State Health Advisory Supplement
Updated Guidance for Coronavirus Disease 2019 (COVID-19) Testing
Coronavirus Disease 2019 Advisory #10.1
Wyoming Department of Health
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SITUATION SUMMARY
The purpose of this addendum is to provide updated information on COVID-19 testing at the Wyoming Public Health Laboratory (WPHL), serologic COVID-19 testing, rapid COVID-19 testing, the use of source control in healthcare settings, and new clinical guidance from the National Institutes of Health (NIH).

All information provided in COVID-19 Health Advisory #10, issued on 4/10/20, remains applicable except for the updates provided here. Health Advisory #10 can be found at:

EXPANDED CAPACITY OF TESTING FOR COVID-19 AT THE WPHL
The Wyoming Public Health Laboratory (WPHL) has received sufficient supplies to expand testing capacity. The WPHL will now accept all samples from patients with symptoms...
**compatible with COVID-19.** The WPHL will continue to prioritize samples from patients within priority categories for faster turn-around times.

Priority categories include hospitalized patients, symptomatic healthcare workers and first responders who provide direct patient care, patients who are residents or staff in communal settings, patients who are over 65 or with chronic health conditions, patients who have close contact with people over 65 or with chronic health conditions, and pregnant women. WDH may request testing outside of these priorities, including asymptomatic patients, as part of epidemiological investigations; the WPHL will accept and prioritize requested samples.

The continued ability of WPHL to accept samples from patients outside of priority categories will depend on availability of laboratory reagents.

Providers who have not received results within 3 days of collection may email the WPHL at WDH-COVID-RESULTS@wyo.gov. Please provide, at minimum, the patient full name, date of birth, and medical record number and a fax number or secure email address. Personal email (e.g., @gmail.com or @yahoo.com) addresses are not acceptable.

**SEROLOGICAL IgM/IgG SARS-CoV-2 (COVID-19) TESTS**

The Food and Drug Administration (FDA) has issued a letter to healthcare providers regarding the use of COVID-19 serological antibody tests. The letter can be found here: [Important Info on the Use of Serological (Antibody) Tests for COVID-19](https://www.fda.gov/media/133360/download).

The FDA recommends that healthcare providers **DO NOT** use serological tests as the sole basis to diagnose COVID-19, and warns that not all marketed serological tests have been evaluated by the FDA.

Further information from the FDA can be found at the following links:

- [FAQs on Diagnostic Testing for SARS-CoV-2](https://www.fda.gov/media/133360/download)
- [FDA FACT SHEET - Serological Testing for Antibodies to SARS-CoV-2 Infection](https://www.fda.gov/media/133360/download)
- [Coronavirus (COVID-19) Update: Serological Test Validation and Education Efforts](https://www.fda.gov/media/133360/download)

**The Wyoming Department of Health (WDH) has the following concerns regarding the use of serological tests in the diagnosis and management of COVID-19:**

- A negative result does not rule out SARS-CoV-2 infection, particularly in those who may be presymptomatic, early in their illness course, or immunocompromised.
- Positive results may be due to present or past infection with a non-SARS-CoV-2 coronavirus due to cross-reactivity with other common non-COVID-19 human coronaviruses.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
FDA has warned against fraudulent test kits that are being sold online (https://www.fda.gov/consumers/consumer-updates/beware-fraudulent-coronavirus-tests-vaccines-and-treatments).

WDH recommends the following with regard to the use of serological tests in the diagnosis and management of COVID-19:

- To date, evidence is lacking on the utility of serological testing in the management of individual patients with suspected or confirmed COVID-19.
- To avoid fraud, health care systems should exercise caution when evaluating kits from manufacturers or vendors of rapid serological tests for COVID-19 and should check the FDA FAQs on Diagnostic Testing for SARS-CoV-2, under section 6, “What serology tests are being offered...” for a list of bona fide commercial manufacturers and laboratories known to have developed these tests.
- The performance of these tests (sensitivity and specificity) is highly variable and the majority have not been reviewed by the FDA. If your lab is considering using one of these tests, please review the package insert very carefully to fully understand the limitations of the test.
- Interpretation of serological results should involve careful consideration of the total clinical picture as well as the limitations of these tests.

