



# Pathology and Laboratory Medicine

## New Test Announcement

PRC-PALM-5.18 polpro 1-fm1: New Test Announcement Form

### Test Name: Anti-SARS-Cov-2 Antibody, IgG

Test Change Effective Date: June 15, 2020

Memo Release Date: June 15, 2020

**Test Background:** Henry Ford Health System now offers a validated COVID-19 antibody (serologic) test with high sensitivity and specificity. The test is performed at the Henry Ford Health System Core Laboratory and will be resulted by 6 a.m. the next morning, 7 days a week.

The assay recognizes IgG antibodies to the SARS-CoV-2 Anti Receptor-Binding-Domain-Spike Protein (RBD-S). This test has a 99.1% sensitivity and 99.8% specificity for IgG antibodies to SARS-CoV-2, with extremely low cross-reactivity to other similar viruses, such as common cold coronaviruses and to viruses such as CMV, Flu A/B and HIV.

**Link(s) To Medical Literature:** CDC Interim Guidelines for COVID-19 Antibody Testing in Clinical and Public Health Settings (May 23, 2020). [https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-testsguidelines.html#anchor\\_1590264231244](https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-testsguidelines.html#anchor_1590264231244)

**Report Content:** Qualitative result with result-specific interpretive comments reported as Reactive (Positive), Indeterminate or Nonreactive (Negative) for antibodies. Find FAQs for Patients and Healthcare providers, and Flow Chart Guidance for Serology and PCR testing linked to the opening page of the Lab User Guide.

- **HFHS Intranet** <http://pathology.hfhs.org/lug>
- **Internet:** <https://lug.hfhs.org>, then login with User Name: Lug & Password: Homelug.

**Locations of Test Result In Epic:** Results will be in the "Labs" tab.

#### Recommended Indications for Testing:

- Participant in seroprevalence studies.
- Asymptomatic individual with history of prolonged exposure to a confirmed COVID-19 patient.
- Symptomatic patient consistent with COVID-19 who is repeatedly PCR negative. Do not rely solely on antibody results in this setting. Correlate results with clinical findings (*see below for SARS-CoV-2 Testing Algorithm*).

#### Result Interpretation:

- **Positive** (Reactive) result: May indicate CoV-2 exposure.
  - **Not known** if a positive result indicates protective "neutralizing" antibodies.
  - A positive result **cannot** be **assumed** to equal immunity to re-infection **or** that patient is not infectious to others.
- Given a low prevalence of COVID-19 in Michigan, there is a significant chance that a positive antibody result is a **False Positive** (*See chart below of positive predictive values and false positives per 10,000 tested*).
  - At **5% disease prevalence**, about **1 out of 25 positives** would be **False Positive**.
  - At **3% prevalence**, about **1 out of 15 positives** would be **False Positive**.
  - At **1% prevalence**, about **1 out of 6 positives** would be **False Positive**.
  - Michigan disease prevalence is estimated to be 5.9% (4.5-7.8%, May 2020) doi: <https://doi.org/10.25561/79231>
- Due to false positives & uncertainty that a true positive equates to immunity, a **positive antibody result should not be used** for return-to-work decisions.
- **Indeterminate** result: means the test does not detect a clearly positive signal of anti-SARS CoV-2 antibody, but is close to it. This may be due to too little time elapsed between viral infection and blood sampling, or this may be a true nonreactive with a borderline signal. In either instance, **consider repeat antibody testing in 7 to 10 days**.
- **Negative** (Nonreactive) result: May indicate lack of exposure to SARS-CoV-2. **False negatives** may occur when:
  - Blood specimens drawn < 14 days from viral exposure or onset of symptoms.
  - In some immunosuppressed / immunocompromised patients.
  - In a small fraction of immunocompetent COVID-19 patients.
  - Loss of detectable antibody with time. It has not known how long SARS-CoV-2 antibodies may persist.
- **This test is NOT cleared to assess convalescent serum for therapeutic purposes.**

#### Epic/Atlas Order code & test name:

- Epic: LAB5491 & "COVID-19 Antibody, IgG"
- Atlas: COVABB & "COVID-19 Ab IgG "

**Insurance Prior-Authorization:** n/a



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**Acceptable Specimen Source(s) & Storage / Transport Conditions:** Venous Blood only; Gold Top Tube, Serum Separator (GO); Transport at room temperature. If required, centrifuge and store refrigerated.

**Causes For Rejection:** Improper label or identification, gross hemolysis, specimen contamination; finger-stick specimen.

**For More Information:**

For Questions About This Specific New Test Contact: Dr. Bernard Cook (bcook10@hfhs.org); Dr. John Carey (jcarey1@hfhs.org)

Search our Electronic Lab Users Guide Test Catalog: <http://pathology.hfhs.org/lug>

Call 313.916. LABS (5227) for Lab Customer Service or to speak with a Pathologist

