸檢測試劑盒 GB SARS-CoV-2 Real-time RT-PCR 普生病毒核酸萃取試劑 GB SimPrep Viral DNA/RNA Extraction Kit	普生股份有限公司 GENERAL BIOLOGICALS CORP.	核酸檢測 Nucleic acid
19	2020/11/13	列特博新型冠狀病毒RNA檢測 試劑組 LabTurbo AIO COVID-19 RNA Testing Kit	諾貝爾生物有限公司二廠 Taigen Bioscience Corporation Second Factory	核酸檢測 Nucleic acid

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20	2020/11/13	威創新型冠狀病毒抗原快速檢驗試劑 VTRUST COVID-19 (SARS-CoV-2)Antigent Rapid Test	泰博科技股份有限公司五股廠 Taibo Technology Co., Ltd. Wugu Factory	抗原檢測 Antigen
21	2020/11/23	奎克數位PCR新型冠狀病毒核酸檢驗組 DigiChip SARS-CoV-2 Assay Kit 奎克基因檢測分析儀 Q Station	奎克生技光電股份有限公司 QUARK BIOSCIENCES TAIWAN, INC.	核酸檢測 Nucleic acid
22	2020/12/2	達基 SARS-CoV-2檢測試劑盒 Dagene G SARS-CoV-2 Test Assay 達基核酸萃取試劑盒 Dagene GS1 Nucleic Acid Extraction Kit 達基全自動核酸分析儀 Dagene G1 Automated Nucleic Acid Analysis System	達爾生技股份有限公司委託 日祥生命科學股份有限公司製造 Manufactured by ISTAT BIOMEDICAL CO., LTD. for DELBIO, INC. 達爾生技股份有限公司委託 日祥生命科學股份有限公司製造 Manufactured by ISTAT BIOMEDICAL CO., LTD. for DELBIO, INC. 達爾生技股份有限公司委託 致茂電子股份有限公司林口廠製造 Manufactured by CHROMATE INC. LINKOU PLANT for DELBIO, INC.	核酸檢測 Nucleic acid
23	2020/12/14	泓佑新型冠狀病毒抗體快速篩檢試劑組	泓佑生物科技有限公司委託 瑞智生化科技股份有限公司	抗體檢測 Antibod

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		ACE COVID-19 Antibody Rapid Detection Kit	製造 Manufactured by (SWISCA RE TECHNOLOGY CO., LTD.) for (ACE BIOLABS CO., LTD.)	y
24	2020/12/22	福又達新型冠狀病毒多重螢光核酸檢驗試劑組 SBC SARS-CoV-2 MDx qPCR Kit	福又達生物科技股份有限公司委託台塑生醫科技股份有限公司製造 Manufactured by FORMOSA BIOMEDICAL TECHNOLOGY CORPORATION for SCHWEITZER BIOTECH COMPANY LTD.	核酸檢測 Nucleic acid
25	2020/12/30	麥博森新冠病毒定溫核酸檢測試劑組 MobioSense COVID-19 Isothermal Nucleic Acid Diagnostic Kit	麥博森股份有限公司委託泉沂醫學科技股份有限公司製造 Manufactured by GeneOne Diagnostics Co., Ltd. for MobioSense Corp.	核酸檢測 Nucleic acid
26	2021/1/5	達基 新型冠狀病毒核酸檢測試劑盒 Dagene M SARS-CoV-2 Assay	達爾生技股份有限公司委託日祥生命科學股份有限公司製造 Manufactured by (ISTAT BIOMEDICAL CO., LTD.) for (DELBIO INC.)	核酸檢測 Nucleic acid
27	2021/1/11	普生新冠肺炎抗體檢測試劑 GB SARS-CoV-2 Ab ELISA	普生股份有限公司 GENERAL BIOLOGICALS CORPORATION.	抗體檢測 Antibody

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28	2021/1/12	台塑生醫迅知新型冠狀病毒抗原快速檢驗試劑 Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit	台塑生醫科技股份有限公司 宜蘭廠 FORMOSA BIOMEDICAL TECHNOLOGY CORPORATION Yilan Plant	抗原檢測 Antigen
29	2021/1/12	瑞基新型冠狀病毒檢測試劑 POCKIT Central SARS-CoV-2 (orf 1ab) Premix Reagent 瑞基萃取耗材組 POCKIT Central Cartridge Set (B)	瑞基海洋生物科技股份有限公司 GeneReach Biotechnology Corporation	核酸檢測 Nucleic acid
30	2021/1/21	普生新冠肺炎核酸檢測試劑盒 GBC SimPrep SARS-CoV-2 RT-PCR	普生股份有限公司 GENERAL BIOLOGICALS CORPORATION.	核酸檢測 Nucleic acid
31	2021/1/28	“亞諾法” 新型冠狀病毒抗原快速檢驗試劑 “Abnova” COVID-19 Viral Antigen Rapid Test	亞諾法生技股份有限公司委託龍騰生技股份有限公司新市廠製造 Manufactured by Long Term Bioresearch Inc. Xinshi Factory for Abnova (Taiwan) Corporation	抗原檢測 Antigen
32	2021/2/4	三鈺新型冠狀病毒抗原快篩檢測試劑 TRICAN COVID-19 Antigen Rapid Test Kit	三鈺生物科技股份有限公司委託鼎群科技股份有限公司製造 Manufactured by (TRISON TECHNOLOGY INTEGRATION CORPORATION) for (TRICAN BIOTECHNOLOGY CO., LTD.)	抗原檢測 Antigen



