

Tennessee Medical Laboratory Board Meeting

April 16, 2015

Minutes

Date: April 16, 2015

Time 09:00AM CST/CDT

Location: Tennessee Department of Health
Division of Health Licensure and Regulation
Metro Center Complex, Iris Room, Ground Floor
665 Mainstream Drive
Nashville, TN 37243

Members Present: Cheryl Arnott, S.A.-Cytotechnologist, Chairman
Stephanie Dolsen, Medical Technologist, Supervisor, Vice Chair
Kathleen Kenwright, Medical Technologist, Educator
Patti J. Walton, Hospital/Lab Manager/Adm. Dir.
Carla M. Davis, MD, Pathologist
Tereyo M. Cox, Medical Technologist, General
Mark A. Calarco, DO Independent Lab Manager/Administrator
Jason S. Nolan, MD, Pathologist Non Educator

Members Absent: Royce Joyner, MD, Pathologist Educator
VACANT: Non-Pathologist Physician
VACANT: Citizen Representative
VACANT: Hospital Administrator
VACANT: Medical Technologist Generalist

Staff Present: Lynda S. England, Medical Technologist Consultant, Director, TMLB
Mollie Gass, Advisory Attorney, Office of General Counsel
Devin Wells, Deputy General Counsel, Office of General Counsel
Julia Daniels, Medical Technologist Consultant/ Surveyor, East Tennessee Regional Office
Taylor Carpenter, Medical Technologist Consultant/Surveyor, East Tennessee Regional Office
Richard Carroll, Medical Technologist Consultant/Surveyor, Middle Tennessee Regional Office
Mary Hamblen, Medical Technologist Consultant/Surveyor, West Tennessee Regional Office
Karon Hathcoat, Medical Technologist Consultant/ Surveyor, West Tennessee Regional Office

Staff Absent: Jerry A. Gowen, Medical Technologist Consultant
VACANT: Medical Technologist Consultant/Surveyor, Middle Tennessee Regional Office

CLIA Manager/Representative: Sandra Bogard, CLIA Manager

Presiding Officer: Cheryl Arnott, S.A.-Cytotechnologist, Chairman

Call To Order: The meeting was called to order at 9:00 AM CST/CDT by Cheryl Arnott, S.A.-Cytotechnologist, Chairman

Introductions of Board Members: The Board and staff made their introductions to the public in attendance.

Quorum: Seven members of the Board constitute a quorum. A sufficient number of Board members were present establishing a quorum of the Board.

Approve Minutes:

P & E Committee Meeting **A motion to approve the January 14, 2015 Personnel & Education Committee minutes was made by:** Ms. Kenwright
Second: Ms. Dolsen
Motion approved

Full Board Meeting **A motion to approve the January 15, 2015, Board meeting minutes was made by:** Ms. Walton
Second: Dr. Davis
Motion approved

Board Reports:

Ratification of Initial Determinations of the P&E Committee Meeting: Ms. Kenwright reported the actions of the Board’s Personnel & Education Committee meeting, April 15, 2015.
Motion to ratify: Dr. Nolan
Second: Ms. Dolsen
The actions of the Board’s P&E Committee were ratified as presented.

Contested Cases No Contested Cases were presented.

Consent, Agreed, Compliance Orders & Letters of Reprimand

Consent Orders No Consent Orders were presented

Agreed Orders No Agreed Orders were presented

Compliance Orders Mr. Brett A. Norrod, seeking reinstatement of his revoked Medical Laboratory Technician license was not in attendance when this agenda item was called. This agenda item delayed.

Letters of Reprimand No Letters of Reprimand were presented

Presentations to the Board:

**Tennessee Professional
Peer Assistance Program
(TNPAP):**

Mr. Mike Harkreader, Executive Director of TN PAP presented the TN Pap Report.

For the period July 1, 2014, through March 31, 2015, there were zero (0) individuals being monitored. There were zero (0) referrals. There was one (1) completed file and one (1) being monitored but in noncompliance. The noncompliant individual was reported to the Tennessee Department of Health.

Move to accept the TN PAP report as presented: Ms. Walton
Second: Dr. Nolan

(It is noted the report time period is incorrect showing July 1, 2014 – March 31, 2014. Ms. England stated she would contact TN PAP for a corrected report)

The chairman stated there was a motion on the floor to accept the TN PAP report as presented and this motion was then seconded by Dr. Calarco

Report accepted.

