

**MAY 28, 2020**

## **HEALTH ADVISORY**

### **COVID-19 Diagnostic Testing Guidance**

The NDDoH continues to recommend that clinicians use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Health care providers should not turn patients away for COVID-19 testing who have upper or lower respiratory illness. **COVID-19 testing is critical in order to identify cases and prevent further spread through case investigation and contact tracing. Health care providers are asked to have a high suspicion for COVID-19 and test accordingly.**

Clinicians should consider testing any patient with **one (1)** of the following signs/symptoms with new or worsening onset:

- cough
- shortness of breath
- difficulty breathing
- fever (measured or subjective)
- runny nose
- sore throat
- chills
- myalgia
- fatigue
- headache
- loss of taste and/or smell

#### **Priorities for Testing:**

##### **High Priority:**

- Hospitalized patients
- Healthcare facility workers, workers in congregate living settings (long term care, correctional facilities, group homes, homeless shelters, etc.), and first responders **with** symptoms
- Residents in long-term care facilities or other congregate living settings **with** symptoms
- Persons identified through public health cluster and selected contact investigations
  - Symptomatic close contacts

##### **Priority:**

- Persons **with** symptoms of potential COVID-19 infection

- Persons **without** symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to: public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to state and local plans.
  - **Asymptomatic close contacts may be tested after an exposure to COVID-19. Testing should occur ideally 7 to 10 days after last exposure.** For household contacts this means after the case in the household is released from isolation (10 days after onset and 72 hours fever free and symptom improvement). A negative PCR test result does not mean that the person won't go on to develop COVID-19 in the 14 days after exposure. If exposed, these individuals should be quarantined for 14 days, even with a negative test result.

Healthcare providers may choose to test all pregnant women upon delivery for COVID-19. If positive, health care providers should follow [CDC guidance](#) for management of newborns.

Providers may also submit specimens to the NDDoH Division of Microbiology for preoperative testing. Turn-around time for testing is generally 48 hours from specimen receipt. As a reminder, PCR results are for a single point and time, so even if negative, at the time of surgery, if not the same day as specimen collection, the patient may be positive for COVID-19. Providers should continue to implement appropriate [infection control measures](#) in surgical settings to prevent COVID-19 transmission.

Collection kits are available for order from the [NDDoH Division of Microbiology](#). An updated [Test Request Form](#) is available. **Providers no longer need to complete the COVID-19 Evaluation and Test Report Form.**

**Health care providers should not refer patients to the NDDoH for medical consultation or screening to determine the need for testing. Health care providers should not diagnose a patient with COVID-19 without testing and/or reporting to the NDDoH.**

For questions related to COVID-19, health care providers can call the NDDoH Division of Disease Control at COVID-19 hotline at 888-391-3430 Sunday through Saturday, 24/7.

## **Abbott Architect SARS-CoV2 IgG Testing Available from NDDoH**

**CDC does not recommend using antibody testing to diagnose acute infection.** More information is needed to determine how the results of serologic tests correlate with possible immunity. It is recommended to use a viral (nucleic acid or antigen) test to diagnose acute infection.

North Dakota health care providers may now order FDA EUA COVID-19 IgG serology from the NDDoH Division of Microbiology. The acceptable specimen is 2mL serum or plasma. The turn-around time is expected to be 48 hours after receipt of the specimen. There is no charge for this test. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus DKU1, NL63, OC43, or 229E.

Health care providers may want to consider ordering IgG for close contacts to laboratory confirmed COVID-19 cases who were previously identified by public health and who wish to donate plasma.

Serologic testing can be offered as a method to support diagnosis of acute COVID-19 illness for persons who present late. For persons who present 9-14 days after illness onset, serologic testing can be offered in addition to [recommended](#) direct detection methods such as polymerase chain reaction. This will maximize sensitivity as the sensitivity of nucleic acid detection is decreasing and serologic testing is increasing during this time period.

Serologic testing should be offered as a method to help establish a diagnosis when patients present with late complications of COVID-19 illness, such as multisystem inflammatory syndrome in children.

Please refer to the [Fact Sheet for Healthcare Providers](#) and the [Fact Sheet for Recipients](#) for additional information.

Insurance will not reimburse for serology that is not ordered by a provider.

## **Additional Information About COVID-19 Serology**

**The NDDoH does not recommend use of serology tests that are not authorized under FDA EUA.**

Patients who are positive for IgG for COVID-19 will be considered suspect cases. A case investigation will not be initiated by public health for IgG positive individuals because it would be too late in the course of infection for isolation of cases or quarantine of contacts.

Patients who are IgM positive for COVID-19 should have specimens collected for PCR testing. IgM positive individuals will be considered suspect cases. A case investigation will not be initiated by public health for IgM positive individuals, unless also PCR positive.

