

 **Updated Specimen Acceptance Criteria**

**Effective Immediately- September 05, 2025**

The **Pennsylvania Department of Health Bureau of Laboratories (PADOH BOL)** is committed to advancing public health through high-quality laboratory services. PADOH BOL operates under multiple accreditation standards, including the federally regulated **Clinical Laboratory Improvement Amendments (CLIA)** overseen by the **Centers for Medicare and Medicaid Services (CMS)**.

In accordance with **CLIA regulation §493.1232 Standard: Specimen Identification and Integrity**, PADOH BOL must adhere to the specimen collection, handling, shipping, and integrity guidelines outlined in **FDA-approved test method package inserts**. To ensure compliance, specimens must arrive at the **required temperature** and within the **specified timeframe** to be accepted for testing.

Due to a recent CLIA finding, PADOH BOL is **monitoring the arrival temperatures** of packages containing clinical specimens and isolates to **verify acceptability for testing**.

Effective immediately, **any specimen** that does **not meet** the stated **temperature** and **specimen receipt timeframe** requirements will be **rejected**.

Detailed instructions for specimen collection, storage, and shipping are available in the **PADOH BOL Directory of Services (Test Menu)** on the Pennsylvania Department of Health website. If a requested test is not listed, please contact PADOH BOL directly by calling **610-280-3464** and requesting to speak with the **testing laboratory**.

We appreciate your cooperation and support in helping PADOH BOL maintain the highest standards in laboratory testing for the Commonwealth of Pennsylvania.

Sincerely,



**Wade Aldous, PhD, D (ABMM)**  
**Assistant Bureau Director**  
**Pennsylvania Department of Health | Bureau of Laboratories**