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33	2021/2/17	福又達新冠肺炎IgG抗體檢測 試劑組 SBC COVID-19 IgG ELISA Kit	福又達生物科技股份有限公司 委託精專生醫股份有限公司 製造 Manufactured by SCHWEI TZER BIOTECH COMPANY L TD. for ACCUBIOMED CO., LTD.	抗體檢測 Antibod y
34	2021/3/5	台塑生醫新冠病毒抗體酵素免 疫檢驗試劑 MeDiPro SARS-CoV-2 Antib ody ELISA	台塑生醫科技股份有限公司 宜蘭廠 Formosa Plastics Biomed ical Technology Co., Ltd. Yil an Plant	抗體檢測 Antibod y
35	2021/3/17	安特羅新型冠狀病毒抗原快速 檢驗試劑 Enimmune Speedy COVID-1 9 Ag Rapid Test	安特羅生物科技股份有限公司 委託聯華生技股份有限公 司製造 Manufactured by ENIMMU NE CORPORATION for FIRS TEP BIORESEARCH INC.	抗原檢測 Antigen
36	2021/4/6	COVIDual COVID-19 IgM/IgG 快速檢測試劑 COVIDual COVID-19 IgM/IgG Rapid Test	長興材料工業股份有限公司 ETERNAL MATERIALS CO., LTD.	抗體檢測 Antibod y
37	2021/4/6	COVIDual COVID-19 IgM/IgG 快速檢測試劑 COVIDual COVID-19 IgM/IgG Rapid Test	長興材料工業股份有限公司 委託聯華生技股份有限公 司製造 Manufactured by FIRSTEP BIORESEARCH INC. for ET ERNAL MATERIALS CO., LT D.	抗體檢測 Antibod y

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
38	2021/4/7	美克優新型冠狀病毒S-RBD/S1-NTD抗體快速檢驗試劑 ViroCure CO-19 S-RBD/S1-NTD Ab Rapid Test	東耀生物科技有限公司 TONYAR BIOTECH. INC.	抗體檢測 Antibody
39	2021/4/6	COVID-19抗原快速檢測試劑 COVID-19 Antigen Rapid Test	長興材料工業股份有限公司 ETERNAL MATERIALS CO., LTD.	抗原檢測 Antigen
40	2021/4/28	飛確 新型冠狀病毒抗原快速檢驗試劑 卡匣式 Vstrip COVID-19 Antigen Rapid Test cassette	寶齡富錦生技股份有限公司 汐止廠 Panion & BF Biotech Inc. Xi zhi Factory	抗原檢測 Antigen
41	2021/5/10	伊諾來富新型冠狀病毒抗原檢測試劑 ENNOLIFE COVID-19 Antigen Test	保生國際生醫股份有限公司 PROTECTLIFE INTERNATIONAL BIOMEDICAL INC.	抗原檢測 Antigen
42	2021/5/10	凌越新型冠狀病毒抗原快速檢測試劑 EBSALERT SARS-CoV-2 Antigen Rapid Test	凌越生醫股份有限公司臺北廠 EXCELSIOR BIO-SYSTEM INCORPORATION Taipei Factory	抗原檢測 Antigen
43	2021/5/14	百歐COVID19 Ag快速檢測試劑(IVD) AllBio COVID-19 Ag Rapid Test Kit	百歐生命科技股份有限公司 委託龍騰生技股份有限公司 新市廠製造 Manufactured by LOMG TERM BIORESEARCH INC. for ALLBIO SCIENCE, INC.	抗原檢測 Antigen
44	2021/5/21	訊捷 新型冠狀病毒抗原快速檢驗試劑	美特斯生醫股份有限公司委託寶齡富錦生技股份有限公司	抗原檢測 Antigen

