

GUIDELINES

POINT OF CARE EXEMPTION PACKETS

FOR ALL OTHER ANATOMIC OR CLINICAL LABORATORY TESTS THAT ARE NOT ON THE WAIVED TEST LIST THE FOLLOWING PROCEDURES MUST BE FOLLOWED:

Rule 1200-6-3-.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 (MINIMUM)

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 NCCLS protocol.
5. Analyte & Methodology

A correlation summary for:

 - a) any new methodology and
 - b) any change in current methodology.
6. Quality Assurance Protocol(s).
7. Maintenance of records of testing procedures.
8. Protocols for performance & improvement (competency).

BOARD NOTIFICATION PROCESS:

1- PLEASE PUT TO **PDF FILE** AND SEND TO:

lynda.England@tn.gov

IN ADDITION

2-A HARD COPY DOCUMENT OF THE EXEMPTION REQUEST WITH ORIGINAL SIGNATURES PLUS FOUR (4) ADDITIONAL HARD COPIES MUST BE SUBMITTED TO:

**TENNESSEE MEDICAL LABORATORY BOARD
ATTN: LYNDA S. ENGLAND BSMT (ASCP), DIRECTOR
227 FRENCH LANDING SUITE 300
HERITAGE PLACE METROCENTER
NASHVILLE, TN 37247**

ALL EXEMPTION REQUESTS (PDF AND HARD COPY MUST BE IN THE BOARD'S ADMINISTRATIVE OFFICE NO LATER THAN THE END OF THE BUSINESS DAY (MONDAY-FRIDAY 4:30 PM CST/CDT) **THIRTY (30) DAYS PRIOR TO THE SCHEDULED BOARD MEETING.** ALL QUARTERLY BOARD MEETING DATES ARE POSTED ON THE HEALTH DEPARTMENT AND MED LAB BOARD'S WEB SITE.

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

SHOULD YOU HAVE FURTHER QUESTIONS, PLEASE CALL THE OFFICE TOLL FREE 1-888-778-4123 EXT. 2-1945.

NOTE: A FACILITY THAT HAS RECEIVED APPROVAL FROM THE BOARD FOR INSTRUMENT/METHOD TO BE USED BY IDENTIFIED PERSONNEL AND/OR DEPARTMENT(S) FOR POINT OF CARE TESTING OF AN ANALYTE DOES NOT HAVE TO APPEAR BEFORE THE BOARD AGAIN TO ADD ANALYTES TO THE APPROVED INSTRUMENT/METHOD AND MAY ADD THEM BY SUBMITTING WRITTEN NOTIFICATION TO THE BOARD'S ADMINISTRATIVE OFFICE.

IT IS ONLY WHEN THE FACILITY WANTS TO CHANGE OR ADD PERSONNEL OR DEPARTMENT(S) TO THE PREVIOUSLY APPROVED INSTRUMENT/METHOD THAT ANOTHER HEARING BEFORE THE BOARD IS REQUIRED.

(Rule 1200-3-6.16 (1) (b) 2. Rules Governing Medical Laboratories)