CLUNGENE COVID-19 IgG/IgM Rapid Test Cassette Point of Care testing

APAC Security (APAC) markets an IgM/IgG immunoassay screening device that measures the IgG and IgM response to SARS-CoV-2. The main benefit of this Device is for post disease screening, finding out whether a person:

a. Has been infected by SARS-CoV-2.
b. Has an immunological IgG/IgM-response to SARS-CoV-2

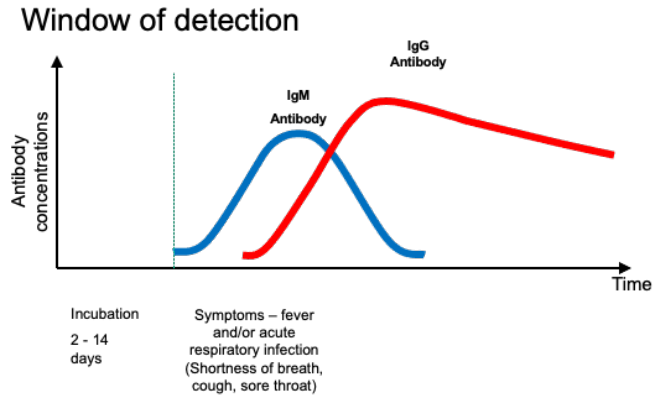
The answers to these two questions can be of significant benefit, for example aiding decisions around whether a person can return to work, travel, or socialise with other people. This can be particularly pertinent in the decision making surrounding at-risk groups, such as the immunocompromised and elderly. If used in the wider population it could also hold a role in determining the timing and extent of social-distancing measures and can help inform whether a staggered lifting of interventions can help avoid a secondary infection peak.

The test kit should not be used for diagnosis of acute COVID-19.

Background

SARS-CoV-2 is a new strain of coronavirus causing the disease COVID-19 in humans. The symptoms range from a mild respiratory infection to more severe pneumonia with acute respiratory distress.

In response to an infection, the human immune system develops antibodies as a defence mechanism. Two important antibodies are IgM and IgG, where IgM develops around the onset of symptoms and IgG weeks later (see picture 1). The concentration of the IgM antibody decreases relatively quickly, while the IgG antibody remains longer. For certain viruses, the IgG remains for life[i], while for others it depletes quicker. For SARS-CoV-19, it is unknown for how long it remains in the body but comparing it with other strains of corona viruses such as SARS-associated coronavirus, the IgG antibody it may be detectable for more than six months. [ii]



Picture 1: IgG & IgM detection window[iii]

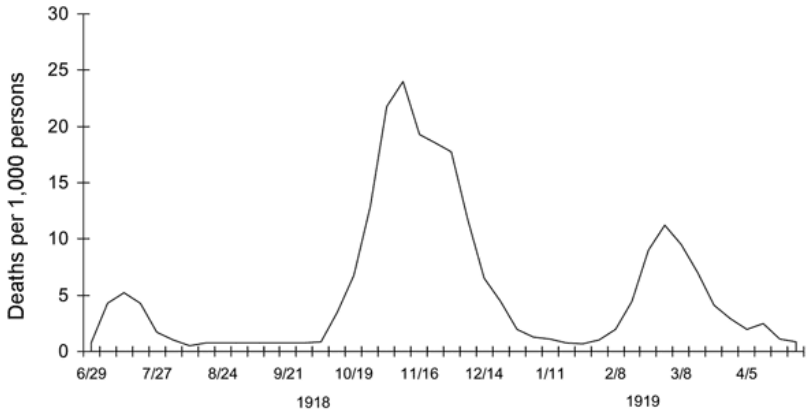
Use of APAC Security's immunoassay screening device

Due to the late and long-lasting IgG response this test kit is useful for identifying individuals that have been infected with SARS-CoV-2 and recovering from the disease COVID-19. One study has shown that our device has a sensitivity of 97.4% for detecting SARS-CoV-2 specific IgG in these patients[iv].