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		ImmTek COVID-19 Antigen Rapid Test	司汐止廠製造 Manufactured by Panion & BF Biotech Inc. Xizhi Factory for METAS BIOMEDICAL INC.	
45	2021/6/7	艾諾斯新冠病毒COVID-19抗原快速檢測試劑 Ainos SARS-CoV-2 Antigen Rapid Test Kit	台灣奈米碳素股份有限公司 TAIWAN CARBON NANO TECHNOLOGY CORPORATION	抗原檢測 Antigen
46	2021/6/8	聯華新型冠狀病毒抗原快速檢測試劑 2019-nCoV Antigen Rapid Test	聯華生技股份有限公司 FIRSTSTEP BIORESEARCH INC.	抗原檢測 Antigen
47	2021/6/17	福爾威創家用新型冠狀病毒抗原快速檢驗套組 FORA/VTRUST COVID-19 Antigen Self Test	泰博科技股份有限公司五股廠 Taibo Technology Co., Ltd. Wugu Factory	抗原檢測 Antigen
48	2021/7/1	飛確RV2家用新型冠狀病毒抗原快速檢驗試劑 Vstrip RV2 COVID-19 Antigen Rapid Test Home Use	寶齡富錦生技股份有限公司 汐止廠 Panion & BF Biotech Inc. Xizhi Factory	抗原檢測 Antigen
49	2021/7/8	研準 新型冠狀病毒抗原快速檢驗試劑 ACADECISE COVID-19 Antigen Rapid Test	中央研究院委託寶齡富錦生技股份有限公司汐止廠製造 Manufactured by Panion & BF Biotech Inc. Xizhi Factory for Academia Sinica	抗原檢測 Antigen
50	2021/8/2	嘉瑞新型冠狀病毒抗體快速檢測試劑組	瑞智生化科技股份有限公司 SWISCARE TECHNOLOGY C	抗體檢測 Antibod

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		Swiscare COVID-19 Antibody Detection Kit	O., LTD.	y
51	2021/8/13	飛確RV2新型冠狀病毒抗原快速檢驗試劑 Vstrip RV2 COVID-19 Antigen Rapid Test	寶齡富錦生技股份有限公司 汐止廠 Panion & BF Biotech Inc. Xi zhi Factory	抗原檢測 Antigen
52	2021/8/25	瑩芳新型冠狀病毒COVID-19病毒抗原快速檢驗試劑 “IF” COVID-19 Antigen Rapid Test	瑩芳有限公司台中廠 IN FUNG CO., LTD.	抗原檢測 Antigen
53	2021/9/6	冷確新型冠狀病毒(SARS-CoV-2)抗原快速檢驗試劑 Q-Check SARS-CoV-2 Antigen Rapid Test	冷泉港生物科技股份有限公司委託鼎群科技股份有限公司製造 Manufactured by TRISON TECHNOLOGY INTEGRATION CORPORATION for COLD SPRING BIOTECH CORP.	抗原檢測 Antigen
54	2021/9/7	碁米庫斯新冠病毒抗原快速檢驗試劑 KEMYTH cassette SARS-CoV-2 Antigen Rapid Test	碁米庫斯生物科技股份有限公司委託鼎群科技股份有限公司製造 Manufactured by TRISON TECHNOLOGY INTEGRATION CORPORATION for KEMYTH BIOTECH CO., LTD.	抗原檢測 Antigen
55	2021/9/23	安盛安必測新冠肺炎抗原快速檢測分析儀 iXensor PixoTest Analyzer 安盛安必測新冠肺炎抗原快速檢測套組	安盛生科股份有限公司內湖廠 IXENSOR CO., LTD.	抗原檢測 Antigen

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		iXensor PixoTest COVID-19 Ag Test Kit		
56	2021/10/6	鼎群新冠肺炎抗原快速檢測試劑 TTREND COVID-19 Antigen Test	鼎群科技股份有限公司 TRISON TECHNOLOGY INT TEGRATION CORPORATION	抗原檢測 Antigen
57	2021/10/29	艾卡爾SARS-CoV-2試劑組 iCareDx SARS-CoV-2 test kit (PSS-1s-COVID-R) (1 test/ki t) 艾卡爾SARS-CoV-2品管試劑 組 iCareDx SARS-CoV-2 Contro l kit (PSS-1s-COVID-Q) (1 tes t/kit) 艾卡爾核酸檢測分析儀 iCareDx RT-PCR analyzer (P SS-1s-C)	富佳生科技股份有限公司 iCare Diagnostics Internati onal Co. Ltd.	核酸檢測 Nucleic acid
58	2021/11/19	福又達新型冠狀病毒多重螢光 核酸檢驗試劑組 SBC SARS-CoV-2 MDx qPCR Kit	台塑生醫科技股份有限公司 FORMOSA BIOMEDICAL TE CHNOLOGY CORPORATION	核酸檢測 Nucleic acid
59	2021/11/29	台塑生醫家用新型冠狀病毒抗 原快速檢驗試劑 Formosa SARS-CoV-2 Antig en Self Test	台塑生醫科技股份有限公司 宜蘭廠 FORMOSA BIOMEDICAL TE CHNOLOGY CORPORATION Yilan Factory	抗原檢測 Antigen
60	2021/12/16	百敏析 SARS-CoV-2 IgG抗體 檢測套組	洵藝科技股份有限公司 AGNITIO SCIENCE & TECH	抗體檢測 Antibod