Note: Review of TNPAP materials via internet counts as clock hours toward continuing education credits. A certificate of completion documenting review of these materials can be completed at the end of the internet session. Internet site: www.TNPAP.org

**Financial Report
Lisa Tittle
Discussion**

Ms. Tittle gave a verbal presentation and explanation of the financial statements that reflect and represent the fiscal status of the Medical Laboratory Board.

Motion to accept report: Dr. Davis
Second: Ms. Walton

Report accepted.

**Investigations Report
Nichelle Dorroh
Presentation/Discussion**

Ms. Nichelle Dorroh presented the investigations report to the Committee. There were no complaint cases and the office is monitoring six (6) other cases. Ms. Dorroh asked if there were any questions or requests from the Committee. There were none.

Motion to accept report: Ms. Dolsen
Second: Ms. Cox

Report accepted.

(Agenda moved back to Tab 12, Consent Orders)

Compliance Orders

Mr. Brett Norrod, having business before the board, was recognized in the audience. That business had been held over earlier to be settled upon his arrival. Being heard under compliance orders is his request to lift the revoked status on his license.

Mr. Norrod's license was revoked April 17, 2014, having being convicted of a felony. As a stipulation of that revocation, his revoked license could not be reinstated without Board approval and reinstatement could not take place less than one year from the date of revocation.

Having met compliance with the stipulations set forth in the Board Order, the Board took the following action:

Move to lift the revoked status on Mr. Norrod's license; thus, allowing for reinstatement of said license: Ms. Kenwright

Second: Ms. Dolsen

Motion Approved with Dr. Calarco abstaining

(As a point of information, Ms. England clarified that the one year period would not be satisfied until April 17, 2015. In addition, having just gone live on the new Computer system would delay the reinstatement even further. Mr. Norrod's reinstatement will take place as soon as all parameters are satisfied)

(Ms. England requested chair to move agenda forward to Tab Q-8)

Discuss, review and take action, if needed, regarding, but not limited to the following:

Q8 EMS request to transport & hang X-Matched blood via ground service for patient in-route to another hospital

Ms. Donna Tidwell, State EMS Director, requested the endorsement of the Medical Laboratory Board for critical care EMS personnel to transport, monitor and hang blood for transfusion in the event that the blood might be needed for transfusion in-route during the patient transport from one facility to another.

It was determined that this could be an acceptable practice under the Rules for Medical Laboratories 1200-06-03-09, with the operational details clearly explained in a memorandum of understanding (MOU) among all concerned parties, i.e. The transferring hospital/facility; the EMS area provider; the receiving hospital/facility; and the State EMS/BHLR when and where appropriate.

Motion to Approve a practice change to allow critical care EMS personnel to hang and administer blood during transport. The basis for this motion and more detailed information is contained within Rule 1200-06-03-.09(34a through 34f). Ms. Dolsen
Second: Dr. Nolan

Motion approved.

(Ms. England requested chair to resume normal agenda at Tab 15O1)

Ratifications: The following items were presented to board members for ratification per staff, state surveyor or facility request:

Exemptions for point of care testing procedures (POCT) in a licensed Facility

**1: Mid-South Transplant Foundation, INC.
Memphis, TN 38018**

Requests a modification of previous exemptions granted in (2009 and 2012) to allow a Certified Organ Procurement Specialist to perform and report Blood Gasses and Troponin utilizing the Abbott i-Stat Analyzer.

Questions concerning the educational background of a Certified Organ Procurement Specialist were asked but not answered. The Committee members needed additional information.

Motion to table request until the July, 2015: Ms. Dolsen

Second: Ms. Kenwright

Motion to Send to the Table approved

(The Chair called for a break to complete some administrative duties [photocopies] to facilitate the next business item)

**2: Region One Health Systems and Outpatient Center
Memphis, TN 38013**

The Board reviewed and approved the following exemption requests utilizing the Abbott i-STAT:

1. Add activated clotting times (ACT's) to a previously granted exemption to be performed and reported by registered Cardiac Invasive specialists and registered nurses in the Interventional Radiology/Cardiac Catheterization Laboratory, and
2. Activated clotting times (ACT's) performed and reported by registered Cardiac Invasive specialists and Registered Nurses in the Chandler Operating Room, and
3. Activated clotting times (ACT's) performed and reported by registered Cardiac Invasive specialists and Registered Nurses in the Region One Outpatient Center.

Motion to approve exemption #1: Ms. Walton

Second: Dr. Calarco

Motion to approve exemption #2: Ms. Kenwright

Second: Ms. Walton

Motion to approve exemption #3: Ms. Kenwright

Second: Ms. Cox.

