

Pre-Analytical Updates: Molecular and Quantiferon Specimens

8/19/2025

Effective September 1, 2025, molecular (PCR/TMA/HDA) specimens submitted to the NDHHS, Laboratory Services that are received in a biohazard bag with other patients' specimens **will not be tested, and a rejection report will be issued**. *All specimens should be packaged individually in separate biohazard bags with absorbent pads along with the associated test requisition.* Please refer to the [Test Menu](#) on our website for more information.

In addition, QuantiFERON-TB Gold Plus Blood Collection Tubes must be accompanied by a [Pre-Analytical Attestation form](#).

The exception to the form requirement is if ordering the QuantiFERON-TB Gold Plus test on the Laboratory Web Portal where the attestation questions are asked in the portal – *coming soon!*

Federal Centers for Medicare and Medicaid Services (CMS) regulations under CFR §493.1240 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, processed, and shipped to the testing laboratory for the requested test method where cross-contamination is avoided is vitally important to maintain specimen integrity prior to testing.

If you have any questions, please contact Heather Sease, Director of Laboratory Quality Management, at 701.328.6279 or 701.328.6272.