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		BioIC SARS-CoV-2 IgG Detection Kit	NOLOGY, INC.	y
61	2021/12/27	矽基微量生醫分子檢測儀 Molsentech SENEDIA 矽基新冠病毒快速檢測晶片 Molsentech SARS-CoV-2 Bio-FET 矽基核酸檢測試劑 Molsentech RNA assay Kit	矽基分子電測科技股份有限公司 SILICON-BASED MOLECULAR SENSORING TECHNOLOGY CO., LTD.	核酸檢測 Nucleic acid
62	2022/01/27	凌越家用新型冠狀病毒抗原快速檢測試劑 EBSALERT SARS-CoV-2 Antigen Self Test	凌越生醫股份有限公司 EXCELSIOR BIO-SYSTEM INCORPORATION	抗原檢測 Antigen
63	2022/02/15	速可安家用新冠病毒抗原自我檢測套組 Quicksure COVID-19 Antigen Self Test	安特羅生物科技股份有限公司委託聯華生技股份有限公司製造 Manufactured by FIRSTSTEP BIORESEARCH INC. for ENIMMUNE CORPORATION	抗原檢測 Antigen
64	2022/3/7	福爾威創新型冠狀病毒抗原快速檢驗試劑FORA/VTRUST COVID-19 Antigen Rapid Test 福爾威創新型冠狀病毒抗原快速檢驗試劑-陽性品管刷 FORA COVID-19 Antigen Positive Control Swab 福爾威創新型冠狀病毒抗原快速檢驗試劑-陰性品管刷	泰博科技股份有限公司五股廠 Taibo Technology Co., Ltd. Wugu Factory	抗原檢測 Antigen

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		FORA COVID-19 Antigen Negative Control Swab		
65	2022/3/17	凌越新型冠狀病毒中和抗體檢測試劑 EBSALERT SARS-CoV-2 Neutralizing Antibody Detection ELISA	凌越生醫股份有限公司 EXCELSIOR BIO-SYSTEM INCORPORATION	抗體檢測 Antibody
66	2022/3/28	普生新型冠狀病毒抗原快速檢測試劑 GB COVID-19 Ag Rapid Test	普生股份有限公司 GENERAL BIOLOGICALS CORPORATION.	抗原檢測 Antigen
67	2022/4/18	飛確RV2家用新型冠狀病毒抗原快速檢驗試劑 Vstrip RV2 COVID-19 Antigen Rapid Test HOME USE	寶齡富錦生技股份有限公司 汐止廠二廠 Panion & BF Biotech Inc. Xizhi Factory II	抗原檢測 Antigen
68	2022/4/18	長興家用COVID-19抗原快速檢測試劑套組 ETERNAL COVID-19 Antigen Self Test	長興材料工業股份有限公司 汐止廠 ETERNAL MATERIALS CO., LTD. Xizhi Plant	抗原檢測 Antigen
69	2022/5/13	普生家用新型冠狀病毒抗原快速檢測試劑 GB COVID-19 Ag Home Test	普生股份有限公司 GENERAL BIOLOGICALS CORPORATION.	抗原檢測 Antigen
70	2022/5/20	艾卡爾新冠病毒家用核酸檢測套組(鼻腔) iCareDx SARS-CoV-2 At-Home Nucleic Acid Test Kit (Nasal)  艾卡爾新冠病毒家用核酸品管	富佳生技股份有限公司 iCare Diagnostics International Co. Ltd.	核酸檢測 Nucleic acid

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		物質套組 iCareDx SARS-CoV-2 At-Home Nucleic Acid Quality Control Kit  艾卡爾核酸檢測分析儀 iCareDx Real-Time PCR Analyzer		
71	2022/5/25	飛確 新型冠狀病毒S-RBD抗體快速檢驗試劑 Vstrip COVID-19 S-RBD Antibody Rapid Test<	寶齡富錦生技股份有限公司 汐止廠 Panion & BF Biotech Inc. Xizhi Factory	抗體檢測 Antibody
72	2022/6/13 2022/8/15	艾諾斯家用新冠病毒 COVID-19 抗原快速檢測試劑 Ainos SARS-CoV-2 Antigen Rapid Self Test	台灣奈米碳素股份有限公司 Taiwan Carbon Nano Technology Corporation	抗原檢測 Antigen
73	2022/6/13	嘉瑞COVID-19抗原家用檢測試劑 Swiscare COVID-19 Antigen Self-Testing Kit	瑞智生化科技股份有限公司 Swiscare Technology Co., Ltd	抗原檢測 Antigen
74	2022/8/2	福又達新冠肺炎IgG抗體檢測試劑組 SBC COVID-19 IgG ELISA Kit	福又達生物科技股份有限公司委託精專生醫股份有限公司製造 Manufactured by ACCUBIO MED CO., LTD. for SCHWEITZER BIOTECH COMPANY LTD.	抗體檢測 Antibody
75	2022/8/16	泉沂醫學新冠病毒核酸檢測試劑組	泉沂醫學科技股份有限公司 GeneOne Diagnostics Corp	核酸檢測 Nucleic