RAPID SARS-CoV-2 TESTING WITH THE ABBOTT ID NOW PLATFORM

Fourteen Abbott ID NOW platforms have been or will be distributed to hospitals around the state. Providers should be aware that the sensitivity of this platform for the detection of SARS-CoV-2 is significantly less than the tests being conducted at the WPHL. WDH recommends the following:

- Abbott ID NOW should be used to test symptomatic patients only; asymptomatic patients should not be tested using this platform.
- **Providers should send samples from patients who test negative on the Abbott ID Now platform to the WPHL for confirmatory testing.** Providers will need to collect a second sample from these patients using a separate swab placed in viral transport media and shipped to the WPHL according to the instructions found in Health Advisory #10. **A sample used on the Abbott platform cannot be sent to WPHL; a second nasopharyngeal swab must be collected and submitted to WPHL.**
- Providers are not required to confirm positive results from the Abbott ID Now platform at the WPHL; however, if providers collect a second sample, we request that it be sent to the WPHL for epidemiologic purposes. WPHL will also confirm positive results on request.
- Laboratories performing the Abbott ID NOW COVID-19 test should be aware of the potential biosafety risks associated with the performance of the test. Each laboratory should perform their own risk assessment to help mitigate risk for laboratory exposure.

RECOMMENDATIONS FOR THE USE OF FACE COVERINGS IN HEALTHCARE SETTINGS

CDC has issued updated infection control guidance for healthcare settings recommending source control for everyone entering a healthcare facility, regardless of symptoms, and including
patients, visitors, and staff. Healthcare settings include hospitals, long-term care, and ambulatory settings. This recommendation is intended to protect healthcare personnel by reducing their risk for exposure as we continue to learn how COVID-19 spreads, particularly from presymptomatic and asymptomatic people. The guidance can be found here: Infection Control: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Key points from this guidance include the following:

- When supplies are available, facemasks are generally preferred for healthcare providers to wear while they are in a healthcare facility as it offers both source control and protection for the wearer against exposure to splashes and sprays of infectious material from others.
- Cloth face coverings should not be considered PPE and should NOT be worn instead of a respirator or facemask if more than source control is required.
- Healthcare providers should consider continuing to wear their respirator or facemask (extended use) while in the healthcare facility instead of intermittently switching back to their cloth face covering, which could cause self-contamination. Healthcare providers should remove their respirator or facemask and put on their cloth face covering when leaving the facility at the end of their shift.
- Visitors and patients should be wearing their own cloth face covering upon arrival to the facility per CDC recommendations to the general public. If they are not, they should be offered a facemask or cloth face covering, as supplies allow, and instructed to wear it while in the facility.
- This recommendation does not change CDC’s guidance to use N-95 or equivalent respirators when providing care for patients with suspected or known COVID-19.
  - Facilities that do not have sufficient supplies of N-95s and equivalent respirators for all patient care should prioritize their use for activities and procedures that pose high risks of generating infectious aerosols, using facemasks for care that does not involve those activities or procedures. Once availability of supplies is reestablished, N-95s and equivalent respirators use should resume for all workers caring for these patients.
  - Facilities should consider utilizing CDC’s PPE optimization guidance and PPE Burn Rate Calculator in order to preserve PPE supplies and keep workers safe.

NEW CLINICAL GUIDANCE FROM NIH

The NIH has released COVID-19 Treatment Guidelines. These guidelines can be found here: Coronavirus Disease 2019 (COVID-19) Treatment Guidelines

CONTACT INFORMATION

Wyoming healthcare providers and facilities are reminded to check COVID-19 resources available from WDH and CDC. Healthcare providers or facilities can contact WDH through the following channels:

- Please email questions about preparedness, PPE, infection control, or other non-urgent topics to wdh.covid19@wyo.gov. This email address is monitored 7 days a week and replies will come within 24 hours.
• Please contact WPHL with questions about specimen collection, storage, or shipping at 307-777-7431 or WPHL@wyo.gov.

• Please use the WDH Public Health Emergency Line (1-888-996-9104) for urgent questions about a specific patient, healthcare personnel exposure, or other urgent matter. This line is intended ONLY for healthcare providers. Do not share this number with the public.

Please refer questions from the general public to 211 or to the WDH email box (wdh.covid19@wyo.gov).