Motions 1-3 approved

**3. Parkridge Medical Center
Chattanooga, TN 37404**

The Board reviewed and approved the following exemption requests utilizing the Osmetech Opti Analyzer:

- The addition of another POC location to a Board approved request in 2005 for Clinical Licensed Perfusionists to perform and report electrolytes, arterial blood gases, Hgb, SO2 and glucose testing during cardiopulmonary bypass surgery in the Surgical Services Department.

Motion to approve exemption: Ms. Walton

Second: Ms. Dolsen

Exemption approved

**4. University Health Systems,
Inc. POCT
Knoxville, TN 37920**

Requests an exemption to allow Registered Nurses to perform and report the following Liver Function Testing in the Viral Hemorrhagic Fever Unit, at the patient bedside, utilizing the Piccolo Express Analyzer:

1. Liver Panel Plus:
2. Albumin
3. Alkaline Phosphatase
4. ALT
5. Amylase
6. AST
7. Total Bilirubin
8. GGT
9. Total Protein

Having questions and no one representing this exemption the committee did not wish to act upon the request.

Motion to table exemption until the July 16, 2015 Board Meeting:

Ms. Walton

Second: Ms. Cox

Motion to send to the table approved

**Direct more than three (3)
Laboratories**

To direct more than three (3) Clinical laboratory facilities in the State of Tennessee requires approval by the Medical Laboratory Board. **Venk Mani, MD** requested such approval. The laboratories Dr. Mani listed to be the director were:

1. TriStar Horizon Medical Center – Dickson, TN
2. Dickson Medical Associates – Dickson, TN
3. Houston County Community Hospital – Erin, TN
4. TriStar Horizon Emergency Dept.* – Natchez Park, Dickson, TN

Approval was based on the close proximity of these clinical laboratory sites, as well as work load and laboratory menu.

Move approval for directing more than three (3) clinical laboratories: Dr. Nolan

Second: Dr. Davis

Approved to direct more than three (3) clinical laboratories

**The Emergency Room Department site must be licensed as a separate location because the physical location of the facility is located off campus from any of the other three (3) laboratory locations. An application for a State facility license will need to be submitted once the laboratory is up and in operation.*

Discuss, review and take action, if needed, regarding, but not limited to the following:

Review/Revise Policy-Patient Test Management Reports of April 11, 2011

This policy was/is being revised and several questions were asked at the last meeting which could not be answered at that time; thus, the topic was sent to the table until the present meeting.

1. Is the laboratory testing performed as a part of research or manufacturing considered to be patient testing and can the results of that testing be requested by the patient in accordance with CMS requirements. (Answer) It is considered so by legal counsel. It is clinical laboratory testing and can be requested by patient.
2. Recording responsiveness to the patient's request for their laboratory results. (Answer) The laboratory must respond to the patients request within and no later than thirty (30) days.
3. Adoption of policy. (Answer) Recommend adoption of policy as written without FAQ. The FAQ was never intended to be part of the policy.
- 4.

Move that policy be adopted as written: Ms. Walton

Second: Ms. Dolsen

Motion approved

Vanderbilt University Medical Center – Nashville, TN Stem Cell Laboratory Issue

The Board asked representatives of Vanderbilt University Laboratory to attend the Board Meeting to participate in clarifying an early board action which required the Stem Cell Laboratory to use licensed personnel in the processing of Stem Cells.

Move to clarify an earlier motion that the processing of stem cells, to include storing, thawing and shipping is not considered preparatory portions of testing, pursuant to 1200-06-03-.19, and requires the use of licensed personnel Ms. Walton

Second: Ms. Cox

Motion Approved.

Discuss Licensure of Mother's Milk Bank Collection Facility

After discussion the Board did not have enough information to take any action.

Move that this topic be sent to the table until such time as a representative can be present to answer any question:

Ms. Walton

Second: Ms. Dolsen

Motion Approved

Review/Revisit Lifeline Screening Sponsors for TN Statewide

The Life Line Screening Program is no longer associated with the Larry King Foundation. After discussion the Board accepted the American Nurse Practitioner Foundation as their partner.

Health Fairs/Health Screens

Move to accept the American Nurse Practitioner Foundation (APNF) as Sponsor along with Life Line to conduct Health Fairs/Health Screens: Ms. Dolsen
Second: Dr. Davis

Motion Approved.

Consider Rule Making for 1200-06-01-.1(22) and 1200-06-03-.08(d) (5) relative to pathologists reading slides/location of diagnosis.

