NEWS RELEASE

CONTACT:
RHEA BASA | MORRILL COUNTY COMMUNITY HOSPITAL
308.262.1616 | basar@morrillcountyhospital.org

FOR IMMEDIATE RELEASE

June 5, 2020

Bridgeport, NE (June 5, 2020) – **CoVID-19 Testing, now available at MCCH Lab!**

Our patients are our first priority and as the pandemic continues to develop, we know you still have a lot of questions about the coronavirus disease (CoVID-19) and we're committed to helping you find the answers. Morrill County Community Hospital is happy to announce the availability of the multiple testing platforms for CoVID-19 that will enable our hospital and our clinics to screen and diagnose patients for CoVID-19 on site and obtain results within the same day of sample collection. With the two types of CoVID-19 tests, you need the right information to determine which test may be right for you. MCCH can help you get the answers you need, because knowing gets you back to a healthy, active lifestyle faster.

1. ACTIVE INFECTION SWAB TEST

This type of 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. Your doctor or healthcare provider will collect a specimen through a nasopharyngeal swab. The specimen is then sent to our Clinical Laboratory Department for processing and analysis using the BD MAX System or the BioFire Respiratory Panel 2.1 (RP2.1).

The BD MAX System is a molecular diagnostics instrument that fully automates cell lysis, nucleic acid extraction, Polymerase Chain Reaction (PCR) set-up, target amplification and detection. MCCH Clinical Laboratory uses the BioGX assay for the BD MAX System, the assay is based on the same viral RNA targeting sequence and real-time PCR detection method as the test developed by the US-Centers for Disease Control and Prevention (CDC). The BD MAX system is capable of processing 24 samples simultaneously and is capable of analyzing hundreds of samples per day to detect the presence of the SARS-CoV-2 virus. The BioFire FilmArray Respiratory Panel 2.1 (RP2.1) is the second molecular diagnostic test offered at MCCH in response to the CoVID-19 pandemic. This panel test identifies 18 respiratory viruses and 4 bacterial targets. The BioFire system is a multiplexed nucleic acid test for the simultaneous qualitative detection and differentiation of nucleic acids from multiple viral and bacterial respiratory organisms, including nucleic acids from SARS-CoV-2.

During the MCCH's Clinical Laboratory Department method validation study involving verification samples, quality control materials and sixteen (16) previously tested patient samples from the Nebraska

Public Health Laboratory (NPHL), MCCH Medical Laboratory Scientists were able to detect the SARS-CoV-2 virus from NPHL patient samples at different viral concentrations (low, mid and high) correctly. The validation study revealed 100% Positive/Negative agreement with NPHL results and 100% analytical and diagnostic sensitivity and specificity for both BioGX assay on the BD MAX System and Biofire FilmArray RP2.1.

2. IMMUNE RESPONSE BLOOD TEST

This type of 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.

If your doctor or healthcare provider has submitted an order for you to get a CoVID-19 immune response test or you purchased one through our Direct Patient Access Testing Program offered during our scheduled Health Fair Days, you can schedule an appointment by calling the MCCH Clinical Laboratory Department at (308) 262-1616 Ext 237 or (308) 262-1328. You do not need to fast for this test. A medical laboratory professional will draw your blood and the specimen is then sent to Clinical Laboratory for processing and analysis. The antibody blood test performed at the MCCH-Clinical Laboratory is a chemiluminescent microparticle immunoassay (CMIA) performed on the Abbott's Architect ci41000 system, a high-throughput medical laboratory analyzer which can produce over 2,400 results in 24 hours, with a 29 minute time to first result.

TESTING STATEMENTS

The antibody tests (sometimes known as the serology tests or IgG tests) are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Results are for the detection of SARS-CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Individuals may have detectable virus present for several weeks following seroconversion. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, molecular testing for SARS-CoV-2 is necessary. The antibody test should not be used to diagnose acute SARS-CoV-2 infection. False positive results for the antibody test may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

- All CoVID-19 tests (molecular and antibody tests) performed at MCCH Clinical Laboratory have been authorized by the US-Food and Drug Administration under Emergency Use Authorization for use by authorized laboratories;
- The antibody tests have been authorized only for the detection of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and,
- All tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

ACKNOWLEDGEMENTS

MCCH Clinical Laboratory Department would like to acknowledge and thank the following individuals who had been involved in the acquisition and validation process of CoVID-19 testing instruments: MCCH Board of Directors, MCCH Foundation, MCCH Senior Management, Senator Steve Erdman, Joel Hunt (Legislative Aide for Nebraska State Senator Steve Erdman), Kim Engel (Director of PPHD), Elizabeth Higgins and Lisa Kelly (Becton Dickinson), Marvin & Julie Hernandez (University Medical Center, NY), Romel Canapi (Presentation Medical Center, Rolla, North Dakota), Dr. Pete Iwen (Director of NPHL), Karen Stiles (State Training Coordinator, NPHL) and Dr. Pete Schilke (MCCH Laboratory Medical Director).

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