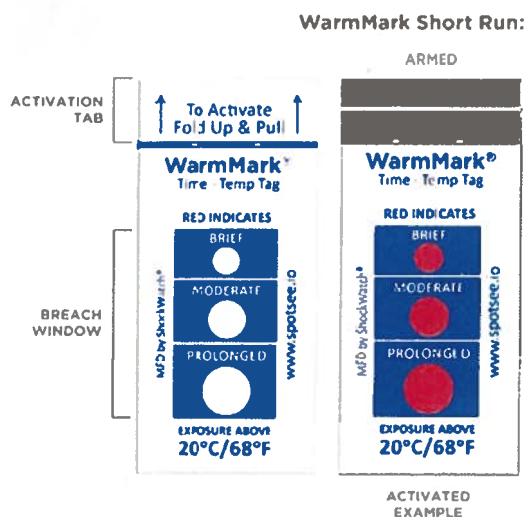


Medical Microbiology Branch Temperature Monitoring Requirements for Clinical Specimens

- A. Purpose: To ensure that all human specimens used for clinical testing are transported, and received at temperatures that maintain specimen integrity and comply with test manufacturer instructions, per CLIA regulations [§493.1242\(a\)\(5\) Standard: Specimen Conditions for specimen transportation](#)
- B. Acceptable Temperature Ranges:
1. Temperature requirements are determined by the Standard Operating Procedure (SOP) for each test. The SOP is derived from package inserts or manufacturers instructions, Centers for Disease and Control and Prevention (CDC), Food and Drug Administration (FDA), and Clinical and Laboratory Standards Institute (CLSI).
 2. Common temperature ranges include:
 - a. Room Temperature: 20–30°C
 - b. Refrigerated: 2–8°C
 - c. Frozen: -20°C or colder (some tests may require -70°C)
- C. Specimen Transport Requirements for the Specimen Provider or Shipping Organization
1. Use insulated containers/coolers with cold packs, dry ice that is able to maintain the appropriate temperature during transport or the Vericor Cool Cube™ system provided by the State Laboratories Division (SLD).
 2. Activate the WarmMark® indicator according to manufacturer instructions prior to transport.



3. Place a single-use time-temperature indicator WarmMark® on top and/or side of a container inside each specimen transport container.

D. Requirements for the State Labs Upon Specimen Receipt

1. Perform visual inspection of the container.
2. Open shipping container and check the Breach Window of the WarmMark® indicator immediately and record the results.

E. WarmMark® Indicator – Interpretation of Color Change

1. A color change (from white to light pink, pink, or red) in the WarmMark® Breach window signifies a temperature excursion meeting or exceeding the indicator's time-temperature threshold.
2. Specimen Acceptance – Color Indicator changed to Light Pink, Pink, or Red in Brief Breach Window
 - a. If the Brief Breach Window of the WarmMark® indicator shows a color of light pink, pink, or red upon opening of the shipping container the sample will be accepted by the SLD and processed.
 - b. A disclaimer will be included in the final report indicating a possible temperature excursion. The disclaimer will be included in the “Comment” section of the report.
3. Specimen Rejection – Color Indicator changed to Light Pink, Pink, or Red in Moderate or Prolonged Breach Window
 - a. Sample will be rejected by the SLD.
 - b. Specimen will be marked as rejected in Clinisys or on SharePoint, as appropriate.
 - c. Notification to the shipper or submitter of sample rejection in Clinisys or SharePoint.
 - d. Rejected samples will be autoclaved and discarded.
 - e. Specimen provider will determine if a new specimen must be submitted for testing.

F. Transition Period (Implementation Phase):

To ensure a smooth implementation of this policy, a transition period will be in effect from August 8, 2025 to October 7, 2025. During this time:

- Submitters will be notified of any temperature monitoring nonconformities, but specimens may still be processed at the discretion of the laboratory director or designee.
- A disclaimer may be added to the final report if temperature integrity cannot be verified.
- Training and guidance will be provided to all relevant personnel and submitting sites on the use of time-temperature indicators and transport requirements.
- Full enforcement of specimen rejection criteria will begin on October 8, 2025.

Reviewed By:



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AUG 08 2025

Date



Edward P. Desmond, Ph.D.
Administrator, State Laboratories Division

8/8/25

Date