

**Tennessee Medical Laboratory Board Meeting**  
**January 15, 2015**  
**Minutes**

**Date:** January 15, 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

**Members Absent:** Jason S. Nolan, MD, Pathologist Non Educator  
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  
Jerry A. Gowen, Medical Technologist Consultant  
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

**Staff Absent:** VACANT: Medical Technologist Consultant/Surveyor, Middle Tennessee Regional Office  
Karon Hathcoat, Medical Technologist Consultant/ Surveyor, West 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 Chair recognized Devin Wells, Deputy General Counsel, Office of General Counsel, who will be replacing Ms. Mollie Gass as the Medical Laboratory advisory attorney. 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.

**Announcements by Ms. England, Board Director:**

Ms. England announced the meeting today, January 15, 2015, is the first Medical Laboratory Board Meeting that is being live streamed to the internet.

Also of note, is today's meeting marks the 25<sup>th</sup> Board Meeting since the Board was established.

Mr. Onzean Otey, surveyor for the Middle Tennessee Regional Office has retired from State Government and is no longer with the Medical Laboratory Board.

**Approve Minutes:**

**P & E Committee Meeting**

A motion to approve the October 15, 2014 Personnel & Education Committee minutes was made by: Ms. Kenwright  
Second: Ms. Walton

**Motion approved**

**Full Board Meeting**

A motion to approve the October 16, 2014, Board meeting minutes was made by: Dr. Davis  
Second: Ms. Dolsen

**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, January 14, 2015.

Motion to ratify: Ms. Walton  
Second: Dr. Calarco

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

<b>Agreed Orders</b>	No Agreed Orders were presented
<b>Compliance Orders</b>	No Orders of Compliance were presented
<b>Letters of Reprimand</b>	No Letters of Reprimand were presented

**Presentations to the Board:**

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

Mr. Mike Harkreader, Executive Director of TnPAP presented the TNPap Report.

For the period July 1, 2014, through December 31, 2014, 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 TnPAP report as presented:** Ms. Kenwright  
**Second:** Ms. Dolsen

**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](http://www.TNPAP.org)*

**Financial Report Vanessa Crutcher Discussion**

Ms. England reported there were no changes since the October report and asked the Board to approve the October report as the January report with no changes.

**Motion to accept report:** Ms. Kenwright  
**Second:** Dr. Davis

**Report accepted.**

*(The Investigations report was inadvertently skipped on the agenda and given later in the meeting)*

**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: **Methodist Medical Center Oak Ridge, TN 37830**

Requests a new exemption to allow licensed Respiratory Therapists to perform and report Lactic Acid, housewide, testing using the CG4+ cartridge on the Abbott i-Stat.

**Motion to approve exemption:** Ms. Dolsen

**Second:** Ms. Walton

**Exemption approved**

- 2: **TriStar Southern Hills  
Medical Center  
Nashville, TN 37211**

Requests a modification of a previous exemption to allow Registered Nurses in the Cardiac Catheterization Laboratory to perform and report oxygen saturations utilizing the AVOXIMETER 1000E replacing the methodology from the Abbott i-STAT

**Motion to approve exemption:** Ms. Walton

**Second:** Ms. Dolsen

**Exemption approved**

3. **University Medical Center  
Lebanon, TN 37087**

*(Notation: This request was initiated in correct order; however, due to questions that could not be answered by the presenter, the request was delayed to allow the presenter to contact the institution for a response to the questions posed.)*

Requests a modification from a previous exemption to allow the performance and reporting of Activated Clotting Times (c-ACT) utilizing the Helena Cascade POC analyzer and the c-ACT test cards. The current exemption is for the surgical suite location and would add the cardiac catheterization Laboratory. Currently the testing is limited to Registered Nurses but the facility is requesting the addition of a registered cardio-vascular invasive specialist and Licensed Practical Nurses.

Representatives returned to the meeting with the credentials of the cardio-vascular invasive specialist. Credentials are consistent with previous approved exemptions.

**Motion to approve exemption:** Ms. Walton

**Second:** Ms. Dolsen

**Exemption approved**

4. **The Jackson Clinic, PA,  
North  
Jackson, TN 38305**

Requests an exemption to allow the performance and reporting of finger stick whole blood PT/INR by Registered Nurses in the Coumadin Clinic, utilizing the Hemochron Signatruue Elite.

