

GUIDELINES – POINT-OF-CARE TESTING (POCT) EXEMPTION REQUESTS

Rule 1200-06-03-.16, Rules for Medical Laboratories, Alternate Site Testing is specific regarding alternate site laboratory testing for non-medical laboratory licensed professionals who perform clinical laboratory testing procedures outside the licensed lab.

ALL point of care testing procedures that are not waived by the Medical Laboratory Board **MUST** be approved by board member review during a quarterly board meeting.

BOARD PRESENTATION PACKET:

1. Title Page. (Please include name and address of facility)
2. Statement of medical need for performance outside a laboratory setting.
3. A signature sheet that includes the following information:
 - a) the legible signature of the current medical laboratory director and
 - b) the legible signature(s) of all personnel who share the authority & responsibility for implementing and maintaining the alternate site procedure(s).
4. A complete procedure written in substantial compliance with CLSI (formerly NCCLS) protocol.
5. Analyte & methodology (includes a correlation summary for):
 - a) any new methodology and
 - b) any change in current methodology
6. Quality Assurance Protocol(s) for performance and improvement (frequency of QC, competency, etc).
7. Maintenance of records of testing procedures.
8. Listing of current approved POCT exemptions (preferably in Excel format).
9. Description of education and State licensure category of testing personnel.
10. Competency training proposed for POCT personnel if request is approved by the Board.
11. Listing of all locations the POCT will be utilized.
12. Copy of State issue laboratory facility license.

Board Notification Process:

- Save exemption packet as a pdf file and email to:
sandra.bogard@tn.gov
- Submit one (1) paper copy of the exemption request to the Board's administrative office.

All exemption requests MUST be in the Board's Administrative Office no later than thirty (30) days prior to the scheduled board meeting date. All quarterly board meeting dates are posted on the Medical Laboratory Board's website located at:

<https://www.tn.gov/health/health-program-areas/health-professional-boards/medlab-board/ml-board/meeting-schedule.html>

Incomplete packets may delay the review by the board and may result in the request being deferred to the next scheduled board meeting.

A facility is required to request a point-of-care exemption from the Medical Laboratory Board for the following:

- New instrumentation/methodology
- New location for POCT
- New personnel or department(s)

Remote presentation of POCT exemption request is permitted in the following instances:

- New instrumentation/methodology for facility but, already approved in the State of TN
- New location for POCT for the facility but, already approved in the State of TN.
- New personnel or department(s) for the facility but, already approved in the State of TN.

To verify if an instrument/method, location, or personnel/department has been previously approved for a POCT exemption in the State of TN please contact the Board's Administrative Office.

In person POCT exemption requests are required for:

- Laboratories that are requesting their first POCT exemption.
- New instrument/methodology, location, personnel, or department NOT already approved in the State of TN.

Urgent point-of-care (POCT) exemption requests must meet one of the following criteria:

- New instrumentation/methodology for facility but, already approved in the State of TN.
- New location for POCT for the facility but, already approved in the State of TN.
- New personnel or department(s) for the facility but, already approved in the State of TN.

The Board would make a final determination after review at the next upcoming meeting.

The Point-of-Care Exemption packet would need to indicate that it is an "urgent request".

Should you have any further questions, please call the Board's Administrative Office toll free 1-800-778-4123 EXT. 532-1945.

