

## Indications and Fact Sheet for Healthcare Providers: Serologic Testing for Anti-SARS-CoV-2 (COVID-19) IgG Antibodies

There are no restrictions or priority considerations for ordering this COVID-19 related test

### Primary Indication:

Evaluating patients for evidence of *prior* SARS-CoV-2 (COVID-19) infection, with best sensitivity if done 14 days or later *after* the acute illness.

### Secondary Indications:

- Evaluating patients with unexplained COVID-19-like symptoms to determine if those symptoms may have been caused by SARS-CoV-2, particularly in patients who:
  - were unable to obtain molecular testing acutely
  - repeatedly had negative results by molecular assay for SARS-CoV-2 despite acute symptoms concerning for COVID-19 disease
  - have symptoms or a presentation suggesting mixed inflammatory syndrome associated with COVID-19 (e.g. Kawasaki-like inflammatory syndromes)
- Aid in the identification of potential SARS-CoV-2 convalescent plasma donors.

### Non Indications:

- NOT INDICATED as a sole test for patients with acute symptoms nor for the diagnosis of active COVID-19.
  - **Molecular testing is necessary for diagnosis of acute illness.**
- NOT INDICATED to determine if a person is protected against future or repeat COVID-19 infection.
  - It has not been established that detectable antibodies against SARS-COV2 confer protection to subsequent COVID-19 infection.

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### Background:

- Clinical laboratory tests with high sensitivity and specificity to detect antibodies to the SARS-CoV-2 virus are available at Michigan Medicine.
- Anti-SARS-CoV-2 antibodies, generated by the immune system in response to viral infection, are detectable within two to three weeks following symptom onset in most COVID-19 patients.

### Clinical Utility:

- A positive result is evidence of prior SARS-CoV-2 infection and may be especially helpful in determining whether a patient's previous unexplained COVID-19-like symptoms were caused by SARS-CoV-2.
- Detection of anti-SARS CoV-2 antibodies may be useful for aiding identification of potential plasma donors.
- Serological tests **SHOULD NOT** be used as a standalone diagnostic test in patients with acute symptoms for which COVID-19 is suspected, as antibodies are not produced in early stages of infection.
- Molecular testing is required for a definitive diagnosis of acute COVID-19 illness.

### Test Results:

- A positive result (i.e. detection of IgG antibodies) indicates likely exposure and infection by SARS-CoV-2, depending on disease prevalence (see **Predictive value of results** below). Positive results do not exclude current disease in symptomatic individuals.
- A negative result indicates antibodies to SARS-CoV-2 were not detected. This may be explained by any of the following:
  - The patient was not previously infected by SARS-CoV-2.
  - The patient is infected by SARS-CoV-2 but was either tested before they generated an antibody response or they have an altered immune function resulting in delayed, decreased, or absent IgG production.
- Repeat testing in two to three weeks should be considered if there is clinical concern or suspicion of a false positive or false negative result.

### Predictive Value of Results:

- The analytical specificity of the serologic tests used at Michigan Medicine is >98%, indicating a low relative risk of false positives.
- The Positive Predictive Value (PPV) – or likelihood that a positive serology means this patient was previously infected with SARS-CoV2 – relates to not only test performance but also disease prevalence.
- The Negative Predictive Value (NPV) – or likelihood that a negative serology means this patient was *not* previously infected with SARS-CoV2 – is greater than 99% for expected prevalence ranges.

### Cautions:

- There is no current conclusive evidence that anti-SARS-CoV-2 antibodies provide immunity to subsequent infections, although this is an area of active investigation.
- The duration and relative amount of antibodies remaining in the blood following COVID-19 is unknown, and is also an area of active investigation.