SARS-CoV-2 [COVID-19] by Real-Time PCR Reverse Transcription (CDC NI, N2, RP targets)

What is COVID-19?

- Coronavirus Disease 2019, or COVID-19, is the name for the respiratory syndrome caused by infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
- The virus, which has infected and caused deaths of over 4 million people worldwide, originated in Wuhan City, China.
- Additional cases have now been reported in the United States.
- An infection with coronavirus 229E, NL63, OC43, or HKU1 is not the same as a COVID-19 infection.
- Patients with COVID-19 are evaluated and cared for differently than patients diagnosed with a common coronavirus.

What are the symptoms?

- Common signs of infection may appear **2-14 days after exposure** and include:
  - Fever
  - Cough
  - Shortness of breath & breathing difficulties
- In severe cases, infection can cause:
  - Pneumonia
  - Severe acute respiratory syndrome
  - Kidney failure
  - Death
- People with heart or lung disease, weakened immune systems, and older adults are at higher risk for severe lower respiratory tract illness.

How is COVID-19 spread?

- This virus is spread person-to-person by someone who is currently sick with COVID-19 through:
  - Respiratory droplets produced while coughing and sneezing
  - Close personal contact (i.e., within about 6 feet)
  - Touching or shaking hands
- It may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or possibly their eyes, but this is not reported to be the primary way the virus spreads.

Diagnosis of COVID-19

- Patients who meet the testing criteria described by the Centers for Disease Control and Prevention (CDC), should undergo testing for SARS-CoV-2.
- Other respiratory pathogens (e.g., influenza, respiratory syncytial virus) should be assessed in the differential diagnosis.
- COVID-19 cannot be properly diagnosed by clinical means due to symptom overlap with other common viral infections.
- Molecular techniques detect the actual virus itself.

Testing for SARS-CoV-2

- Medical Diagnostic Laboratories (MDL) offers test:

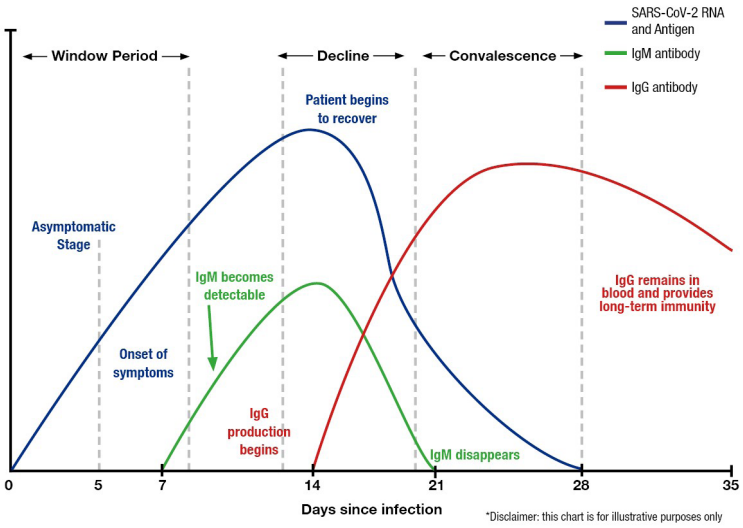
  1131 **SARS-CoV-2 [COVID-19] by Reverse Transcription Real-Time PCR (CDC NI, N2, RP targets)**
  - Approval has been granted by the New Jersey State Department of Health to perform the SARS-CoV-2 (COVID-19) by Real-Time Reverse Transcription PCR (CDC N1, N2, RP Targets) in accordance with Food and Drug Administration (FDA) emergency use authorization (EUA) policy.
  - This test has not been FDA cleared or approved.
  - This test has been submitted for authorization by the FDA under an EUA for use by authorized laboratories.
- Acceptable specimens include:
  - Nasopharyngeal swab OR oropharyngeal swab specimen collection submitted in a **COVID-*OneSwab***™ viral transport media vial
  - ***NasoSwab***® specimen collection for adult patients ONLY of the mid-turbinate area (may be self-collected on-site)
- Specimens should be refrigerated until ready for transport and shipped within 72 hours of collection.

SARS-CoV-2 Serology Test

The new SARS-CoV-2 virus and COVID-19 pneumonia

In mid-December 2019, the Chinese Government announced the existence of a new virus that causes a serious respiratory disease termed “COVID-19”. The virus spreads very quickly, and many infected individuals may require treatment in a hospital. A serological (“antibody”) test can tell you if you have been exposed to the virus and developed an immune response against it.

Antibodies against SARS-CoV-2



When infected by SARS-CoV-19, even if a person doesn’t develop symptoms, the body will still makes antibodies against the outside of the virus. These bind to the virus and prevent it from entering cells. Early in the infection, the immune system makes IgM, which soon gives way to IgG. IgG can stay in the blood for months or years to help prevent reestablishment of COVID-19 disease. A simple antibody test requires a small volume of patient serum. It returns a simple “positive” or “negative” result for each of IgM and IgG.

Significance of the presence of antibodies

Anti-SARS-CoV-2 antibodies tell us that the immune system has responded to the virus, even if the patient never had any symptoms. Such antibodies would normally be expected to be protective, but a positive IgM or IgG test cannot be interpreted as meaning that the patient is completely immune to future episodes of COVID-19. However, physicians and other providers may decide that a positive result means that patients are able to return to work.

Anti-SARS-CoV-2 antibodies are very likely highly-specific

Antibodies against the SARS-CoV-2 virus do not cross react with other viruses such as influenza A or B, RSV, or other seasonal respiratory viruses. They may cross-react with the original SARS virus, but the chances of this are very low, since there were very few cases of original SARS in the USA. Therefore, it is highly likely that only patients with the actual COVID-19-causing virus will test positive in this assay.

The great majority of patients develop antibodies to SARS-CoV-2

Although the virus was only identified at the very end of 2019, we already know people do make antibodies against the virus. At the time of writing in early April 2020, five studies have been presented, examining almost six hundred and fifty patients. Overall, almost 90% had IgM and almost 80% had IgG antibodies, often after they no longer showed signs and symptoms of the virus or the associated COVID-19 disease. These results indicate that the majority of people with confirmed SARS-CoV-2 infection do develop antibodies to the virus.

FDA notice regarding SARS-CoV-2 ELISA testing

This test is not “FDA Approved”. However, it is being run under the following FDA guidelines:

“The FDA does not intend to object to the development and distribution by commercial manufacturers, or development and use by laboratories, of serology tests to identify antibodies to SARS-CoV-2, where the test has been validated, notification is provided to the FDA, and information along the lines of the following is included in the test reports:

- *This test has not been reviewed by the FDA.*
- *Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic test should be considered to rule out infection in these individuals.*
- *Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.*
- *Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, LN63, OC43, or 229E.”*