COVID19 Test FAQs

What services are being offered by Hamilton Health Box?

PCR Test:

- Sample: either saliva or nasal & throat swab (ideally no food or drink for 10 minutes prior)
- Sent to certified laboratory for analysis
- Informs if a person is currently infected and contagious
- Does not identify if an individual has already been infected and cleared virus

Serology (Blood) Test:

- Sample: blood draw via finger prick
- Analyzed on site to identify antibodies against COVID-19
- Informs a person that has been previously infected and produced an immune response
- Results in 3-5 business days

What's the difference between SARS CoV 2 and COVID-19?

SARS-CoV-2 means "Severe Acute Respiratory Syndrome Corona Virus 2" is the virus that causes the disease we call CoViD-19 "Corona Virus Disease 2019".

What does the PCR test check for?

The PCR test measures the viral load i.e. how much of the SARS-CoV-2 virus is in the mucosal tissues. The test, however, does not indicate whether you previously had the virus and have already cleared it.

What does the serology (blood) screen check for?

The serological test measures your body's antibody response i.e. immune response. This means whether or not your body has started fighting the virus. This test only tests positive 3-7 days after being infected, when the body mounts an immune response, however also continues to test positive once the virus has been cleared, thereby showing whether you have recovered, or were asymptomatic.

How is the PCR test administered?

To get a good sample, you can't eat or drink for 10 minutes prior; you will then be asked to spit into a sample cup. This cup will be labelled and sent to a certified laboratory for analysis. Results return within 3-5 business days. The nasal and throat swab samples are collected at the entrance of the nose, and by swabbing the back of the throat.

How is the serology (blood) test administered?

The blood test is administered by finger prick by a healthcare provider. Your finger tip will be cleaned, pricked with a lancet (like a diabetes needle), and a single drop of blood will be placed in the test kit. The test kit requires 5-15 minutes to develop and show a result.

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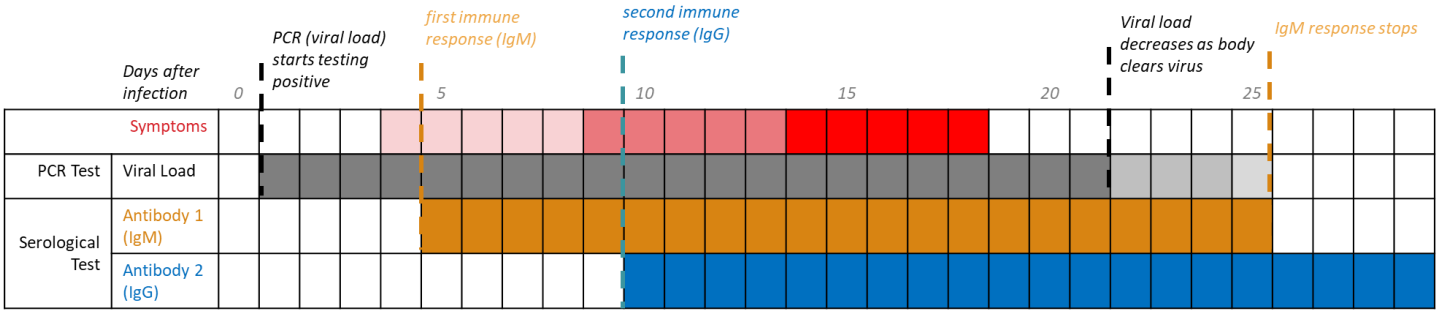
What's the difference between the two tests?
The PCR test checks for the presence of active the virus – it starts testing positive about 1 day after being infected, and continues testing positive until your body clears the virus, at which point it tests negative. In contrast, the serological (antibody) test, checks your body's immune response, i.e. has your body started fighting the virus. This test starts testing positive 3-7 days after infection (with the IgM antibody), however will continue testing positive once your body has developed a long lasting immune response, even after clearing the virus (IgG antibody) – see schematic below.



How accurate is the PCR test?
The PCR assay has been validated, and submitted the data to the FDA; it is being used under compliance with Section IV.A. of the FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency.

How accurate is the antibody test?
Three principal validation studies have been conducted with the Orient Gene Biotech IgG/IgM Rapid Test kit as used by HHB:

- A comparative study of three finger prick antibody tests run at Erasmus University Rotterdam in the Netherlands at a WHO center showed sensitivity of the Orient Gene Biotech antibody test was 83.3% and specificity of 100% and outperformed all other tests
- A peer reviewed study from Uppsala University in Sweden shows IgM sensitivity of 69%, IgG sensitivity of 93.1%, IgM specificity of 100%, IgG specificity of 99.2%
- Validation studies from the manufacturer showing sensitivities ranging from 85-100% and specificities of 98-100% depending on the sample set.

Is the PCR test FDA approved?
Samples will be sent to a high complexity CLIA certified laboratory that is permitted to distribute under Section IV A of the Policy for Coronavirus Disease-2019 Tests from the FDA.

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Is the antibody test FDA approved?
COVID-19 antibody test used by HHB has FDA Emergency Use Authorization (EUA), and is distributed in the US by Healgen Scientific LLC. You can find Healgen Scientific LLC on the FDA website here under “In Vitro Diagnostics EUAs”. Press release available here.

Will these results be private?
All information is stored and handled in compliance with HIPAA and HITECH. The participant consent form confirms that all testing results will be kept between the individual and Hamilton Health Box, which is a third-party healthcare provider. Deidentified information may be used for research purposes.