# COVID-19 Serology Antibody Tests

**Abbott COVID-19 Antibody Serology Tests Immunoglobulin M (IgM)**

Serology Tests for Antibody Immunoglobulin M (IgM) detects IgM antibodies. It is the first antibody the body produces when it encounters a new pathogen and it is found primarily in the blood and lymph fluid. Before more long term antibodies are created, it serves as an initial line of defence against pathogens.

The presence of IgM indicates that you may have recently been infected with the virus that causes Covid-19 or that you may have developed antibodies because of a recent immunization with one of the Covid-19 vaccines. There is still a chance the antibodies point to a previous infection with another coronavirus. These other coronaviruses are responsible for the common cold.

**Abbott COVID-19 Antibody Serology Tests Immunoglobulin G (IgG)**

Serology Tests for Covid-19 Antibody Immunoglobulin G (IgG) is a blood test for detecting IgG antibodies. It is the most prevalent antibody and is present in the blood and other bodily fluids. IgG helps guard against bacterial and viral infections. After an infection or vaccination, IgG may take some time to develop.

The presence of IgG indicates that the illness either occurred anytime from several weeks to months ago or that you have produced antibodies in response to immunization with one of the Covid-19 vaccines. This test does not detect the antibodies produced by mRNA-based vaccines.

**Roche Total Antibodies (IgG and IgM) Test**

This tests for Covid-19 by identifying both IgG and IgM antibodies, which are created by the body to combat the virus. The type of IgG and IgM targeted in this test binds to a different part of the virus and is not influenced by mRNA-based vaccination, making it useful for confirming recent or prior infection.

**COVID-19 Quantitative Antibody Test (Roche Elecsys)**

This test is used to quantify antibodies in the blood stream for those who have been exposed to Covid-19 or have completed the vaccination regimen. It is also able to determine the degree of the body's immunological response. Antibodies designed against the spike protein, which is responsible for binding to cells, are targeted in this assay.

Quantitative detection of antibodies is critical in the evaluation of any Covid-19 vaccination programme globally. The quantitative Elecsys antibody test can assist physicians in monitoring patients' antibody levels.

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# Express Covid-19 PDT PCR test

**Innoquest Diagnostics** has recently launched our Express Covid-19 PDT PCR test. Expect a turnaround time of 3 hours upon a sample reaching our lab. For further information, please reach out to your designated commercial manager.

# Stand Alone Covid-19 Courier Service

**ARI/NON ARI/PDT:**

Collection Hours: 9am to 10pm (Mon - Sun, inclusive of PH)
Collection Hotline: Tel: 62356955/ WhatsApp message: 87863170 (Last call/message for collection at 9pm)
Collection will be done within 90 mins from time of call for collection. Please ensure ample time is provided for collection before clinic's closing time.

**ART+:**

Tel: 91820886 (Quote "Innoquest ART+")
*24 hours service, 7 days a week

***Please do not hesitate to contact your Commercial Manager responsible for your clinic if you wish to know more about our range of tests for COVID-19. Alternatively, you can check out our website at www.innoquest.com.sg for more information.***

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**July 2021**

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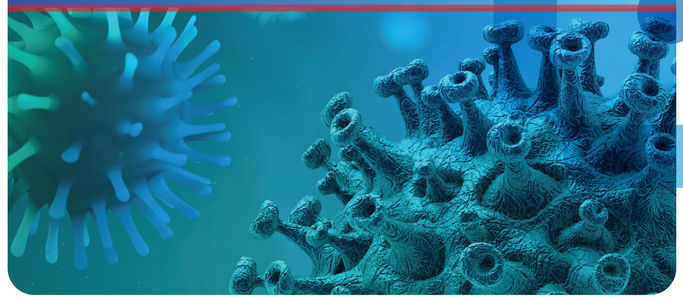
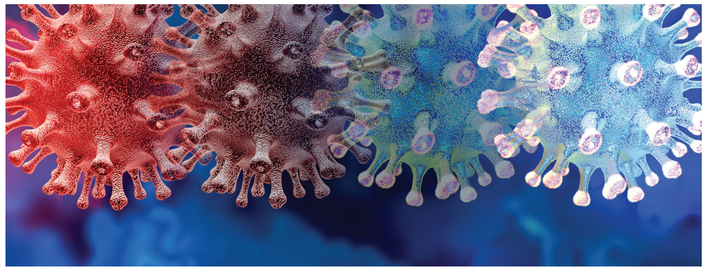
# Innoquest Diagnostics Newsletter Covid-19



In December 2019, a novel coronavirus classified as SARS-CoV-2 (colloquially referred to as Covid-19) by the World Health Organization was first detected in Wuhan, China. The highly contagious pathogen transmitted globally in a matter of months, culminating in the first pandemic since H1N1 in 2009. When Covid-19 first struck Singapore in early 2020, authorities enlisted the help of Innoquest Diagnostics to set up Covid-19 polymerase chain reaction (PCR) testing capacity to enhance the nation's detection capabilities, allowing Singapore to successfully manage a surge in Covid-19 infections. Singapore was praised globally for its management of the pandemic. Since April 2020, Innoquest Diagnostics has performed over 2.1 million PCR tests with over 6 million patient results released.

Despite stringent lockdowns and global vaccination programmes proceeding apace, Covid-19 continues to mutate, creating more infectious strains and new waves in multiple countries. Singapore has seen numerous unlinked clusters in recent weeks causing additional restrictions to be imposed under Phase 2 (Heightened Alert) to minimise further transmission of the virus.. Every resident has a role to play to ensure that Singapore stays on track in pursuit of the new normal. Innoquest Diagnostics will continue to innovate and support national testing demands in this challenging time. Together, we will emerge stronger!



