SONIC HEALTHCARE USA

SARS-CoV-2 (COVID-19) Client Communication

PROMEDICA PATHOLOGY LABORATORIES

A Partnership of ProMedica and Sonic Healthcare

NOTE: Effective May 12, 2020, the disclosed IgG test was renamed to SARS-COV-2 IGG (EUROIMMUN) for differentiation with a new IgG (ABBOTT) offering available as of May 12, 2020.

April 29, 2020

ProMedica Pathology Laboratories (PPL) would like to inform you of an update made to the recently released offering for SARS-Cov-2/COVID-19 serologic testing. **The IgA portion of our originating serologic offering has been discontinued due to technical issues with the IgA component. Therefore, all serologic testing will be conducted reporting the IgG antibodies to SARS-COV-2 only.**

CLINICAL INFORMATION:

The Euroimmun ELISA is designed to detect IgG antibodies to the S1 portion of the spike protein of SARS-CoV-2 in serum and plasma from patients who have signs and symptoms of infection, are suspected of coronavirus disease (COVID-19), or in subjects that may have been infected by SARS-CoV-2. For diagnosis, symptomatic patients suspected to have acute COVID-19 should be tested using a molecular assay to detect SARS-CoV-2 RNA, such as 39429 SARS-COV-2 (COVID-19) BY RT-PCR.
The incubation period for COVID-19 ranges from 5 to 7 days. SARS-CoV-2-specific antibodies can be detected in approximately 90% of COVID-19 patients by day 14 after symptom onset. Serologic testing is recommended for symptomatic patients at least 14 days post symptom onset.

In accordance with the US FDA Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency (https://www.fda.gov/media/135659/download), the test is offered for use prior to Emergency Use Authorization (EUA) or In-Vitro Diagnostic (IVD) designation by the manufacturer. Under the FDA emergency guidance (provision IV.D), FDA does not object to the utilization of serology tests provided the following information is included in the reports:

- This test has not been reviewed by the FDA.
- 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.

Orderable Test Code: 39432 SARS-COV-2 IGG (EUROIMMUN)

Result Codes:

- 394321 - SARS-COV-2 IGG

LOINCS:

94563-4

Ordering Recommendations:

To detect IgG antibodies against SARS-CoV-2 in serum and plasma from patients who have signs and symptoms of infection, are suspected of coronavirus disease (COVID-19), or in subjects that may have been infected by SARS-CoV-2.

Specimen Requirements:

Sample Type:

- Serum or Plasma
- 1.0 mL (0.5 mL minimum, does not allow for repeat testing)

Container Type:

- Preferred- Serum Separator Tube
- Alternate- Plain Red Top Tube, EDTA (Lavender Top) Tube, Heparin (Green Top) Tube, Citrate (Light Blue Top) Tube

Handling Instructions:

Collect specimen per tube manufacturer's instructions. Centrifuge sample and separate serum or plasma from cells ASAP or within 2 hours. Aliquot and refrigerate or freeze.

Transport: Frozen or Refrigerated
Unsuitable Specimens: Grossly hemolyzed or lipemic specimens.
Stability: Ambient: 24 Hours; Refrigerated: 4 Days; Frozen: 1 Month

Testing:

- Testing is performed Monday through Friday.
- Expected TAT is 2-4 days.
- Reference Range: SARS-CoV-2 IgG: <0.80 Ratio

CPT Codes: 86769
Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)

COMPLIANCE STATEMENT: This test is performed according to guidance of the U.S. Food and Drug Administration (FDA) for serologic testing for antibodies to SARS-CoV-2 described in policy FDA-2020-D-0987 section IV.D issued 3/16/2020. This test has not been reviewed by the FDA or cleared or approved by the FDA. Sonic Reference Laboratory, performing this test on behalf of PPL, is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. section 263a, to perform high complexity tests.

If you have any questions, please contact our Customer Service Department at 419-291-4414 / 833-960-0241 or your Account Executive. Thank you.