

Department of Health
Rulemaking Hearing Rules
Tennessee Medical Laboratory Board
Division of Health Related Boards

Chapter 1200-6-3
General Rules Governing Medical Laboratories

Amendments

Rule 1200-6-3-.12 Referral of Cultures to the Department of Health, is amended by deleting subparagraph (1) (o) in its entirety and substituting instead the following language, and is further amended by adding the following language as new subparagraphs (1) (p) and (1) (q) and renumbering the remaining subparagraphs accordingly, so that as amended, the new subparagraphs (1) (o), (1) (p) and (1) (q) shall read:

(1) (o) Escherichia coli O157

(1) (p) Shiga-like toxin producing Escherichia coli non-O157 (STEC)

(1) (q) Shiga-like toxin positive stools and/or EIA positive broth for shiga-like toxin

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-107.

Rule 1200-6-3-.16 Alternate Site Testing, is amended by deleting part (1) (b) 2. in its entirety and substituting instead the following language, so that as amended, the new part (1) (b) 2. shall read:

(1) (b) 2. For all other tests not covered under Part 1 of this subparagraph (above), a facility must petition, and appear before the Board and satisfy the Board that approval for point of care testing is appropriate. A facility that has received approval from the Board for an 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 those 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.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-104, and 68-29-105.

Legal Contact: Robert J. Kraemer, Jr., Deputy General Counsel, Office of General Counsel, 220 Athens Way, Suite 210, Plaza I, MetroCenter, Nashville, TN 37243, (615) 741-1611.

Contact for disk acquisition and/or party who will approve final copy for publication:
 Jerry Kosten, Regulations Manager, Division of Health Related Boards, 1st Floor, Cordell
 Hull Building, 425 5th Avenue North, Nashville, TN 37247-1010, (615) 532-4397.

Signature of the agency officer or officers directly responsible for proposing and/or
 drafting these rules:

Linda Lahr, Chair
 Tennessee Medical Laboratory Board

The roll call vote by the Tennessee Medical Laboratory Board on these rulemaking
 hearing rules was as follows:

Board Members	Aye	No	Abstain	Absent
Thomasa Cooper	_____	_____	_____	_____X_____
Norman Crowe	_____	_____	_____	_____X_____
Yvonne Davis	_____X_____	_____	_____	_____
Martha Duncan	_____X_____	_____	_____	_____
Linda Lahr	_____X_____	_____	_____	_____
Alison K. McDonald-Spakes	_____X_____	_____	_____	_____
Kelly S. Terry	_____	_____	_____	_____X_____
Delores W. Voigt	_____X_____	_____	_____	_____
Dennis C. Carter, M.D.	_____X_____	_____	_____	_____
Jere Ferguson, M.D.	_____X_____	_____	_____	_____
Edward McDonald, M.D.	_____X_____	_____	_____	_____
John C. Neff, M.D.	_____X_____	_____	_____	_____
Vacant	_____	_____	_____	_____

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully

promulgated and adopted by the Tennessee Medical Laboratory Board on the 12th day of January, 2006.

Further, I certify that the provisions of T.C.A. § 4-5-222 have been fully complied with, that these rules are properly presented for filing, a notice of rulemaking hearing has been filed in the Department of State on the 18th day of October, 2005 and such notice of rulemaking hearing having been published in the November 15th, 2005 issue of the Tennessee Administrative Register, and such rulemaking hearing having been conducted pursuant thereto on the 16th day of December, 2005.

Robbie H. Bell, Director
Health Related Boards

Subscribed and sworn to before me this the 12th day of January, 2006.

Notary Public

My commission expires on the 25th day of March, 2006.

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Paul G. Summers
Attorney General and Reporter

The rulemaking hearing rules set out herein were properly filed in the Department of State on the 10th day of July, 2006, and will become effective on the 23rd day of September, 2006.