

Montana Health Alert Network

DPHHS HAN

ADVISORY

Cover Sheet

DATE

July 21, 2020

SUBJECT

COVID Healthcare IPC Guidance Updates

INSTRUCTIONS

DISTRIBUTE to your local HAN contacts. This HAN is intended for general sharing of information.

- Time for Forwarding: **As Soon As Possible**
- Please forward to DPHHS at hhshan@mt.gov
- **Remove this cover sheet before redistributing and replace it with your own**



For LOCAL HEALTH DEPARTMENT reference only
DPHHS Subject Matter Resource for more information regarding this HAN, contact:

DPHHS CDCP

**Epidemiology Section
1-406-444-0273**

For technical issues related to the HAN message contact the Emergency Preparedness Section at 1-406-444-0919

DPHHS Health Alert Hotline:
1-800-701-5769

DPHHS HAN Website:
www.han.mt.gov

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Categories of Health Alert Messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

Information Service: passes along low level priority messages that do not fit other HAN categories and are for informational purposes only.

Please update your HAN contact information on the Montana Public Health Directory

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Information Sheet



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BACKGROUND & INFORMATION

COVID-19 activity in Montana continues to increase and the update below provides important updates on selected topics. COVID Updates, including detailed descriptions of activity by counties and other analyses are available at:

- <https://dphhs.mt.gov/publichealth/cdepi/diseases/coronavirusmt>

COVID Healthcare IPC guidance has been updated:

- *Discontinuation of Transmission-Based Precautions* (updated July 17, 2020):
 - <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html>
- *HCP Return to Work Guidance* (updated July 17, 2020):
 - <https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html>

RECOMMENDATIONS

Please share the update with relevant partners to help ensure that we are all approaching the challenges with as much consistency as possible. Specific contacts for each area are also provided below if additional information is required. Please note that many local jurisdictions may be addressing some of these issues with slight variations depending on local resources and COVID-19 impacts. Specific questions should begin with your local public health department or unified command.

CDC Updated guidance on Duration of Isolation and Precautions for Adults with COVID-19 from Home isolation.

Key points are listed below. Questions may be directed to your local health department. Full detail on the revisions can be found at:

- <https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>

1. Duration of isolation and precautions

For most persons with COVID-19 illness, isolation and precautions can generally be discontinued 10 days after symptom onset¹ and **resolution of fever for at least 24 hours**, without the use of fever-reducing medications, and with improvement of **other symptoms (no longer limited to “improvement of respiratory symptoms”, to address expanding list of symptoms associated with COVID-19)**. A limited number of persons with severe illness may produce replication-competent virus beyond 10 days that may warrant extending duration of isolation and precautions for up to 20 days after symptom onset; consider consultation with infection control experts.

For persons who never develop symptoms, isolation and other precautions can be discontinued 10 days after the date of their first positive RT-PCR test for SARS-CoV-2 RNA.

2. Role of PCR testing² to discontinue isolation or precautions

For persons who are severely immunocompromised, a test-based strategy could be considered in consultation with infectious diseases experts.

For all others, **including healthcare workers**, a test-based strategy is no longer recommended except to discontinue isolation or precautions earlier than would occur under the strategy outlined in Part 1, above.

3. Role of PCR testing² after discontinuation of isolation or precautions

For persons previously diagnosed with symptomatic COVID-19 who remain asymptomatic after recovery, retesting is not recommended within 3 months after the date of symptom onset for the initial COVID-19 infection. In addition, quarantine is not recommended in the event of close contact with an infected person.

For persons who develop new symptoms consistent with COVID-19 during the 3 months after the date of initial symptom onset, if an alternative etiology cannot be identified by a provider, then the person may warrant retesting; consultation with infectious disease or infection control experts is recommended. Quarantine may be considered during this evaluation based on consultation with an infection control expert, especially in the event symptoms develop within 14 days after close contact with an infected person.

For persons who never developed symptoms, the date of first positive RT-PCR test for SARS-CoV-2 RNA should be used in place of the date of symptom onset.

4. Role of serologic testing

Serologic testing should not be used to establish the presence or absence of SARS-CoV-2 infection or reinfection.

