

## NEWS RELEASE



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### FOR IMMEDIATE RELEASE

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Bridgeport, NE (June 3, 2020) – **FAQs: CoVID-19 Testing**

#### **1. What types of testing are you offering?**

MCCH Clinical Laboratory is offering 2 types of CoVID-19 Testing:

##### **Active Infection Test**

MCCH Clinical Laboratory is offering services for the BioGX SARS-CoV-2 Assay for the BD MAX System (RT-PCR). This test has been issued Emergency Use Authorization by the US-FDA. This test is not yet approved or cleared by the US-FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). A swab is inserted into one nostril to the nasopharynx. The swab is then rotated in a circle around the entire inside of the nasopharynx at least five times. Test results are typically sent to the ordering provider/facility within 1 day.

##### **Immune Response Test**

MCCH Clinical Laboratory is offering services for the Abbott Architect SARS-CoV-2 IgG Antibody test. This test has been issued Emergency Use Authorization by the US-FDA. This test is not yet approved or cleared by the US-FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). A blood sample is collected via a blood draw from the patient's arm and results are typically sent to the ordering provider/facility within 1 day.

#### **2. What is the difference between the tests?**

The Active Infection Test helps to diagnose whether you currently have an active CoVID-19 infection. A diagnosis can guide you and your doctor or healthcare provider to make an informed decision about self-quarantining to protect your family, friends and our community. Active infection testing may be right for you if you are currently experiencing CoVID-19 symptoms or were exposed to the virus in the last 14 days. Common CoVID-19 symptoms include fever, cough, and shortness of breath.

The Immune Response Test is the test detects antibodies that show if you have already been exposed to and produced an immune response to CoVID-19 even if you never experienced symptoms. Previous exposure means you may now have some level of immunity to the virus. Understanding your immune response gives you and your doctor or healthcare provider the information to assist in making an informed decision about returning to work or activity. Immune response testing is available only to patients who are not currently experiencing CoVID-19 symptoms and have not experienced symptoms within 14 days.

#### **3. Where are the tests processed?**

Both the active infection test and immune response offered at MCCH Clinical Laboratory are processed and tested in-house (Bridgeport, NE).

**4. Will the test results be reported to the Panhandle Public Health Department?**

Yes, all results will be reported to PPHD and Nebraska Department of Health and Human Services.

**5. Is MCCH Clinical Laboratory certified, permitted to perform CoVID-19 Testing?**

Yes, MCCH Clinical Laboratory is fully compliant and accredited by COLA and CLIA to perform moderate and highly complex laboratory tests.

**6. How accurate is your test methodologies?**

Data published on the US-FDA's website suggest that the BioGX SARS-CoV-2 Assay on the BD MAX System has Sensitivity (Positive Percent Agreement) of 100% and Specificity (Negative Percent Agreement) of 100%; MCCH internal study using clinical specimens revealed a Sensitivity and Specificity of 100%; although it should not be assumed the test is 100% accurate over an infinite sample size.

Data published on the US-FDA's website suggest that Abbott Architect SARS-CoV-2 IgG Antibody test has a sensitivity (PPA) of 100% and specificity (NPA) of 99.6%; MCCH internal study using clinical specimens revealed a Sensitivity and Specificity of 100%; although it should not be assumed the test is 100% accurate over an infinite sample size.

**7. Will insurance pay for CoVID-19 tests?**

Please refer to your insurance plan for coverage details.

**Morrill County Hospital Clinic Update: Covid-19 Testing**

- Covid-19 Testing requested thru the Lab or Clinic is by appointment only. We are not taking walk-ins at this time.
- **Please call the hospital or clinic to schedule your drive thru testing time. Hospital 308.262.1616 Clinic 308.262.1755.**
- Please refer to your insurance plan for coverage details especially for asymptomatic patients.
- Ideal testing time is 3-4 days after symptom onset or known positive exposure.
- If an asymptomatic individual's testing is negative but they have a known close contact, especially in the same household, repeat testing 7 days later is strongly recommended. It is possible the initial test was done too early.
- If you are an established patient, notes indicating positive or negative status can be provided for school/work. However, an appointment will be required prior to any treatment.
- If you are a new patient, or have not been seen within the past 3 years at this clinic, an appointment will be required prior to any notes or treatment.

We are doing everything we can to see as many patients as safely as possible. Thank you for your patience and understanding.

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