These findings support our view that the screening device is a helpful tool, determining whether an asymptomatic person:

a. has been infected by SARS-CoV-2.
b. has built up an IgG anti-SARS-CoV-2 immunology response.

Considering that other pandemics have arrived in waves, it may be useful determining whether a person has whole or partial anti-SARS-CoV-2 immunity in the event of a secondary peak occurring. For example, the Spanish Flu (1918-1919) came in three waves, wherein the second wave caused the most deaths (see picture 2), with 20-70 million deaths in total .[v]



Picture 2: Deaths from Spanish Flu[v]

An article in the Lancet has explained the usefulness of social distancing precautions and 'the need to carefully calibrate their lifting to avoid second and subsequent waves of a COVID-19 epidemic.[vi] Measuring the presence of an immunological IgG/IgM-response to SARS-CoV-2 in the wider population may therefore provide useful data in regard to the susceptibility and transmissibility SARS-CoV-2 in a population. This may help influence the timing and extent of social-distancing measures and can help inform whether a staggered lifting of interventions can help avoid a secondary infection peak.

Warnings and precautions

The use of this screening device for diagnosis of acute COVID-19 is not recommended. The IgM levels, despite an early onset, initially are low and may therefore be difficult to detect. A

detectable IgG level develops later in time and may therefore not be useful for the diagnosis of acute disease.

About us

APAC Security was founded in 2006 as a result of The Commonwealths decision to purchase Drug and Explosive Detection systems from Biosensor[vii] in Sweden, which are still deployed throughout Australia. A part of the team who developed the detection system, based on an immunoassay technology, moved to Australia and continued the design and development. In 2010, APAC commenced development of a urine drug screening device, also based on immunoassay chemistry – The APAC Cup, which was accredited to the Australian Standard in 2015. The APAC drug testing devices and services are today used by NSW Corrections, NSW Drug Court, ACT Corrections, ACT Drug Court, NT Corrections and various work places throughout Australia.

APACs partner in China, Hangzhou Clongene, has since 2012 assisted APAC with manufacturing the devices which we have designed. In addition to Research & Development and manufacturing, APAC has built up a Quality Assurance system, whereby our team members from our sister company, APAC China, inspects every production batch before it is shipped to Australia. We believe this is an important component to our success story in Australia.

In conjunction with the COVID-19 outbreak in China, our partner, Hangzhou Clongene has developed a point of care COVID-19 disposable screening device, also based on immunoassay technology. With one drop of blood from your fingertip, the device screens for two types of antibodies which the human immune system develops as a defence mechanism. The screening takes 15 minutes.

The Australian Department of Health decided to include the **CLUNGENE COVID-19 IgG/IgM Rapid Test Cassette Point of Care testing**, Class 3 in the Australian Register of Therapeutic Goods, ARTG as of March 26.

The common nominator – and passion - for our products are immunoassays in different shapes and forms.

References:

[i] Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.pdf

[ii] L-P Wu, N-C Want, X-Y Tian et. Al. Duration of Antibody Responses after Severe Acute Respiratory Syndrome, Emerging Infectious Diseases. DOI: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2851497/

[iii] World Health Organization https://www.who.int/immunization/monitoring_surveillance/burden/laboratory/manual_section1.7/en

[iv] Clongene clinical study report-covid-19 igg igm 20200305

[v] Vaccines Today. https://www.vaccinestoday.eu/stories/100-years-spanish-flu-world-ready-next-pandemic/

[vi] Prem K, Liu Y, Russel TW, Kucharski AJ, Eggo RM, et al. The effect of control strategies to reduce social mixing on outcomes of the COVID-19 epidemic in Wuhan, China: a modelling study. *The Lancet.* March 2020. DOI: https://doi.org/10.1016/S2468-2667(20)30073-6.

[vii] Biosensor Applications. http://www.biosensor.se/