1 Symptom onset is defined as the date on which symptoms first began, including non-respiratory symptoms.

2 PCR testing is defined as the use of an RT-PCR assay to detect the presence of SARS-CoV-2 RNA.

COVID-19 Testing Priorities at the Montana Public Health Laboratory and Partners

The Montana Department of Public Health and Human Services is working with several partners to support COVID-19 testing. Unfortunately, one of our major partners has become backlogged and is unable to accept further testing at this time. That has led to a reprioritization of tests at the state health laboratory. We will provide an update when additional testing resources are identified, and we can resume sentinel surveillance testing of asymptomatic individuals. We are also in the process of developing and distributing new laboratory requisition forms to reflect the addition of asymptomatic close contacts to the priority list and hope to make these forms available next week.

Priorities for COVID-19 Testing at the Montana Public Health Laboratory (MTPHL)

(Revised 7/20/2020)

Currently DPHHS is prioritizing testing at the MTPHL to ensure critical testing needs of patients and providers are met. As a result, testing performed will be prioritized as follows:

Priority 1 - Testing supporting response activities:

- a. Symptomatic, regardless of hospitalization
- b. Close Contacts³ and Outbreak Investigations coordinated by Public Health Authorities

Priority 2 - Testing supporting surveillance/monitoring activities:

- a. Frontline workers (Health Care Workers in high-risk situations, staff of Assisted Living Facilities and Long Term Care centers participating in surveillance testing)

- b. Residents of select congregate settings such as group homes, institutions, and other facilities

Other non-priority testing will be conducted as resources allow but may not be a priority for the MTPHL. These include, but are not limited to:

- Testing of asymptomatic people for activities such as travel
- Pre-procedural testing such pre-ops, dental visits and similar activities
- Testing of individuals in the general public who are not symptomatic
- Other individuals who seek testing that do not fit into the priority categories above

The MTPHL is developing a revised laboratory requisition form to reflect these testing priorities and will begin distribution of the forms during the week of July 20th. For questions, clinical and laboratory partners may contact the state health department at 444-0273.

3 Close contacts are generally identified and referred to providers by local public health officials, but instances of patient referrals may occur. If necessary, consultation with local public health officials, when feasible, if concerns regarding whether someone is a valid close contact exist.

Request to Immediately stop use of Primestore COVID-19 collection kits/tubes

The attached bulletin was issued by FDA to alert laboratories to a potential danger with select collection kits. Tubes pictured below cannot be tested at the current time and unused inventory should be disposed of. We are currently working to identify a facility capable of testing samples on hand and will keep you posted. Please contact DPHHS at 444-0273 if additional information or supplies to replace these supplies are needed.



Governor's Directive on Mask Usage

The Governor issued a *Directive implementing Executive Orders 2-2020 and 3-2020 and providing for the mandatory use of face coverings in certain settings* on July 15th, 2020. More information on the directive can be found at the following sites, for specific information on this directive under Mask/Face Coverings:

- <https://covid19.mt.gov/>
- <https://covid19.mt.gov/Frequently-Asked-Questions>

Please note that the directive applies to all counties with 4 or more active COVID-19 cases. We ask county health departments to work closely with your partners and DPHHS to keep information updated so we can provide

accurate information on the COVID-19 map available at the site above. More information on this issue can be obtained by contacting the Joint Information Center at:

- <https://covid19.mt.gov/joint-information-center>

Transport Media Safety Risk - Use Compatible Transport Media with SARS-CoV-2 Tests that Use Bleach - Letter to Clinical Laboratory Staff and Health Care Providers

The U.S. Food and Drug Administration (FDA) reminds laboratory staff to use transport media (the liquid that maintains a specimen sample while it is transported to a laboratory) that are compatible with the SARS-CoV-2 testing platforms and the processes used in their laboratory to process samples collected from people who are being tested for SARS-CoV-2. There is a risk of exposure to harmful cyanide gas, a by-product of a reaction between guanidine thiocyanate or similar chemicals and bleach (sodium hypochlorite), when certain transport media are used with an incompatible testing platform or laboratory process. Guanidine thiocyanate may be referred to as guanidinium rhodanide, guanidinium thiocyanate, or guanidinium.