This topic was discussed but the members decided they needed more input and research before making any moves or changes

Motion to continue researching this topic with the intent to bring forward to possibly a taskforce and then to the BME: Dr. Davis

Second: Dr. Nolan

Motion Approved

Statutes/Rules for submission of non-pathogenic Specimens to Tennessee from outside the United States

After discussion, the following motion was submitted

Move that so long as international, Federal and State law is followed this is an acceptable practice: Dr. Nolan

Second: Dr. Davis

Motion Approved

Chiropractic Physicians performing Urinalysis testing in their offices

Tiffany Stevens, Executive Director of the Tennessee Chiropractic Association, came before the Board. The inquiry was concerned with the performance of Urinalysis.

(The Chair called for a break to complete some administrative duties to facilitate this business item)

Two practicing Chiropractic physicians, Drs. Hozenfelt and Cole also appeared before the Board.

Based upon information learned in the meeting the Board moves that Chiropractic Physicians may obtain urinalysis specimens in their offices and refer them out to intrastate laboratories licensed by this Board: Ms. Walton

Second: Ms. Kenwright

Motion Approved based upon statutes §§ 68-29-104(2) and 68-29-103(19). Chiropractic physicians do not fall under the POL exemption.

(Item Tab Q-9 skipped)

Approval of Laboratory Director

None to Present

**RECEIVE REPORTS AND /OR
REQUESTS:**

Board Director's Report

Ms. England gave her report covering January 1, 2015 thru March 31, 2015.

A statistical report was given and Ms. England elaborated on TSAC Suspension.

Motion to accept Director's report: Ms. Walton

Second: Ms. Cox

Report accepted

(Copy of report is on file in the Administrative Office)

REINSTATEMENT OF LICENSES

Nothing to present

**ADDITIONS/DELETIONS TO THE
BOARD'S WAIVED TEST LIST**

Nothing to present

**Office of General Counsel's
Report: Mr. Wells**

There are two (2) open cases in OGC.

Rules for Tenn. Comp R. & Rags. 1200-06003-.22, RE: Esoteric Laboratories have been approved by the Attorney General's Office. These rules have an effective date of June 30, 2015.

Personnel Rules 1200-06-01 are in internal review.

SB0851/HB1100: Regarding ACO's to be established. These are not State enacted boards; thus, they should have no effect on the TMLB.

Mr. Wells discussed an anti-trust case before the Supreme Court regarding teeth whitening. Should have no bearing upon this board.

Motion to accept Counsel's report: Dr. Davis

Second: Dr. Calarco

Report accepted

(Copy of report is on file in the Administrative Office)

Regional Surveyors Reports

Complaint Investigations and proficiency testing (East, West and Middle TN)

**ETRO Report
Julia Daniels**

East TN Regional Office: Taylor Carpenter for the first quarter of 2015.

Unsatisfactory/ Unsuccessful Proficiency Testing: One (1) with acceptable plans of correction.

Complaint Investigations: Zero (0)

**MTRO Report
Richard Carroll**

Middle TN Regional Office: Richard Carroll for the first quarter of 2015.

Unsatisfactory/Unsuccessful Proficiency Testing: Zero (0)
Complaint Investigations: Zero (0)

**WTRO Report
Mary Hamblen**

West TN Regional Office: Mary Hamblen for the first quarter of 2015.

First unsuccessful occurrence of PT: One (1)
Second unsuccessful occurrence of PT: One (1)
Complaint Investigations: Zero (0)

Move to accept regional surveyor's reports as presented:

Ms. Walton

Second: Ms. Dolsen

Reports accepted

**Board Ratification of Laboratory
Initial License:**

**Industry Lab Diagnostic
Partners, LLC
8122 Sawyer Brown Road
Suite#210
Nashville, TN 37211**

Medical Director:

Theodore Feintuch, MD
Anatomic and Clinical Pathology

Specialties:

Toxicology, Routine Chemistry
(Creatinine)

Surveyor:

Richard Carroll
Consultant 2/Surveyor MTRO

Move to approve license: Ms. Kenwright

Second: Ms. Walton

Licenses Approved

**Erlanger Bledsoe Sequatchie
Valley Emergency
Department
16931 Rankin Avenue
Dunlap, TN 37327**

Medical Director:

Steven LaRue, MD
Anatomic and Clinical Pathology

Specialties:

Hematology, General
Immunology, Clinical Chemistry,
Urinalysis, Toxicology, pH and
Blood Gasses

Surveyor:

Richard Carroll/Onezean Otey
Consultant II/Surveyor MTRO

Move to approve license: Dr. Davis

Second: Dr. Nolan

Licenses Approved

**St. Thomas West Hospital
POCT
4220 Harding Road
Nashville, TN 37205**

Medical Director: Peter F. Jelsma, MD
Anatomic and Clinical Pathology
Transfusion Medicine

