



DEPARTMENT OF HEALTH

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Laboratories Administration
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TO: Health Officers, Laboratory Directors, and Healthcare Providers

FROM: Robert A. Myers, Ph.D., Director MDH Laboratories Administration *R.A.M.*

RE: Clinical Specimen Transport/Receipt Temperature Monitoring

DATE: 1/22/2024

The federal Centers for Medicare and Medicaid Services (CMS) regulations under CFR §493.1232 & §493.1242 require laboratories to maintain and follow policies and procedures that ensure optimum integrity of patient specimens submitted for testing by strictly following specimen acceptability/rejection criteria. Ensuring that specimens are stored and shipped to the testing laboratory at the correct temperature for the requested test method is vitally important to maintain specimen integrity prior to testing. Therefore, MDH Laboratories Administration is implementing a specimen receipt temperature monitoring system.

Specimen coolers, other containers and packaging materials must maintain the required test method transport temperature as outlined in the updated MDH Laboratories Guide to Public Health Laboratory Services found at the link below.

<https://health.maryland.gov/laboratories/Pages/Home.aspx>

Click on "Guide to Public Health Laboratory Service," located on the left side menu.

General transport/receipt temperature categories include, but are not limited to, the following:

- **Refrigerated:** Transport and deliver to the lab at 2-8°C on cold packs in a cooler (Example: Serology Testing (HIV, MMRV, Syphilis, Hepatitis, etc.)
- **Frozen:** Transport and deliver to the lab at -2°C or colder on dry ice in a cooler
- **Room/Ambient temperature:** 2-30°C

It is the submitter's responsibility to ensure that specimens are appropriately packaged to prevent leakage and to maintain the appropriate temperature during transit. Refer to Appendix 1 for proper packing of specimen(s) for transport guidance. The MDH Laboratories Administration will be

providing additional outreach and training materials as it pertains to patient specimen(s) packaging and transport.

If specimens are received at the MDH Laboratories Administration outside of the required transport temperature range noted in the MDH Laboratories Guide to Public Health Laboratory Services, they will not be tested, and a rejection report will be issued beginning **2/14/2024**.

Thank you for your cooperation and attention to this matter. Maintaining the optimum integrity of patient specimens submitted for testing is critically important to ensure accurate results. For questions, please contact Heather Peters, the Quality Assurance Officer of the MDH Laboratories Administration at 443-681-3791 or email heather.peters@maryland.gov.

Appendix 1 - Specimen Packaging Transport Instructions

****Please note these instructions are for specimens transported using private couriers only. For specimens shipped using commercial carriers (i.e. FedEx, UPS, etc.) refer to the IATA/DOT requirements for shipping biological materials. Links to relevant regulations provided below.****

IATA: <https://www.iata.org/contentassets/b08040a138dc4442a4f066e6fb99fe2a/dgr-62-en-3.6.2.pdf>

DOT: <https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2020-04/Transporting-Infectious-Substances-Safely.pdf>

- Ensure that specimens are at the proper temperature prior to shipment based on the MDH Laboratories Guide to Public Health Laboratory Services. Specimens must be stored and shipped within the required transport temperature range for the requested test method(s) from time of collection until delivery to the testing laboratory.
- Specimen(s) must be packed into a sealed leakproof secondary container which consists of a plastic biohazard bag. (Image 1)
 - Use a separate biobag for each form and each temperature requirement. Place the specimen container in the zip lock portion of the bag and seal it closed. Place the MDH Laboratories Administration lab requisition form in the pouch on the outside of the biohazard bag.
 - If multiple specimen containers are required for various tests marked on 1 form, place each container in a separate biobag to protect it from leakage/breakage or cross contamination from the other container(s). Then place them all into an outer biohazard bag with the MDH Laboratories Administration lab requisition form in the outer pocket.



Image 1

- **An MDH Form #4676 Infectious Agents: Culture/Detection, #4677 Serological Testing form, or paperwork representing an electronic test order is required for clinical testing results to be reported to the submitting healthcare provider.**
- Specimen(s) must be packed in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the plastic zip closure biohazard bags.

- Place specimen(s) in biohazard bag(s) in a rigid outer insulated container such as a cooler.



- Line cooler with several cold packs to transport specimens requiring refrigerated transport conditions of 2-8°C. Specimens should be surrounded by cold packs. Number of cold packs will vary based on the number of specimens, cooler size, and varying environmental weather conditions. **The outside of the cooler must be labeled to identify the submitter so that couriers can properly identify coolers for pickup and return to your facility for re-use.**



- For specimens requiring frozen transport at -2°C or colder, surround the specimens in dry ice.



- After specimens are packaged and ready for transport to the lab, the package must be kept secured in a climate-controlled area away from direct sunlight.
- **Couriers will leave the packed specimen cooler(s) prepared by the healthcare provider on the MDH Laboratories Administration Loading Dock. Couriers must not remove the specimens from the temperature-controlled packaging.** The next time the courier drops off the specimen cooler(s) from your facility they will pick up emptied coolers (with cold packs if applicable) to return them to your location for re-use.