

Clinical Laboratory Communication

Notification Date: April 27, 2020

Effective Date: Immediately

Coronavirus (COVID-19) SARS-CoV-2 IgG Antibody Testing

Explanation: Effective Friday April 24, 2020; UnityPoint Health – Des Moines is now testing for COVID-19 IgG Antibody in our Core Laboratory Department at Pathology Laboratory in Ankeny.

Testing Times and Expectations: Testing time may fluctuate based on patient volume.

1. Testing Set up and Frequency
 - a. Testing performed daily Monday through Friday in the evening
2. Sample Priority
 - a. Not Applicable
3. Reporting
 - a. Results will be reported as Positive or Negative with the following notes:
 - This assay has been approved for use by the FDA under the Emergency Use Authorization for Medical Devices. <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidinvitrodev>
 - 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 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, NL63, OC43, or 229E.
 - Not for the screening of donated blood.
 - This test may be useful for its negative predictive value in patients whom symptoms began at least 14 days ago.

Epic Ordering Information: SARS COV 2 IGG AB [LAB3079]

Sample Requirements:

1. Tube Types:
 - a. Red (No Additive)
 - b. SST (Serum Separator)
 - c. Lavender (EDTA)
2. Minimum Volume:
 - a. Whole blood – 1.0 mL
 - b. Serum or Plasma – 0.3 mL

Questions, please contact:

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Clinical Laboratories of UnityPoint Health – Des Moines
Iowa Lutheran, Iowa Methodist, Methodist West
Pathology Laboratory – Ankeny, Pathology Laboratory – Downtown, and
Pathology Laboratory - Lakeview