



## LAB ALERT

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### ***NEW TEST***

**New Test: SARS-CoV-2 IgG qualitative (test code LAB1230638)**

**Sample Type: Serum (preferred) and EDTA (acceptable)**

**Performing Lab: Berkeley Medical Center (BMC)**

**Effective Date: 5/11/2020**

**EXPLANATION:** Following successful validation, the BMC laboratory now offers qualitative SARS-CoV-2 IgG serologic testing (this assay received FDA emergency use authorization). Test method is chemiluminescent microparticle immunoassay (CMIA).

Stat testing is not available, but batch testing will be performed several days per week on our chemistry analyzer, the Abbott Architect i1000. The test detects the presence of IgG antibodies against nucleocapsid (N) epitopes, which are unique to SARS-CoV-2. Testing can be performed at least 2-3 weeks after symptom onset.

This test is intended to assist with documentation of immune response to past SARS-CoV-2 infection. Essentially, the IgG antibody titer rises as viral load declines. Serology is **NOT** intended for screening acutely symptomatic patients; rather, PCR-based nucleic acid testing (NAT) via nasopharyngeal swab is indicated for acute diagnosis.

- Per FDA, at this time do not test patients without history of probable COVID-19
- Do not use IgG assay for recovery planning (e.g. return-to-work) or blood donor screening
- Patients that are positive for the IgG assay may still be infectious to others
- Positive results do not imply immunity to reinfection
- Rare false positive results may occur due to interfering antibody, infection or condition
- Negative results do not entirely exclude COVID-19
- Healthcare provider fact sheet: <https://www.fda.gov/media/137381/download>
- Patient fact sheet: <https://www.fda.gov/media/137382/download>

\*If you have any questions call BMC at 304-264-1212, option # 7