


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	<p>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></p>	 <p><b>*COVID-19 Antigen Rapid Test (Vstrip)</b></p>	<p><b>*Rapid test COVID-19 antigen</b></p>	<p><b>*Government relative health care</b> <b>*Hospital</b> <b>*Testing facility (laboratory)</b> <b>*Agent &amp; distributors</b></p>	<p><b>*TFDA submission by middle of April</b> <b>*EUA submission by end of April in USA</b></p>	<p><b>*May/June of 2020</b></p>
2	<p>General Biologicals Corporation (GBC) <a href="https://www.gbc.com.tw/">https://www.gbc.com.tw/</a></p>	 <p><b>*GB SARS-CoV-2 Real-Time RT-PCR - 4PC0002E (3 target genes)</b> <b>*GB SARS-CoV-2 Real-Time RT-PCR - 4PC0042E (2 target genes)</b> <b>*GB Extraction Kit</b> <b>*GB COVID-19 IgG / IgM Rapid Test</b></p>	<p><b>*GB SARS-CoV-2 Real-Time RT-PCR - 4PC0002E (3 target genes)</b> <b>*GB SARS-CoV-2 Real-Time RT-PCR - 4PC0042E (2 target genes)</b> &gt; 36+ years Class III IVD GMP / ISO13485 with high production capability &gt; Already used at clinicals in several countries &gt; High Accuracy and easy to use (including Internal Control)</p> <p><b>*GB Extraction kit</b> &gt; Available based on the requests</p> <p><b>*GB COVID-19 IgG / IgM Rapid Test</b> &gt; Fast and easy to use (15 ~ 20 mins) &gt; Reliable and proven working raw materials &gt; No cross contamination (one-time use)</p>	<p><b>* Hospitals</b> <b>* Labs</b> <b>* Government agency</b> <b>* Distributors</b></p>	<p><b>*GB SARS-CoV-2 Real-Time RT-PCR</b> &gt; CE estimated the end of April &gt; TFDA estimated in May</p> <p><b>*GB Extraction</b> &gt; CE (self-declaration)</p> <p><b>*GB COVID-19 IgG / IgM Rapid Test</b> &gt; CE (May) &gt; US EUA (end of April/May) &gt; TFDA (end of May/June)</p>	<p><b>*Available now by requests</b></p>
3	<p>Kimforest Enterprise Co.Ltd <a href="https://www.kimforest.com/">https://www.kimforest.com/</a></p>	 <p><b>*P/N: KP2019CoV01</b> <b>SARS-CoV-2 Detection kit V1</b> <b>*P/N: KP2019CoV02</b> <b>SARS-CoV-2 Detection kit V2</b></p>	<p><b>*P/N: KP2019CoV01</b> <b>SARS-CoV-2 Detection kit V1</b> &gt;target gene: RdRP gene 96 reactions/kit</p> <p><b>*P/N: KP2019CoV02</b> <b>SARS-CoV-2 Detection kit V2</b> &gt;target gene: RdRP gene, N gene 96 reactions/kit</p>	<p><b>*Company</b> <b>*Hospital</b> <b>*Laboratory</b> <b>*Research institute</b></p>	<p>TFDA EUA: 45 days US EUA: 2 months</p>	<p><b>*2 weeks</b></p>
4	<p>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></p>	 <p><b>*Leadgene® SARS/SARS-CoV-2 Antigen Rapid Test</b> <b>*Leadgene® SARS-CoV-2 Antibody Rapid Test</b></p> <p><b>*COVID-19 related antigens and antibodies</b> (<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=DM158442632125&amp;lang=en">http://www.leadgenebio.com/web/product/product.jsp?dm_no=DM1584426383145&amp;subdm_no=DM158442632125&amp;lang=en</a>)</p>	<p><b>*Leadgene® SARS/SARS-CoV-2 Antigen Rapid Test: RUO. Undergoing and looking for further clinical validation cooperation.</b></p> <p><b>*Leadgene® SARS-CoV-2 Antibody Rapid Test: Will have a prototype for evaluation within 0.5-1 month.</b></p> <p><b>*COVID-19 related antigens and antibodies (catalog products, for academic use or IVD manufacturing raw materials)</b></p>	<p><b>*Hospital and Clinical laboratory for diagnostics development and validation.</b></p> <p><b>*Company and Research institute for antigens and antibodies materials.</b></p>	<p>It depends on the clinical validation.</p>	<p><b>*Leadgene® SARS/SARS-CoV-2 Antigen Rapid Test: Sample products are ready. It depends on the quantities.</b></p> <p><b>*Leadgene® SARS-CoV-2 Antibody Rapid Test: Will have a prototype for evaluation within 0.5-1 month.</b></p> <p><b>*COVID-19 related antigens and antibodies: Products are in stock and continuously producing.</b></p>

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.)  *Mvc SARS-CoV-2 qPCR Kit</p>	<p>*CE /TFDA registration on-going</p>	<p>*Hospital and Clinical laboratory  *Agent &amp; Distributors  *Government  *Research insitutions</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  *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.  *The assay also features a high level of precision, specificity, and an impressive dynamic range of 8 logs.  *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>