**Serologic tests should generally not be used to diagnose acute cases of COVID-19 or to infer immunity, because\*:**

1. ***There is a lag in production of antibodies.*** It can take 7-14 days after symptom onset for antibodies against SARS-CoV-2 to be detectable by serologic assays. This delay means that these tests are not useful in making the diagnosis of acute disease.
2. ***A positive IgM test does not mean current infection.*** While presence of IgM is often considered a sign of current infection, the lag between symptom onset and antibody production against SARS-CoV2 means that detection of IgM may not indicate acute infection. Studies suggest that detection of IgM can lag symptom onset by 12 days or more, and fewer than 40% of patients will have detectable antibodies in the first week of infection.
3. ***A positive serologic test may not mean a patient is immune.*** A number of different SARS CoV-2 antibodies may be produced during an immune response. It is not clear which antibodies confer immunity or how long persons who develop detectable antibodies are

protected against later reinfection with SARS-CoV-2. Until more information is available, patients with a positive serologic assay should not be assumed to be immune to SARS-CoV-2.

4. ***There is a high degree of variability in sensitivity and specificity between different serologic assays.*** Serologic tests are generally less specific than RT-PCR tests and have a greater potential to cross-react with Coronaviruses other than SARS-CoV-2. Remember that the positive predictive value of a test depends on not only the sensitivity and specificity of a test, but also on prevalence of disease. In a population with a 5% prevalence of SARS-CoV-2 infection, a serologic test with 95% sensitivity and 95% specificity will have 50% positive predictive value.

\*Adapted from the California Department of Public Health

Please see the table below to better understand what COVID-19 results may or may not mean.

PCR	IgM Antibody	IgG Antibody	Interpretation
POSITIVE	NEGATIVE	NEGATIVE	Results suggest early, active infection.
POSITIVE	POSITIVE	NEGATIVE	Results suggest active infection with an early immune response. Possible false positive IgM results.
NEGATIVE	POSITIVE	NEGATIVE	Results suggest recent infection with an early immune response. Possible false negative PCR results. Possible false positive IgM results.
POSITIVE	NEGATIVE	POSITIVE	Results suggest past infection with an immune response. Possible reinfection. Possible false positive IgG results.
POSITIVE	POSITIVE	POSITIVE	Results suggest active or recent infection with immune response. Possible false positive IgM and/or IgG results.
NEGATIVE	POSITIVE	POSITIVE	Results suggest past or recent infection and immune response. Patient is likely in recovery. Possible false negative PCR results. Possible false positive IgM and/or IgG results.
NEGATIVE	NEGATIVE	POSITIVE	Results suggest past infection and recovery. Possible false positive IgG results.
NEGATIVE	NEGATIVE	NEGATIVE	Results suggest no recent or past infection. Possible false negative PCR and/or serology results if too early in the course of infection.

## **NDDoH Inconclusive Results Update**

The NDDoH Division of Microbiology experienced a recent malfunction on two pieces of lab equipment. Out of an abundance of caution, 82 positive results from May 19 – 21 were considered inconclusive and the individuals were asked to retest. All the facilities involved have been notified. The issue was caught quickly and early; the malfunction has been corrected and has not impacted lab processing.

## **Abbott ID Now Update**

Health care providers should be aware for the potential of [false negative results](#) associated with the Abbott ID Now. On May 14, 2020, Abbott updated information about the ID Now analyzers. Click [here](#) for the full details.

“Further clarifying our product information to provide better guidance to healthcare providers that negative results should be considered in the context of a patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. Negative results should be presumed negative, but if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with an alternative molecular assay. We are also reinforcing proper sample collection and handling instructions. We are communicating this to our customers.”

Positive and negative results from the Abbott ID Now are required to be reported to the NDDoH Division of Disease Control.

To order ID Now reagents, please visit the website at <http://www.ndhealth.gov/microlab/>.

## **Definition of Close Contact**

The NDDoH is following CDC’s definition of who is considered a close contact to a COVID positive case.

“Based on our current knowledge, a close contact is someone who was within 6 feet of an infected person for at least 15 minutes starting from 48 hours before illness onset until the time the patient is isolated. They should stay home, maintain social distancing, and self-monitor until 14 days from the last date of exposure.”

## **COVID-19 is a Mandatory Reportable Condition**

North Dakota Administrative Rules 33-06-01 requires the reporting of novel severe acute respiratory illness, which includes COVID-19. North Dakota health care providers are required to report all individuals who tested positive or negative for COVID-19 to the NDDoH. This includes FDA EUA serology results.

**Categories of Health Alert Network messages:**

**Health Alert** Requires immediate action or attention; highest level of importance

**Health Advisory** May not require immediate action; provides important information for a specific incident or situation

**Health Update** Unlikely to require immediate action; provides updated information regarding an incident or situation

**HAN Info Service** Does not require immediate action; provides general public health information