Specialties: All previous POCT testing
procedures granted under the
laboratory license to be moved
under this license

Surveyor: Richard Carroll
Consultant II/Surveyor MTRO

Move to approve license: Dr. Nolan

Second: Ms. Walton

Abstain: Dr. Davis

Licenses Approved

**CSL Plasma, Inc
1628 South Middle TN Blvd
Murfreesboro, TN 37130**

Medical Director: Kevin O. Dennis, MD
Family Practice

Specialties: Plasmapheresis Center
Total Serum Protein

Surveyor: Richard Carroll
Consultant II/Surveyor MTRO

Move to approve license: Ms. Dolsen

Second: Ms. Walton

Abstain: Dr. Calarco

Licenses Approved

**Samaritan Labs
d/b/a Asperio Laboratories
4715 Trader's Way, STE 201
Thompson Station, TN**

Medical Director: Stuart C. Bogema, Jr. Ph.D
Director – Toxicology
American Board Forensic
Toxicology
American Board of Clinical
Chemistry

**Specialties:
(Esoteric Lab)** Toxicology, Molecular
Diagnostics (Pharmacogenetics)

Surveyor: Richard Carroll

Move to approve license: Ms. Walton

Second: Ms. Dolsen

Licenses Approved

**East TN. Pathways
4845 West AJ Highway
Morristown, TN 37814**

Medical Director: Kevin Catney, MD
Internal Medicine

Specialty: Collection Station

Surveyor: Julia Daniels
Consultant II/Surveyor ETRO

Move to approve license: Dr. Nolan

Second: Ms. Walton

Licenses Approved

**PCLS@Joel T. Hargrove, M.D.
820 Hatcher Lane
Columbia, TN 38401**

Medical Director: Phillip A. Newman, DO
Osteopathic Medicine
Emergency Medicine

Specialty: Collection Station

Surveyor: Richard Carroll
Consultant II/Surveyor MTRO

Move to approve license: Ms. Kenwright

Second: Dr. Calarco

Licenses Approved

**Providence Laboratory
Diagnostics
201 Jordon Road, STE 120
Franklin, TN 37067**

Medical Director: Charles B. Bramlett, Jr. MD
Anatomic/Clinical Pathology

Specialty: Clinical Chemistry,
Endocrinology, Hematology

Surveyor: Richard Carroll
Consultant II/Surveyor MTRO

Move to approve license: Dr. Davis

Second: Ms. Kenwright

Licenses Approved

PCLS@Bowdoin Smith, D.O. –

Medical Director: Phillip A. Newman, D.O.

**Carthage, TN 37030-2151
9 Maggart Circle
Carthage, TN 37030-2151**

Emergency Medicine

Specialty:

Collection Station

Surveyor:

Richard Carroll
Consultant II/Surveyor MTRO

Move to approve license: Ms. Walton

Second: Dr. Nolan

Licenses Approved

**Blood Assurance Donor
Station – Kingsport
300 Clinchfield ST. STE 320
Kingsport, TN 37660**

Medical Director:

Elizabeth Culler, MD

Specialty:

Hemoglobin

Surveyor:

Julia Daniels
Consultant II/Surveyor ETRO

Move to approve license: Ms. Dolsen

Second: Ms. Cox

Licenses Approved

OTHER BUSINESS:

Clarification of 1200-06-03-.09 and 1200-06-03-.06 pertaining to use of External/Internal QC to Meet daily testing events.

Electronic QC is satisfactory to use so long as manufacturers specifications are followed.

Use of POCT Strips taken off market by FDA 04/2014. Need for statement from FDA before use even though Manufacturer say ok to use?

The Alere Instruments were discontinued due to the test strips. Manufacturer says OK to use. No FDA Notification. Board says FDA must show a release before labs can use.

VERSA Live

Ms. England asked that everyone be patient during the "GO LIVE" of the VERSA System.

Return Agenda to Tab Q-9

Wording Change for Rule Change 1200-06-01-.22(h)

A wording change for the personnel rules revision was presented by Ms. Gass. The Board asked Tennessee be removed.

Move to approve proposed language in 1200-06-01-.22(h) : Ms. Walton

Second: Ms. Walton

Motion Approved

Statement of Next Meeting

The next Board Meeting will be July 16, 2015, and will begin at 9AM CDT in the Iris Conference Room, Ground Floor, MetroCenter Complex, 665 Mainstream Drive, Nashville, TN 37243