

## Frequently Asked Questions for Clinicians: Serology (Antibody) Testing for COVID-19

### 1. What is serology (antibody) testing?

Serology testing detects antibodies present in a patient's blood (serum) after exposure to a pathogen, in this case to the virus, SARS-CoV-2, the causative agent of COVID-19. Unlike viral culture, which directly detects the presence of virus (but cannot be done safely in most labs) or Polymerase Chain Reaction (PCR), which detects presence of viral nucleic acid (RNA) but does not always equate with infectivity, serology testing shows that a patient has been exposed to the pathogen, but not whether they are currently infected.

### 2. What serology (antibody) testing is currently available for SARS-CoV-2?

Serology IgG testing reagents have recently become available from a number of suppliers. Only a small number of these reagents have been validated for diagnostic accuracy. **Within BILH, an assay developed by Abbott, and approved under emergency use authorization and validated by participating hospitals, is being offered that detects IgG antibodies directed against the SARS-CoV-2 viral nucleocapsid.**

In the coming months, IgM testing should become available, which may help with diagnosis of acute infection. Eventually, we should be able to offer quantitative titers, which will be helpful both diagnostically and prognostically, once the clinical correlates between titer and immunity are better defined.

### 3. How good is the test?

The sensitivity of the assay in detecting SARS-CoV-2 infection depends upon the time since infection and/or development of symptoms: generally <40% during the first week of symptoms and rising thereafter, eventually reaching >95% after two weeks of symptoms. The specificity is high, with very few false positives detected using test sera from last year (before SARS-CoV-2 was circulating) or from a large panel of sera from patients infected with other respiratory pathogens. Cross-reactivity with other human coronaviruses is not yet fully determined.

### 4. What are the current clinical indications for testing?

At present, there are only very limited clinical indications for serology, since most patients will be seronegative early in the course of illness when they present for medical attention and most will be clinically recovering by the time serology is reliably positive. For most patients, diagnosis should instead use direct RT-PCR detection of SARS-CoV-2 from nasopharyngeal swabs. The principle use for serology at present is for patients with a high clinical suspicion for COVID-19 but negative testing by RT-PCR, since the sensitivity of current PCR testing is not high-enough by itself to rule out COVID-19.

Specific examples where serology might be helpful include:

- Patients with suggestive symptoms of more than one week in duration, for whom PCR testing has been negative and no alternative diagnosis has been found. For these cases, a positive IgG serology would be diagnostic. A negative serology could be repeated at > 2 weeks from symptom onset and repeat negative testing would then effectively rule out COVID-19.
- Patients with initial negative PCR and serology at less than two weeks after symptom onset but who remain symptomatic beyond two weeks without an alternative diagnosis. Repeat serology testing documenting seroconversion would be diagnostic, whereas failure to seroconvert would rule-out COVID-19.
- Symptomatic febrile, PCR+ patients with an unknown time since infection where presence of antibodies might help in choice of therapeutic modalities (e.g., antivirals and/or convalescent serum before antibodies arise vs. anti-inflammatory agents later after seroconversion).

**5. What is known about whether a positive serology implies clinical immunity?**

It is still too early in the epidemic to know with confidence whether infection and development of antibody (IgG) conveys immunity. While there have been reports of re-infection, these appear to be uncommon. The clinical correlates of immunity should become clearer in the coming year, especially as quantitative titers become available. Eventually, these should be helpful in providing guidance regarding susceptibility to infection, but for now patients should be advised that whether or not having detectable antibodies signifies immunity is unknown.

**6. How do I order the test?**

Currently, the ordering of SARS-CoV-2 Ab is institution-specific. Some institutions are able to run this in their own labs (currently BIDMC, LHMC, Beverly and Winchester). Other BILH institutions may choose from one of the following options:

- Send to BIDMC Laboratory
  - See [BIDMC Lab Manual SARS-CoV-2 IgG Test Description](#) for further details
  - Similar to COVID-19 PCR, the results of this test may be viewed in webOMR and in the Excel file provided to each institution every three hours (currently containing only PCR results)
- Send to Lahey Hospital & Medical Center with results viewed in Epic (*Ordering details coming soon*)
- Send to a commercial laboratory (e.g., Quest)