

TENNESSEE MEDICAL LABORATORY BOARD

POLICY STATEMENT

WAIVED TESTING

At the April 28, 2022 board meeting, the Tennessee Board of Medical Laboratories voted to approve this policy statement concerning waived testing that is performed outside the licensed clinical laboratory.

Regarding proficiency testing, the lab must verify the accuracy of waived testing twice a year or enroll with a proficiency testing agency. The performance of proficiency testing can be rotated among the different waived test systems/instruments every six months.

Regarding verification studies, each analyte must perform acceptably during the verification studies/validation prior to being put into use for patient testing. Verification study requirements are the same for all testing regardless of complexity level. Lab directors need to sign off on all validation studies on new procedures. The lab director can delegate validation study approval to the lab supervisor for replacement, or additional instrumentation provided the same instrument or model was used.

Regarding the verification of accuracy, the following options are acceptable:

- Proficiency testing samples
- Split samples
- Test blind/unknown samples

Note: Normal quality control material, with known values, that is run on a regular basis is not acceptable to verify accuracy.

Regarding correlation studies, these studies are burdensome for waived testing and unnecessary.

This policy was adopted on April 28, 2022.