序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		GENEONE COVID-19 Nucleic Acid Diagnostic Kit	oration	acid
76	2022/9/28	安必測新冠肺炎抗原家用快篩套組 PixoTest COVID-19 Antigen Self Test Kit	安盛生科股份有限公司內湖廠 iXensor Co., LTD. Neihu Factory	抗原檢測 Antigen
77	2022/10/4	長興新型冠狀病毒SRBD抗體快速檢測試劑 ETERNAL SARS-CoV-2 SRBD Antibody Rapid Test	長興材料工業股份有限公司 汐止廠 ETERNAL MATERIALS CO., LTD. Xizhi Plant.	抗體檢測 Antibody

## 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	製造商名稱 Manufacturer	檢驗類型 Target
1	2020/3/30	SARS-COV-2 Antibody Test COVID-19 IgG/IgM Rapid Test	廣州萬孚生物技術有限公司 Guangzhou Wondffo Biotech Co., Ltd	抗體檢測 Antibody
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 RealTime SARS-CoV-2 Control Kit	Abbott Molecular Inc.	核酸檢測 Nucleic acid

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
4	2020/4/24	2019-nCoV Ab TEST CASSET EE	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) cobas® SARS-CoV-2 (P/N:09175431190) cobas® SARS-CoV-2 Control Kit (P/N:09175440190)"	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
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
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 TaqPath COVID-19 Combo Kit, 1000 reaction	Life Technologies Corporation	核酸檢測 Nucleic acid
10	2020/5/14	BioFire COVID-19 Test Kit BioFire COVID-19 Test Kit BioFire COVID-19 Test External Control Kit(+)	Biofire Defense, LLC	核酸檢測 Nucleic acid

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
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 SARS-Cov-2 IgG Calibrator Kit SARS-Cov-2 IgG Control Kit	Abbott Laboratories Diagnostics Division	抗體檢測 Antibody
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 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 L	Hologic, Inc.	核酸檢測 Nucleic acid

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		ysis Tubes Panther Fusion Module Panther Fusion Open Access Pack Panther Fusion Tube Trays		
16	2020/6/8	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) ADVIA Centaur SARS-CoV-2 Total Quality Control (COV2T QC)	Siemens Healthcare Diagnostics Inc.	抗體檢測 Antibody
20	2020/7/8	Alinity m SARS-CoV-2 AMP Kit 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	Abbott Molecular Inc.	核酸檢測 Nucleic acid

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
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 Access SARS-CoV-2 IgG calibrator Access SARS-CoV-2 IgG QC	Beckman Coulter, Inc.	抗體檢測 Antibody
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 PreciControl Anti-SARS-CoV-2	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 cobas SARS-CoV-2 & Influenza A/B Quality Control Kit (P/N:09211128190)	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
28	2020/11/9	Panbio COVID-19 Ag Rapid Test Device (Nasopharyngeal)	Abbott Rapid Diagnostics Jenena GmbH	抗原檢測 Antigen

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
29	2020/11/13	cobas® SARS-CoV-2 & Influenza A/B (P/N: 09233474190) Influenza A/B Quality Control Kit (P/N:09233482190)	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
30-1	2020/11/24	APTIMA SARS-CoV2 Assay 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	Hologic, Inc.	核酸檢測 Nucleic acid
30-2	2021/7/1	Direct Load Tube Collection Kit	Hologic, Inc.	核酸檢測 Nucleic acid
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 Elecsys Anti-SARS-CoV-2 S CalSet Anti-SARS-CoV-2 S	Roche Diagnostics GmbH	抗體檢測 Antibody

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		PreciControl Anti-SARS-CoV-2 S		
33	2020/12/28	NeuMoDx Lysis Buffer 2 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	Neumodx Molecular, Inc.	核酸檢測 Nucleic acid
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 Alinity m SARS CoV2 CTRL KIT	Abbot Molecular Inc.	核酸檢測 Nucleic acid
36	2021/1/7	cobas SARS-CoV-2 cobas SARS-CoV-2 Control Kit	Roche Molecular Systems, Inc.	核酸檢測 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

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
38	2021/1/28	TaqPath COVID-19 RT-PCR Kit Advanced TaqPath RT-PCR COVID-19 Kit TaqPath COVID-19 Control TaqPath COVID-19 Control Dilution Buffer	Life Technologies Corporation	核酸檢測 Nucleic acid
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 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	Beckman Coulter, Inc.	抗體檢測 Antibody
41	2021/2/9	cobas SARS-CoV-2試劑 cobas SARS-CoV-2 Control Kit	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
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) AdviseDx SARS-CoV-2 IgG II Calibrator Kit (for Alinity) AdviseDx SARS-CoV-2 IgG II	Abbott Ireland Diagnostics Division	抗體檢測 Antibody



