Department of Health
Tennessee Medical Laboratory Board
Policy Statements

The Policy for Enforcement by Board Consultant(s) and Medical Technologist Consultant(s) Staff and Surveyor(s)

Rule 1200-6-3.08(2) of Chapter 1200-6-3 Medical Laboratories relative to Quality Control requirements for clinical laboratories who perform Point of Care testing only, comply as follows:

(2) (a) Meets all applicable quality control requirements specified in this rule; or

(b) Follows manufacturer=s instructions when using their products (instruments, kits, or test systems). In addition, the laboratory must comply with requirements within any paragraph of this rule that are unique to laboratory facility and cannot be met by manufacturer=s instructions.

That rule was broadened to relate to Point of Care Testing within a licensed laboratory facility by stating the following:

> Quality control regulations for Point of Care Testing shall be the same as those listed in the above Rule. AManufacturer=s Instructions@ means the information found on manufacturer=s FDA approved product labeling.

The new policy rule allows medical laboratories to perform quality control checks in the manner and frequency indicated in the diagnostic test=s official FDA approved product labeling. Recent technological advances have made diagnostic testing potentially more reliable.

This information reflects the Board=s policy and the consultant(s) and staff are authorized to interpret and act on this policy.

Adopted this the 16 day of April, 1997, by a majority roll call vote of the members of the Medical Laboratory Board.

The Policy for Enforcement by Board Consultant(s) and Medical Technologist Consultant(s) Staff and Surveyor(s):

Rule 1200-6-3.15(d)(1) of chapter 1200-6-3 Medical Laboratories relative to Alternate Site Testing Requirements for semi-quantitative glucose testing performed by paramedics licensed in Tennessee.

> (d)(1) Individual packages/bottles of reagent strips will be tested upon opening a fresh package and on each shift of use, against liaison laboratory-established high and low controls.

A new policy was established by the Board stating the following:

> When semi-quantitative blood glucose is performed by Paramedics, manufacturer's procedure shall be followed and this shall be the policy of the Board until Rule 1200-6-3-.15 is amended.

This policy is suggested as a minimum and may be more stringent should the Emergency Medical Service deem necessary.

The new policy rule allows Emergency Medical Services Tennessee Licensed Paramedics to perform quality control checks in the manner and frequency indicated in a diagnostic test's official FDA approved produce labeling. Recent technological advances have made diagnostic testing potentially more reliable.

This information reflects the Board's policy and the consultant(s) and staff are authorized to interpret and act on this policy.

Adopted this the 16 day of April, 1997, by a majority roll call vote of the members of the Medical Laboratory Board.

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