There are numerous transport media that contain guanidine thiocyanate or similar chemicals. PrimeStore molecular transport media (MTM) (LH-1-02 and LH-1-03), Zymo DNA/RNA Shield, Spectrum Solutions Saliva Collection Device, and any other transport medium containing guanidine thiocyanate or similar chemicals, should not be used in a testing platform such as the Hologic Panther and Panther Fusion Systems that use bleach or in laboratories that use bleach as part of their normal laboratory processes. When the bleach interacts with the guanidine thiocyanate or similar chemicals in the transport media, it produces cyanide gas.

While there have been reports of these potentially hazardous interactions, there have been no injuries reported to the FDA associated with exposure to cyanide gas as a result of using incompatible media with testing platforms.

Recommendations

The FDA recommends that clinical laboratory staff and health care providers:

- Do not use PrimeStore MTM, Zymo DNA/RNA Shield, Spectrum Solutions Saliva Collection Device, or any other transport media containing guanidine thiocyanate or similar chemicals with the Hologic Panther or Panther Fusion

Systems due to a disinfecting step involving bleach that is specific to the testing platform.

- Review the manufacturer's instructions for the testing platform used in your laboratory about which transport media should be used.
- Do not use cleaning agents containing bleach on testing platforms that use guanidine thiocyanate or similar chemicals, either in transport media or sample processing reagents.
- Do not separate transport media tubes from the manufacturer's labeling.
- If you can identify the contents of the tube through associated packaging or information from the distributor, you may place a label on a specimen collection tube that does not have a label identifying the type of transport media inside. If you do not have a label, you may contact the manufacturer to obtain one.
- If you cannot identify the type of transport media in the specimen collection tubes or if you do not know if the transport media contains guanidine thiocyanate or similar chemicals as an ingredient, handle tubes as if they contain guanidine thiocyanate or similar chemicals.

Background

PrimeStore MTM (LH-1-02* and LH-1-03*), Zymo DNA/RNA Shield, and Spectrum Solutions Saliva Collection Device contain a transport medium which maintains patient specimens while they are transported to a laboratory for RNA and DNA testing. These media contain guanidine thiocyanate or similar chemicals, which produces a potentially hazardous chemical reaction that releases cyanide gas when exposed to bleach (sodium hypochlorite) and should not be used in a testing platform, or in laboratory processes, that use bleach. Many laboratories may use bleach in their cleaning or decontamination processes in response to laboratory spills.

Other transport media may contain guanidine thiocyanate or other similar chemicals, and ingredients in transport media may not be listed on individual tubes. If laboratory staff do not know the ingredients in the transport media, they should handle it as though it has guanidine thiocyanate or similar chemicals to avoid a potential reaction. If laboratory staff receive samples in unfamiliar transport media, or transport media without appropriate labeling, they should make sure the media does not contain guanidine thiocyanate or similar chemicals before processing the samples in a testing platform that uses bleach, or before using the samples in a laboratory that regularly uses bleach for laboratory cleaning and decontamination processes.


FDA Actions

The FDA is collaborating with manufacturers of transport media and SARS-CoV-2 testing platforms to improve product labeling.

The FDA is working with federal and state health agencies to inform laboratory staff about the risk of exposure to harmful cyanide gas when certain transport media are used with an incompatible testing platform or laboratory process.

The FDA will continue to keep clinical laboratory staff, health care providers, manufacturers, and the public informed of new or additional information.

Additional Resources

- What If I Do Not Have...? (/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#whatif) section on the FAQs on Testing for SARS-CoV-2 (/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2) page
- PrimeStore MTM decision summary DEN170029 (https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170029.pdf)
- Longhorn Vines and Diagnostics LLC Client Letter (<https://www.lhnvd.com/client-letter>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with transport media and SARS-COV-2 testing sample kits.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user organizations must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).

- Health care personnel employed by organizations that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their organizations.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact COVID19DX@fda.hhs.gov (<mailto:COVID19DX@fda.hhs.gov>).