序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		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)		
44	2021/4/21	Alinity m Resp-4-Plex AMP Kit Alinity m Resp-4-Plex CTRL Kit	Abbott Molecular Inc.	核酸檢測 Nucleic acid
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 Mod ule? QIAstat-Dx Analytical Modul e QIAstat-Dx Respiratory SAR S-CoV-2 Panel	QIAGEN Gmbh	核酸檢測 Nucleic acid
47	2021/5/10	Panbio COVID-19 Ag Rapid T est Device (NASAL)	Abbott Rapid Diagnostics J ena Gmbh	抗原檢測 Antigen
48	2021/5/17	cPass SARS-CoV-2 Neutraliz ation Antibody Detection Ki t	Genscript USA,Inc.	抗體檢測 Antibod y
49	2021/5/25	BD Veritor System for Rapid Detection of SARS-Cov-2	Becton, Dickinson And Co mpany	抗原檢測 Antigen

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
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
53-1	2021/5/25	TaqPath RT-PCR COVID-19 Kit, 1,000 reactions TaqPath COVID-19 Control TaqPath COVID-19 Control Dilution Buffer	Life Technologies Corporation	核酸檢測 Nucleic acid
53-2	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 Alinity m SARS CoV2 CTRL KIT	Abbott Molecular Inc.	核酸檢測 Nucleic acid
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

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
57	2021/5/26	cobas SARS-CoV-2 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	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
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) ADVIA Centaur SARS-CoV-2 Total (COV2T) ADVIA Centaur SARS-CoV-2 Total Quality Control (COV2T QC)	Siemens Healthcare Diagnostics Inc.	抗體檢測 Antibody
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 ACCESS SARS-CoV-2 IgM QC ACCESS SARS-CoV-2 IgM Calibrator ACCESS SARS-CoV-2 IgG ACCESS SARS-CoV-2 IgG Calibrator	Beckman Coulter Inc.	抗體檢測 Antibody

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		ACCESS SARS-CoV-2 IgG QC ACCESS SARS-CoV-2 IgG II ACCESS SARS-CoV-2 IgG II C alibrator ACCESS SARS-CoV-2 IgG II Q C		
63	2021/6/11	APTIMA SARS-CoV-2 Assay Kit APTIMA SARS-CoV-2 Control Hologic Specimen Lysis Tubes Hologic Specimen Lysis Tubes	Hologic Inc.	抗原檢測 Antigen
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, Inc	抗原檢測 Antigen
68	2021/6/18	STANDARD Q COVID-19 Ag STANDARD F COVID-19 Ag FI A	Sd Biosensor, Inc.	抗原檢測 Antigen

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
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	核酸檢測 Nucleic acid
71	2021/6/21	SARS-CoV-2 IgG Kit SARS-CoV-2 IgG Calibrator Kit SARS-CoV-2 IgG Control Kit	Abbott Laboratories	抗體檢測 Antibody
72	2021/6/22	QuickVue AT-Home OTC COVID-19 Test QuickVue AT-Home OTC COVID-19 Test QuickVue AT-Home OTC COVID-19 Test	Quidel Corporation	抗原檢測 Antigen
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) 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)	Abbott Ireland Diagnostics Division	抗體檢測 Antibody

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		AdviseDx SARS-CoV-2 IgG II Control Kit(for Architect)		
75	2021/6/22	INNOSCREEN covid-19 Antigen Rapid Test Device	INNOVATION SCIENTIFIC P TY LTD	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	EURORealTime 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 Module 1/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

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
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 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	Abbott Ireland Diagnostics Division	抗體檢測 Antibody
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) ADVIA Centaur SARS-CoV-2 IgG Quality Control (sCOVG QC)	Siemens Healthcare Diagnostics Inc.	抗體檢測 Antibody
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

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
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88	2021/7/8	Panbio COVID-19 Antigen S ELF-TEST	Abbott Rapid Diagnostics J ena Gmbh	抗原檢測 Antigen
89	2021/7/8	INNOSCREEN COVID-19 IgG/ IgM Rapid Test Device	Innovation Scientific Pty Lt d	抗體檢測 Antibod y
90	2021/7/8 ~2022/8/22	QuickVue SARS Antigen Test	Quidel Corporation	抗原檢測 Antigen
91	2021/7/8	COVID-19 IgG/IgM Rapid Tes t Cassette	Hangzhou Clongene Biotec h Co., Ltd.	抗體檢測 Antibod y
92	2021/7/13	STANDARD Q COVID-19 Ag H ome Test	SD Biosensor Inc.	抗原檢測 Antigen
93	2021/7/14	SARS-CoV-2 IgM Reagent for Alinity SARS-CoV-2 IgM Calibrator f or Alinity SARS-CoV-2 IgM Control for Alinity SARS-CoV-2 IgM Reagent for ARCHITECT SARS-CoV-2 IgM Calibrator f or ARCHITECT SARS-CoV-2 IgM Control for ARCHITECT	Abbot Ireland Diagnostics Division	抗體檢測 Antibod y
94	2021/7/14	SARS-CoV-2 IgG reagent kit for Alinity SARS-CoV-2 IgG Calibrator k	Abbott Ireland Diagnostics Division	抗體檢測 Antibod y



