In response to the COVID-19 public health crisis, bioMONTR Labs is proud to now offer both molecular and antibody-based platforms for SARS-CoV-2 detection.

bioMONTR® Labs

bioMONTR Labs is dedicated to accelerating response efforts towards COVID-19 mitigation by offering rapid clinical testing for SARS-Cov-2 detection. We continue to work closely with leading diagnostic companies to provide CLIA certified high-complexity laboratory services. With the addition of molecular and antibody-based assays, bioMONTR Labs stands ready to support your SARS-CoV-2 testing needs. Increase your test capacity by outsourcing to our CLIA certified laboratory or to support your drug development studies. bioMONTR Labs test menu includes:

Abbott RealTi*me* SARS-CoV-2 assay (Available NOW):

- Qualitative detection of nucleic acid from SARS-CoV-2
- RT-PCR on the Abbott *m*2000 RealTi*me* System
- Sample Input: Nasopharyngeal (NP) or Oropharyngeal (OP) swabs
- Intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. The assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

Abbott SARS-CoV-2 IgG Test (Available May 11, 2020):

- Lab based serology blood test for the detection of the IgG antibody
- Immunoassay technology on the ARCHITECT® i1000SR laboratory instrument
- Sample Input: Human Serum or Plasma
- For In Vitro Use, Rx ONLY. This test is allowed to be marketed under policy D of the FDA *Policy for Diagnostic Tests for Coronavirus Disease 2019 during the Public Health Emergency; Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* document issued March 16, 2020.

Cellex qSARS-CoV-2 IgG/IgM Rapid (Coming Soon):

- Lateral Flow Immunoassay for qualitative detection and differentiation of IgG and IgM antibodies to SARS-CoV-2
- Sample Input: Human Serum or Plasma, Venipuncture whole blood
- For Prescription Use Only. For In vitro Diagnostic Use Only. For Emergency Use Authorization Use Only.

- If you are experiencing severe symptoms, seek medical advice. If possible, call ahead before visiting a healthcare facility.
- Specimens must be collected by a healthcare provider and then sent to bioMONTR Labs using standard procedures. bioMONTR Labs DOES NOT collect samples for COVID-19 testing.
- The North Carolina Department of Health and Human Services (NCDHHS) and Center for Disease Control (CDC) provide guidelines for when testing may be appropriate.
- Refer to the CDC Interim *Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)*.

Contact us via our website http://www.biomontr.com
or at 1-866-609-3870 for more information regarding these assays

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