# Covid 19 Variant

**As Covid-19 mutates, there are concerns about how testing and vaccination initiatives will be affected. Mutations in the spike-like S protein increase the virus' ability to connect to and infect cells. In Singapore, some recent variants of concern include:**

**Delta variant (B.1.617).** This variant was first discovered in India in October 2020. It has three noteworthy sub-variants. Existing vaccinations are less effective against it because the B.1.617.1 sub-variant has two important changes (L452R and E484Q) in the outer spike protein of the virus that connect to human cells. Some B.1.617.1 viruses contain a third mutation in the spike protein termed V382L, making it a triple mutant. In May 2021, this highly transmissible strain of Covid-19 became prevalent among Singapore's increasing number of cases.

**Alpha variant (B.1.1.7).** This variant was first discovered in the United Kingdom in September 2020. According to studies, it appears to spread more easily and may pose a higher risk of mortality. This variant has been found in numerous countries throughout the world, and it was first detected in Singapore in December 2020.

**Beta variant (B.1.351).** Studies have shown that this strain is more transmissible because of the enormous number of mutations in its spike proteins, with concerns that several vaccines may have decreased efficacy against this variant. This variant has been linked to cases in a number of locations outside of South Africa, including Singapore.

**Gamma variant (P.1).** This variant was thought to have first emerged in Japan, but it was later found to have already been circulating in Brazil. It has been found to be 2.5 times more infectious than the original coronavirus strain. The three mutations in the spike protein - the lines bristling out from the virus - are grounds for alarm with this strain.

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# Impact On Testing

Thus far, the gene mutations have only affected a handful of PCR test kits in Singapore (Table 1). Thankfully, it has not caused any significant impact to the sensitivity of the tests.

**TABLE 1**

| Test Kit | Manufacturer | No. Of Gene Targets | Analysis | Impact |
|---|---|---|---|---|
| **TaqPath COVID-19 Combo Kit** | Thermo Fisher Scientific, Inc | **3** | Due to some mutations in one of the 3 targets, will the test sensitivity be significantly reduced? (e.g. mutations in the B.1.1.7 variant). | As this kit targets 3 genes instead of 2, there is no significant reduction in sensitivity. In fact, certain detection patterns may identify new variants in patients. |
| **Xpert Xpress SARS-CoV-2** | Cepheid | **2** | There are reports where single point mutations have been shown to reduce the test's sensitivity for detecting the N2 target. | As this kit detects 2 genes, the detection of E gene target only will lead to a "presumptive positive" result. Thus, the impact on performance has not been found to be significant. |

Reference: FDA 2021, SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests, accessed 6/7/2021 < https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests#mutations>

# Covid-19 Tests and Services provided

*by Innoquest*


## Summary of the Types of Tests:

**Covid-19 Polymerase Chain Reaction (PCR) Swab Test** is conducted for groups of people who experience flu-like acute respiratory infection (ARI) symptoms, for individuals taking a Pre-Departure Test, or as required as part of Ministry of Health's evolving use cases such as the Rostered Routine Testing (RRT) or Worried Well.

**Covid-19 Antibody Serology Tests (IgM or IgG)** are for those who think that they have contracted COVID-19 recently, in the past, or as required as a form of Pre-Departure Testing (IgM).

**Roche Total Antibodies Tests (IgM and IgG)** helps to reveal both antibodies that are present during an active or past infection. This test will not detect the antibodies produced by mRNA-based vaccines.

**Covid-19 Quantitative Antibody Test** helps to measure SARS-CoV-2 neutralising antibodies in people who have been exposed to SARS-CoV-2 or have completed their Covid-19 vaccination regimen.

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# Covid-19 PCR Tests

## Covid-19 Polymerase Chain Reaction (PCR) Swab Test

This test helps to detect the presence of Covid-19 genetic material in a person and is globally recognized as the gold standard test for Covid-19 diagnosis due to its high accuracy and reliability. Trained personnel collect the sample by using a long swab to collect respiratory debris from the back of the nose where it connects to the throat.

The swab is then sealed in a Universal Transport Medium (UTM) tube and delivered to the laboratory for Covid-19 testing using the PCR analysers. If the result is positive, it indicates the presence of viral genetic material.

A negative result means that the Covid-19 virus genetic material was not detected. If the infection is recent, it is possible that insufficient virus exists in the body for the PCR Swab Test to identify Covid-19. Table 2 lists the various PCR kits used at Innoquest Diagnostics for the detection of Covid-19 and their specific targets.

**TABLE 2**

| Reagent Kit | Brand | Targets |
|---|---|---|
| Hologic Aptima SARS-CoV-2 Assay | Hologic | 2 targets on Orf1ab |
| Cobas 6800 SARS-CoV-2 | Roche | Orf1ab & E |
| PerkinElmer New Coronavirus Nucleic Acid Detection Kit | PerkinElmer Singapore Pte Ltd | N & Orf1ab |
| RESOLUTE 2.0 SARS-CoV-2 Direct Detection Kit | A* STAR DxD and DSO National Laboratories | E & N |
| TaqPath COVID-19 Combo RT-PCR Kit | ThermoFisher Scientific | Orf1ab, S & N |
| Xpert Xpress SARS-CoV-2 test | GeneXpert | E & N2 |
| Cobas LIAT SARS-CoV-2 & Influenza A/B nucleic acid test | Roche | Orf1ab & N |