序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		it for Alinity SARS-CoV-2 IgG Control kit f or Alinity SARS-CoV-2 IgG reagent kit for Architect SARS-CoV-2 IgG Calibrator k it for Architect SARS-CoV-2 IgG Control kit f or Architect		
95	2021/7/14	Biocredit COVID-19 Ag	RapiGEN Inc	抗原檢測 Antigen
96	2021/7/19	Humasis COVID-19 Ag Hom e test	Humasis Co., Ltd.	抗原檢測 Antigen
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 Ho me 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 Antibod y
102	2021/7/28	BioPlex 2200 SARS-CoV IgG Reagent	BIO-RAD LABORATORIES I NC.	抗體檢測 Antibod

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		BioPlex 2200 SARS-CoV IgG Calibrator Set BioPlex 2200 SARS-CoV IgG Control Set		y
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 SARS-CoV-2 IgG II Calibrator for ARCHITECT 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	Abbott Ireland Diagnostics Division	抗體檢測 Antibody
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

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
		STANDARD F COVID-19 IgM/IgG Combo FIA		y
109	2021/8/5	Celltrion DiaTrust COVID-19 Ag Home Test	Humasis Co., Ltd.	抗原檢測 Antigen
110	2021/8/9	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 Kit	Humasis Co., Ltd.	抗原檢測 Antigen
112	2021/8/30	BIOCREDIT COVID-19 Ag Home Test Nasal	RapiGEN INC	抗原檢測 Antigen
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

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
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 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	Life Technologies Corporation	核酸檢測 Nucleic acid
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	2020/10/25	cPASSTM 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	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

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
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) 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)	Roche Diagnostics GmbH	抗原檢測 Antigen
130	2021/12/06	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrators VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls	Ortho Clinical Diagnostics	抗體檢測 Antibody
131	2021/12/30	Alinity m SARS-CoV-2 AMP kit Alinity m SARS-CoV-2 CTRL kit	Abbot Molecular Inc.	核酸檢測 Nucleic acid
132	2022/2/09	Xpert Xpress SARS-CoV-2	Cepheid Inc.	核酸檢測 Nucleic

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
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133	2022/2/15	GenBody COVID-19 Ag Home Test	GENBODY INC.	抗原檢測 Antigen
134	2022/3/4	Humasis COVID-19 Ag Test	Humasis Co., Ltd.	抗原檢測 Antigen
135	2022/3/28	BioCode CoV-2 Flu Plus assay	Applied Biocode, Inc.	核酸檢測 Nucleic acid
136	2022/3/28	Aptima SARS-CoV-2 Assay Kit	Hologic, Inc.	核酸檢測 Nucleic acid
137	2022/4/18	Virokey SARS CoV-2 RT PCR Test v2.0	Vela Operations Singapore Pte Ltd	核酸檢測 Nucleic acid
138	2022/4/19	Allplex 2019-nCoV Assay	Seegene Inc.	核酸檢測 Nucleic acid
139	2022/4/21	GenBody COVID-19 Ag Home Test	GENBODY INC.	抗原檢測 Antigen
140	2022/4/28	GenBody COVID-19 Ag	GenBody Inc.	抗原檢測 Antigen
141	2022/4/29	Gmate COVID-19 Ag Saliva	Philosys Co., Ltd	抗原檢測 Antigen
142	2022/5/3	BD kit for rapid detection of SARS-CoV-2	BD Rapid Diagnostics (Suzhou) Co., Ltd.	抗原檢測 Antigen

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143	2022/5/6	Humasis COVID-19 Ag Test	Humasis Co., Ltd.	抗原檢測 Antigen
144	2022/5/9	BIOCREDIT COVID-19 Ag Home Test Nasal	RapiGEN INC.	抗原檢測 Antigen
145	2022/5/10	Flowflex COVID-19 Antigen Home Test	ACON Laboratories, Inc.	抗原檢測 Antigen
146	2022/5/10	Humasis COVID-19 Ag Home Test	Humasis Co., Ltd.	抗原檢測 Antigen
147	2022/5/12	Panbio COVID-19 Ag Rapid Test Device (NASAL)	Abbott Rapid Diagnostics Jena GmbH	抗原檢測 Antigen
148	2022/5/13	InnoScreen COVID-19 Antigen Rapid Test Device (Self-Test)	INNOVATION SCIENTIFIC P TY LTD	抗原檢測 Antigen
149	2022/5/13	Indicaid covid-19 rapid antigen at-home test	Phase Scientific International Limited	抗原檢測 Antigen
150	2022/5/13	Panbio COVID-19 Ag Rapid Test Device(Nasopharyngeal)	Abbott Rapid Diagnostics Jena GmbH	抗原檢測 Antigen
151	2022/5/16	Xpert Xpress SARS-CoV-2	CEPHEID	核酸檢測 Nucleic acid
152	2022/5/20	Humasis COVID-19 Ag Home test	Humasis Co.,Ltd	抗原檢測 Antigen
153	2022/5/20	STANDARD Q COVID-19 Ag Home Test	SD BIOSENSOR, INC.	抗原檢測 Antigen

