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Laboratory Bulletin

SARS-CoV-2 Antibody Testing Update

Commencing **September 7, 2021**, Beaumont Laboratory will perform all SARS-CoV-2 IgG antibody testing using the Abbott assay that detects IgG antibody specific for the Receptor Binding Domain (RBD) of the spike protein. Testing will be performed on the automated Abbott Architect platforms using a chemiluminescent microparticle immunoassay method. Test reports will include a qualitative result (i.e. negative or positive) and a semi-quantitative determination of antibody level. Key performance characteristics of this test as determined by Beaumont Laboratory is provided below. The Abbott anti-spike RBD assay will replace testing performed using the qualitative EUROIMMUN ELISA method.

Key Test Performance Characteristics

- **Test Specificity**
  Pre-pandemic sample cohort (N=305 specimens): 99.02%
  Symptomatic COVID-19 PCR negative patients (N=391 specimens): 99.49%
- **Test Sensitivity**: Admitted COVID-19 PCR positive patients, Weeks post-symptom onset
  2-3 weeks (N=250): 95.6%
  4-5 weeks (N=239): 98.7%
  6-7 weeks (N=175): 99.4%
- Test cutoff value: ≥ 50 AU/mL = antibody positive
- Reportable range: 50-50,000 AU/mL
  Notes regarding semi-quantitative measurement of antibody level:
  1. Assay determined to be linear across the analytical measurement range.
  2. No guidance is currently available to correlate numerical value (AU/mL) to clinical history.

Clinical Utility:

- Provides evidence of past exposure to SARS-CoV-2 or responsiveness to COVID-19 vaccination.
- A positive test result cannot be used to discriminate between an antibody response caused by a natural infection vs. vaccination

Ordering Information

- Test Name: **SARS-CoV-2 IgG (Anti-Spike)**
- Epic Test Code: LAB7920
- Specimen Collection Requirement: One gold-top Serum Separator Tube (SST)

For additional information, access the Laboratory Test Directory at:

http://beaumontlaboratory.com/test-lab-directory

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