# 台灣 COVID-19 檢測試劑、藥品及疫苗發展概況與特色

台灣生技醫療產業發展成熟，擁有優質醫療體系，包含 19 家醫學中心、124 家臨床試驗醫院，在檢測我商、醫院及實驗室的共同合作開發下，本次因應疫情有多達 28 家投入檢測試劑，包含快篩與核酸檢測。此外，台灣藥品製造品質優異，完全符合國際 PIC/S GMP 要求，已有 2 家我商有能力合成瑞德西韋、3 家我商投入疫苗開發。

**一、檢測試劑-核酸檢測**

台灣快篩研發單位及廠商能量充足，其中 PCR 核酸檢測多數我商獲歐盟 CE 認證，**普生**核酸檢測取得多國認證，包含歐洲 CE、台 TFDA、印度 CDSCO 及澳洲 ARTG，除產品可辨認 2-3 個基因，具準確性外，目前產能可達 80 萬劑，價格亦具競爭力，目前已銷售到東南亞(印度、印尼、馬)、中東(沙、伊)、非洲、歐美、墨西哥等多國；7 月 1 日亦宣布獲中研院快篩授權。**金萬林**核酸檢測與美 PacGenomics 實驗室合作，其使用金萬林核酸檢測實驗驗證，取得 EUA NOTIFICATION，目前多銷售美國，價格具競爭性。**基亞**擁有完整檢測產品線，包含試劑和儀器，並為少數具核酸檢測和快篩雙產品、獲得 CE、FDA 雙認證的我商，產品具高標準靈敏及準確度。其集團內的**高端疫苗**除與美 NIH 合作開發疫苗外，亦開發核酸檢測試劑，可偵測雙基因、準確率高。

**二、檢測試劑-快篩試劑**

快篩方面，**聯合生物** 2 月就開發出具美 EUA 認證的抗體快篩(ELISA)具 100%準確率，能有效偵測感染約 10 天產生抗體的病患，產能 2 周內可達 50 萬組。目前已銷售至美國科羅拉多、紐約、紐澤西、加州等地。**柏勝生技**已在丹麥與義大利執行多個臨床驗證、收集超過 122 例檢體。臨床驗證數據與(ELISA)檢測相符、與 PCR 一致性超過 9 成，高度準確。該技術僅需一滴血液檢體(10 ul)，12 分鐘可得結果，已取得 CE 認證，並向義大利、丹麥與沙烏地阿拉伯等地出貨。

**三、檢測試劑-研究單位技轉開發**

除廠商外，我研究單位也積極開發快篩及檢測儀器，**中研院** 19 天內及即合成研發快篩的抗體材料，目前抗原快篩技轉給**瑩芳、泰博、寶齡富錦、台塑、東耀、普生**。抗體快篩技轉給**洹藝、台塑生醫、普生**。除佈局國內更與國外接洽合作，歐洲經貿辦事處 3 月 18 日即宣布歐盟與中研院將共同研發快篩和疫苗。**國**

**衛院與國防醫學院**共同開發的抗原快篩已技轉給**台灣尖端先進、台灣奈米碳素、安特羅、鼎群、冷泉港生技**。

**四、檢測儀器**

**工研院**開發「疫開罐」-手持式核酸分子快篩系統，體積僅一般易開罐大小、重量 600 克，與一般核酸檢測儀約 32 公斤，相差了 57 倍。篩檢時間由一般 4 小時縮短到 1 小時，獲第 15 屆國家新創獎肯定。**大江基因**之自動化新冠病毒檢疫設備能 24 小時運作，每日可檢測近 900 個檢體，提升檢疫能量與速度。**瑞基海洋**除核酸檢測試劑第三季可達百萬劑外，亦有核酸萃取及核酸檢測雙功能儀器，於 85 分鐘內完成萃取及檢測雙功能，不需要兩台儀器先後作用，檢測試劑和儀器都已通過美 EUA notified、歐 CE-IVD 及台 TFDA，自動化儀器在檢測需求量大的情況下，具國際競爭性。

**五、藥品與疫苗**

台灣研究單位早就儲備醫藥開發能量，**國衛院及中研院** 2 月即完成瑞德西韋公克級高純度合成，**生技中心** 3 月合成法維拉韋。廠商則有**台耀化學及中化生**具備合成瑞德西韋公克級的能力，其中**台耀化學** 4 月合成 168 克，若因疫情需求且獲得美國原廠 Gilead 專利授權，即可開發生產。疫苗方面，基亞集團內的**高端**與美國 NIH 合作開發疫苗已進入動物及毒理測試。**國光**亦有特殊進展，其負責早期研發及疫苗量產，子公司安特羅 7 月 1 日發布與國衛院共同開發 DNA 疫苗，已完成動物試驗，結果發現可誘發專一性抗體、中和病毒，促進免疫反應。

## Taiwan's Developments in COVID-19 Test Kits, Drugs and Vaccines

Taiwan has developed a mature biomedical industry and a high-quality healthcare system, including 19 medical centers and 124 clinical trial hospitals, of which 28 are engaged in the joint development of reagents, including those for rapid screening and nuclear acid tests for COVID-19. Moreover, Taiwan's pharmaceutical industry is of excellent quality and fully complies with international PIC/S GMP requirements. At present, two Taiwanese companies are capable of synthesizing remdesivir and three have invested into developing vaccines to combat COVID-19.