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154	2022/5/20	STANDARD Q COVID-19 Ag Home Test	SD Biosensor, Inc.	抗原檢測 Antigen
155	2022/5/20	InnoScreen COVID-19 Antigen Rapid Test Device	Innovation Scientific Pty Ltd	抗原檢測 Antigen
156	2022/5/20	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	SolGent Co., Ltd	核酸檢測 Nucleic acid
157	2022/5/23	PCL SELF TEST-COVID19 Ag	PCL, Inc	抗原檢測 Antigen
158	2022/5/23	INDICAID COVID-19 Rapid Antigen At-home test	PHASE Scientific International Ltd.	抗原檢測 Antigen
159	2022/5/25	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	SolGent Co., Ltd.	核酸檢測 Nucleic acid
160	2022/6/6	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Reagent Pack VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Controls	Ortho-Clinical Diagnostics, Inc.	抗體檢測 Antibody
161	2022/6/6	PCL SELF TEST-COVID19 Ag	PCL, Inc.	抗原檢測 Antigen



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162	2022/6/8	VERI-Q COVID-19 Ag Rapid Test	MiCo BioMed Co., Ltd	抗原檢測 Antigen
163	2022/6/10	Rapid Response™ COVID-19 Antigen Rapid Test Cassette - At Home	BTNX, INC.	抗原檢測 9Antigen
164	2022/6/10	NeuMoDx Lysis Buffer 2 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	NeuMoDx Molecular, Inc.	核酸檢測 Nucleic acid
165	2022/6/10	BIOCREDIT COVID-19 Ag Home Test Nasal	RapiGEN, Inc.	抗原檢測 Antigen
166	2022/8/9	PCL SELF TEST COVID19 Ag	PCL Inc.	抗原檢測 Antigen
167	2022/8/11	TaqPath COVID-19 RNase P Kit 2.0 TaqPath COVID-19 Plus Con	Life Technologies Corporation Microgenics Corporation	核酸檢測 Nucleic acid

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		trol TaqPath COVID-19 Control Dilution Buffer	Life Technologies Corporat ion	
168	2022/8/17	TaqPath COVID-19 Module 1/MS2 Phage Control、Taq Path COVID-19 Module2 Ass ay Kit COVID-19 Control COVID-19 Module 2 Control Dilution Buffer	Life Technologies Corporat ion Microgenics Corporation Life Technologies Corporat ion	核酸檢測 Nucleic acid
169	2022/8/18	obas SARS-CoV-2 Duo cobas SARS-CoV-2 Duo Cont rol Kit	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
170	2022/8/18	Xpert Xpress CoV-2 plus	Cepheid	核酸檢測 Nucleic acid
171	2022/8/18	cobas SARS-CoV-2 cobas SARS-CoV-2 Control Kit	Roche Molecular Systems, Inc.	核酸檢測 Nucleic acid
172	2022/8/19	TaqPath RT-PCR COVID-19 K it TaqPath RT-PCR COVID-19 C ontrol TaqPath RT-PCR COVID-19 C ontrol Dilution Buffer	Life Technologies Corporat ion Microgenics Corporation Life Technologies Corporat ion	核酸檢測 Nucleic acid
173	2022/8/19	PCL SELF TEST-COVID19 Ag	PCL,Inc.	抗原檢測 Antigen

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
174	2022/8/19	PCL SELF TEST COVID19 Ag	PCL,Inc.	抗原檢測 Antigen
175	2022/8/23	PCL SELF TEST COVID19 Ag	PCL,Inc.	抗原檢測 Antigen
176	2022/8/24	ID NOW COVID-19 2.0	Abbott Diagnostics Scarborough, Inc.	核酸檢測 Nucleic acid
177	2022/8/30	PCL SELF TEST COVID19 Ag	PCL,Inc.	抗原檢測 Antigen
178	2022/9/13	BioFire Respiratory Panel 2.1 (RP2.1)	BioFire Diagnostic, LLC	核酸檢測 Nucleic acid
179	2022/9/16	Xpert Xpress SARS-CoV-2 /Flu/RSV plus	Cepheid	核酸檢測 Nucleic acid
180	2022/10/5	STANDARD M10 SARS-CoV-2 STANDARD M10	SD Biosensor, Inc.	核酸檢測 Nucleic acid

發布日期：110-10-22

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