



COVID-19 Testing Information for Health Care Providers

On March 11, 2020, the World Health Organization declared the novel coronavirus disease (COVID-19) a global pandemic. Due to the limited availability of testing especially for health care workers and first responders, Pennsylvania Specialty Pathology (PSP) is excited to announce that we will be offering the **COVID-19 IgG/IgM Rapid Test**.

ABOUT THE TEST

The COVID-19 IgG/IgM Rapid Test is intended for all patients, health care providers and first responders, symptomatic AND asymptomatic, and relies on whole blood, serum, or plasma for results. This test is an immunochromatographic assay utilizing lateral flow technology for qualitative, differential detection of anti-SARS-CoV-2 IgG and IgM antibodies.

- **Detection Window:** Symptomatic – 3 - 15 days after symptoms appear
Asymptomatic – 8 - 21 days after infection
- **Turnaround Time:** 1 day
- **High sensitivity and high specificity** to COVID-19 pathogen SARS-CoV-2
 - IgM sensitivity - 88%
 - IgM specificity - 97%
 - IgG sensitivity - 98-100%
 - IgG specificity - 98-100%

Specimen Collection

- Lavender Top (K2EDTA) – Whole Blood:** after collecting, invert the tube 8-10x and store/transport whole blood in an upright position at 2-8°C.
OR
- Red/Grey Striped Top (SST) – Serum:** After collecting, invert sample 5x and allow the blood to clot in an upright position for 30 minutes at room temperature. Centrifuge specimen for 20 minutes at 2200-2400RPM to separate serum **within 1 hr of collection**. Store/transport in an upright position at 2-8°C.

Other information

- Please call PSP at (717) 393-7771 with any questions, to order supplies and to schedule specimen pick-up.
- This test has not been reviewed by the FDA, but the FDA has determined under the COVID-19 EUA that this approval is not required.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus or early in the disease. Follow-up testing with a molecular diagnostic test should be considered to rule out infection in these individuals (PCR is more sensitive in the first 7 days of symptoms)
- 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. A positive IgM test should be confirmed by pa RT-PCR test.
- Positive IgG alone can be seen with past infection, but there is insufficient data at present to determine the degree of immunity that this may confer
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E