### 1. RT-PCR (reverse transcription polymerase chain reaction) kit

Taiwan's R&D facilities and manufacturers have sufficient capacity to develop rapid test reagents. Most of these facilities and manufacturers involved in producing PCR nucleic acid tests have obtained the EU CE marking. Among them, General Biologicals Corporation (GBC) has obtained a number of international certification (including the European CE marking, Taiwan FDA, Indian CDSCO and Australian ARTG) for its PCR kits, which can accurately identify 2 to 3 genes. Currently it has a monthly production capacity of 800,000 kits, and exports its competitively-priced products to Southeast Asia (India, Indonesia and Malaysia), the Middle East (Saudi Arabia and Iraq), Africa, Europe, the US, Mexico and other countries. GBC also announced on July 1 that it received authorization from Academia Sinica for the technology transfer of a rapid immune-based test.

Kim Forest Enterprise Co., Ltd., (KF) worked with US-based PacGenomics Laboratory to use Kim Forest's PCR kits for experimental verification, which obtained the emergency use authorization (EUA) notification from the US Food and Drug Administration (FDA). The KF test kits are currently sold in the United States at a competitive price. Having gained both CE marking and FDA certificate, Medigen Biotechnology Corp. (MBC), one of the few Taiwanese firms whose PCR kits and rapid screening tests have both received double certification from CE and FDA. MBC has a complete line of test products, including reagents and instruments with high-standard sensitivity and accuracy. Medigen Vaccine Biologics Corp. (MVC), a subsidiary of the MBC group, has joined hands with the US National Institutes of Health (NIH) to develop vaccines. It also has developed high quality PCR kits that can detect double genes with high accuracy.

### 2. Rapid screening tests

In terms of rapid screening test kits, United BioPharma (UBP) developed an antibody rapid test kit (ELISA) with 100% accuracy as early as February. The kit has been certified under the US EUA and can effectively detect the antibodies of patients who have been infected for about 10 days. With a production capacity of 500,000 sets over 2 weeks, UBP has sold the ELISA test kit to Colorado, New York, New Jersey, and California. BluSense Diagnostics (BSD) has performed multiple clinical verifications and collected more than 122 specimens in Denmark and Italy. The clinical verification data have been consistent with the ELISA test and have consistency of over 90% with PCR tests, indicating its high level of accuracy. The test requires only a drop of blood sample (10 ul), and the test result is obtained in 12 minutes. BSD has obtained CE marking and has shipped the kits to Italy, Denmark and Saudi Arabia.

### 3. Rapid tests – technology transfers with research facilities

In addition to manufacturers, our R&D facilities in Taiwan have also been actively developing rapid screening test and instruments. This March, Academia Sinica synthesized

and developed antibody materials for the rapid test in just 19 days! It has since transferred the antigen rapid test technology to **Infung, TaiDoc, Panion & BF Biotech, Formosa Biomedical, Tonyar Biotech, and GBC** for mass production and the antibody rapid test technology to **Agnitio Science and Technology, Formosa Biomedical, and GBC**. In addition to domestic collaboration, Academia Sinica has also partnered foreign countries. The European Economic and Trade Office announced on March 18 that the EU and Academia Sinica will jointly develop a rapid screening test and vaccine. Additionally, the antigen rapid screening test jointly developed by the **National Health Research Institutes (NHRI)** and the **National Defense Medical Center** has been transferred to **Taiwan Advance Bio-Pharmaceutical Incorporation**, **Taiwan Carbon Nano Technology Corporation**, **Enimmune Corporation**, **Trison Tech Corp.**, and **Cold Spring Biotech**.

## 4. PCR Instruments

The **Industrial Technology Research Institute (ITRI)** has developed a "portable intelligent rapid molecular diagnostic system", the size of a drink can. Weighing only 600 grams, this handheld detector is only one-57th of the weight of an ordinary nucleic acid instrument, which is around 32 kg. Its portable size and short test time, of one hour compared to the usual 4 hours, won award at the 15$^{th}$ National Innovation Award.

Additionally, **TCI GENE Inc.**'s automated coronavirus detector operates around the clock to detect close to 900 specimens per day. Meanwhile, **GeneReach Biotechnology Corp**. is not only capable of producing up to one million PCR kits in the third quarter this year, it has also invented an instrument that can extract and test the nucleic acid at the same time, all within 85 minutes. The instrument makes a breakthrough in overcoming the need for two instruments to process the specimen in succession. Both the reagents and instruments of GeneReach areUS EUA notified, and are approved by the European CE-IVD and the Taiwan FDA. As overseas demand for such devices increases, their automated detectors will be highly competitive globally.

## 5. Drugs and vaccines

Research facilities in Taiwan have long built up capabilities in new drug development. The NHRI and **Academia Sinica** completed the synthesis of 100-mg high-purity remdesivir in February 2020, while the **Development Center for Biotechnology** synthesized Favipiravir in March 2020. In terms of manufacturers, both **Formosa Laboratories, Inc. (FLI)** and **Chunghwa Chemical Synthesis & Biotech Co., Ltd.** are capable of synthesizing 100-mg remdesivir. Among them, **FLI** synthesized 168 grams in April 2020, and is ready for further development and production pending demands and licensing from the patent owner, US-based Gilead Sciences.

In terms of vaccines, **MVC**, a subsidiary of the MBC group, has joined hands with the US' National Institute of Health (NIH) to develop vaccines, which has currently entered the animal and toxicology testing stage. Meanwhile, **Adimmune Corporation**, a company that does early stage vaccine R&D and mass production has also made special progress. Its subsidiary, Enimmune Corporation, announced on July 1 that the DNA vaccine it developed with NHRI has completed animal testing which showed that the vaccine can induce specific antibodies to neutralize the virus and help with the immune response.