






2020年4月27日 COVID-19快篩檢測發表會 [TAIWAN BIOTECH SOLUTION (PARTNERING) FOR COVID-19-TESTING KITS & RAPID TEST]

	Company name	Product name	Product features/Development status	Target would like to Invite	Predict when can get FDA、CE、TFDA certificate	Estimated time of delivery Sample or product.
1	AEP Alliance (Taiwan) (EirGenix, Inc. is one of the testing kits members, other two companies will announce next week) <a href="http://www.eirgenix.com/index.aspx">http://www.eirgenix.com/index.aspx</a>	  *COVID-19 Antigen Rapid Test (Vstrip)	*Rapid test COVID-19 antigen	*Government relative health care *Hospital *Testing facility (laboratory) *Agent & distributors	*TFDA submission by middle of April *EUA submission by end of April in USA	*May/June of 2020
2	General Biologicals Corporation (GBC) <a href="https://www.gbc.com.tw/">https://www.gbc.com.tw/</a>	  *GB SARS-CoV-2 Real-Time RT-PCR - 4PC0002E (3 target genes) *GB SARS-CoV-2 Real-Time RT-PCR - 4PC0042E (2 target genes) *GB Extraction Kit *GB COVID-19 IgG / IgM Rapid Test	* GB SARS-CoV-2 Real-Time RT-PCR - 4PC0002E (3 target genes) * GB SARS-CoV-2 Real-Time RT-PCR - 4PC0042E (2 target genes) > 36+ years Class III IVD GMP / ISO13485 with high production capability > Already used at clinicals in several countries > High Accuracy and easy to use (including Internal Control)  * GB Extraction kit > Available based on the requests  * GB COVID-19 IgG / IgM Rapid Test > Fast and easy to use (15 ~ 20 mins) > Reliable and proven working raw materials > No cross contamination (one-time use)	* Hospitals * Labs * Government agency * Distributors	*GB SARS-CoV-2 Real-Time RT-PCR > CE estimated the end of April > TFDA estimated in May  * GB Extraction > CE (self-declaration)  * GB COVID-19 IgG / IgM Rapid Test > CE (May) > US EUA (end of April/May) > TFDA (end of May/June)	*Available now by requests
3	Kimforest Enterprise Co.Ltd <a href="https://www.kimforest.com/">https://www.kimforest.com/</a>	  *P/N: KP2019CoV01 SARS-CoV-2 Detection kit V1 *P/N: KP2019CoV02 SARS-CoV-2 Detection kit V2	*P/N: KP2019CoV01 SARS-CoV-2 Detection kit V1 >target gene: RdRP gene 96 reactions/kit  *P/N: KP2019CoV02 SARS-CoV-2 Detection kit V2 >target gene: RdRP gene, N gene 96 reactions/kit	*Company *Hospital *Laboratory *Research institute	TFDA EUA: 45 days US EUA: 2 months	*2 weeks
4	Leadgene Biomedical, Inc <a href="http://www.leadgenebio.com/web/index/index.jsp?lang=en">http://www.leadgenebio.com/web/index/index.jsp?lang=en</a>	  *Leadgene® SARS/SARS-CoV-2 Antigen Rapid Test  *Leadgene® SARS-CoV-2 Antibody Rapid Test  *COVID-19 related antigens and antibodies ( <a href="http://www.leadgenebio.com/web/product/product.jsp?dm_no=DM1584426383145&amp;subdm_no=DM158442633749&amp;lang=en">http://www.leadgenebio.com/web/product/product.jsp?dm_no=DM1584426383145&amp;subdm_no=DM158442633749&amp;lang=en</a> ) ( <a href="http://www.leadgenebio.com/web/product/product.jsp?dm_no=DM1584426383145&amp;subdm_no=DM1584426322125&amp;lang=en">http://www.leadgenebio.com/web/product/product.jsp?dm_no=DM1584426383145&amp;subdm_no=DM1584426322125&amp;lang=en</a> )	*Leadgene® SARS/SARS-CoV-2 Antigen Rapid Test: RUO. Undergoing and looking for further clinical validation cooperation.  *Leadgene® SARS-CoV-2 Antibody Rapid Test: Will have a prototype for evaluation within 0.5-1 month.  *COVID-19 related antigens and antibodies (catalog products, for academic use or IVD manufacturing raw materials)	*Hospital and Clinical laboratory for diagnostics development and validation.  *Company and Research institute for antigens and antibodies materials.	It depends on the clinical validation.	*Leadgene® SARS/SARS-CoV-2 Antigen Rapid Test: Sample products are ready. It depends on the quantities.  *Leadgene® SARS-CoV-2 Antibody Rapid Test: Will have a prototype for evaluation within 0.5-1 month.  *COVID-19 related antigens and antibodies: Products are in stock and continuously producing.

5	<p>Medigen Vaccine Biologics Corp  <a href="http://www.medigenvac.com/public/en/about_us/our_company">http://www.medigenvac.com/public/en/about_us/our_company</a></p>	<p>(Currently do not have product picture.)</p> <p>*MVC SARS-CoV-2 qPCR Kit</p>	<p>*CE /TFDA registration on-going</p>	<p>*Hospital and Clinical laboratory            *Agent &amp; Distributors            *Government            *Research institutions</p>	<p>*CE - 2020-Apr            *TFDA - 2020-May</p>	<p>*Product - once approved            *Sample - Provide upon request</p>
6	<p>Quark Biosciences, Inc  <a href="https://www.quarkbiosciences.com/en">https://www.quarkbiosciences.com/en</a></p>	 <p>*Platform : dqPCR Analysis System</p> <p>*Assay : DigiChip™ SARS-CoV-2 Assay</p>	<p>*Digital functionality of the assay can detect as low as 3 copies of the virus in a sample, which is 10x more sensitive than conventional qPCR tests available on the market.</p> <p>*The assay also features a high level of precision, specificity, and an impressive dynamic range of 8 logs.</p> <p>*Development status :            At present, a number of experiments and reagent development have been completed, and we will be initiating the testing of clinical specimens soon.</p>	<p>*We are actively looking for partners in the clinical field, such as testing labs, hospitals, medical institutions, and research institutions.</p>	<p>Currently applying for:            US FDA' s EUA            TFDA' s COVID-19 emergency project</p>	<p>*Estimated time of delivery product: June</p>