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Laboratories Administration
Robert A. Myers, Ph.D., Director
1770 Ashland Avenue
Baltimore, Maryland 21205

Date: March 12, 2025
To: Submitters Requesting Syphilis Serology, Rabies Antibody Titer (RFFIT), and Varicella Antibody IgG
From: Heather Goux, PhD
Chief of Virology and Immunology *HG*
Thru: Robert Myers, PhD
Director, Laboratories Administration *R.A.M.*

RE: Notification to Submitters that the Specimen Temperature Acceptability Conditions have been updated for the Following Tests: Syphilis Serology, Rabies Antibody Test (RFFIT), and Varicella Antibody IgG

The federal Centers for Medicare and Medicaid Services (CMS) regulations under CFR §493.1232 and §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. To comply with these CMS requirements, on February 14, 2024, the MDH Laboratories Administration implemented a specimen receipt temperature monitoring system. Over the past year, MDH Laboratories Administration and Specimen Submitters have taken numerous initiatives to address the ongoing issue of high specimen rejection rates, which followed the system's implementation. Two of these initiatives include (1.) Researching the commercial market for FDA-cleared or approved tests that will allow for a broader specimen temperature range than those currently listed in our testing guide and (2.) Conducting stability studies to expand the specimen temperature range for laboratory-developed tests that have a high rejection rate.

The first initiative prompted the MDH Laboratories Administration to verify and implement an additional Syphilis Serology test known as the Abbott Architect Syphilis TP Assay. This new test allows for a wider temperature range for Syphilis specimens during transit. In addition to the previous acceptance criteria, **we can now accept whole blood or separated serum specimens at room temperature (2-30°C) for up to 72 hours after collection for Syphilis TP testing.**

The Varicella Antibody IgG testing method has also been updated to include more flexible specimen transport conditions. **We can now accept whole blood or separated serum/plasma transported within 3 days of collection at room temperature (15-30°C) or up to 7 days after collection transported at 2-8°C on cold packs.** The updated assay also includes plasma as an additional acceptable specimen type.

The second initiative prompted the MDH Laboratories Administration to conduct a specimen temperature stability study on the Rabies Antibody Titer (RFFIT) test. **As a result, we can now accept whole blood specimens and separated serum specimens transported at a temperature of 2 to 23°C for RFFIT testing.**

All of these changes can be found in the newest version of our Guide to Public Health Laboratory Services (<https://health.maryland.gov/laboratories/docs/Guide%20to%20PH%20Lab%20Serv%20v5.0%20Guide%20Updated%202025%20Final.pdf>).

We are committed to finding ways to minimize specimen loss and appreciate you and your patients' willingness to work with us during these challenging times. Should you have any questions, please do not hesitate to contact us (443-681-3930). Also, we encourage you to reach out if you are experiencing ongoing issues with specimen rejections so we can better understand the challenges and work together to develop effective solutions.

Thank you.

CC: Dr. David Blythe