**Motion to approve exemption:** Ms. Walton

**Second:** Dr. Davis

**Exemption approved**

5. **Parkridge Medical Center  
McCallie  
Chattanooga, TN 37404**

Requests an exemption for selected Registered Nurses (selected to work in the designated isolation area) to perform and report Chem 8, pH, PCO<sub>2</sub>, PO<sub>2</sub> and TCO<sub>2</sub>, utilizing the Abbott i-Stat on suspected ebola patients

**Motion to approve exemption:** Ms. Dolsen

**Second:** Ms. Walton

**Exemption approved**

6. St. Francis Hospital  
Memphis, TN 38119

Request to add to previous exemption the addition of Registered Nurses on the Ebola Care Team to the existing exemption for ER Registered Nurses and perfusionist to perform i-Stat testing at the patient bedside in the Ebola isolation unit.

Motion to approve exemption: Ms. Kenwright

Second: Ms. Walton

Exemption approved

Direct more than three (3)  
Laboratories

No requests

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

**Review/Revise Policy-Patient  
Test Management Reports of  
April 14, 2014**

Policy is being updated to be compliant with the CMS requirements. There were several questions that called for more research into the topic thus the topic of discussion was tabled.

Move that the topic be sent to the Table: Ms. Kenwright

Second: Ms. Walton

Motion to send to the Table approved

**Autologous Leukapheresis Blood  
Sampling,  
Manufacture/Relationship to  
State License.**

Question concerns the providing of autologous leukapheresis collection services for other companies to collect cancerous WBC's and to ship back to original company for their treatment to raise the activation level of the WBC's provided for autologous use. There is no infectious disease testing required.

**Medic Regional Blood Center  
Knoxville, TN**

Medic, a Licensed Tennessee Laboratory/Blood Center, has no role in qualifying donors, testing the donor or the final product, manufacturing the product or infusing the product back into the autologous donor.

Motion that the product question from Medic Regional Blood Center is outside the prevue of the Tennessee Medical

Laboratory Board: Ms. Kenwright

Second: Ms. Walton

Motion Approved.

*(Present license is unaffected by the manufacturing process described)*

**Nuclear Medicine/Radiobioassay  
VS. State Licensure:  
St. Thomas West  
Nashville, TN**

The question is whether or not blood volume in-vivo testing should be considered a laboratory point of care test performed in nuclear medicine or is it a medical procedure not regulated by the Medical Laboratory Board?

Move that Nuclear Blood Volume Testing is not considered to be a laboratory test, rather a medical procedure and is not regulated

by the Tennessee Medical Laboratory Board: Dr. Calarco

Second: Ms. Walton

Abstain: Dr. Davis

Motion Approved

**Review guidelines for Director  
Licensing per TCA§68-29-138 in  
Esoteric Laboratories**

Nothing to present at this meeting and to be represented during the April, 2015 meeting.

No action needed or taken

**Revisit VUMC Stem Cell  
Laboratory Personnel Issue**

Ms. Gass elaborated on the previous decision by the Board, prompted by a question from Vanderbilt University Medical Center representatives, regarding whether or not persons working in Stem Cell processing laboratory needed to be licensed or not licensed.

Clarifications regarding the previous decision:

TCA§68-29-103: Definitions of the practice act and the definition of a laboratory.

Under the Rules 1200-06-03-19: Preparatory functions of laboratory testing.

No decisions or determinations can be made on the available information and representatives from VUMC are invited to attend the April meeting to clarify the issues brought forth.

Motion to send to the Table until representatives from  
Vanderbilt University Medical Center can be present: Dr. Davis  
Second: Ms. Walton

Motion to send to the Table approved.

**Discuss facility license necessity  
in location(s): Facility A where  
Case/Slides originate; Facility B  
with lab report containing name  
of Facility B**

After discussion it was determined that more information is needed from all groups concerned, (ie. CLIA, CAP, Tennessee Pathology Association, etc.) is needed before a final decision is made on this subject.

No action taken at this time.

**Review/Revise rules rewrite  
1200-06-01**

*This topic is delayed until the end of the meeting after all other business is completed*

*Chair called for a 20 minute break at 11:00AM*

*Chair called the meeting back in session at 11:20AM*

*(It is noted the Investigations report was not covered earlier and is now presented)*

**Investigations Report  
Nichelle Dorroh, Office of  
Investigations**

The investigations report was inadvertently missed earlier and Ms. Dorroh had to leave the meeting. Ms. England gave the report and stated that one (1) open case remained in investigations.

**Approval of Laboratory Director**

**Mary M. Mayo, Ph.D**  
**Mt. Juliet, TN 37122**  
**Director - General**

**Motion to accept Investigation Report:** Ms. Walton

**Second:** Dr. Calarco

**Report accepted.**

**Application:** Director – General (Upgrade from Director – Chemistry)

**Degree:** Awarded the BS in Chemistry, 1970-1974, Hope College, Holland Michigan, Master of Science, 1977, and the Doctor of Philosophy, 1979, in Biological Chemistry, from the University of Michigan at Ann Arbor.

**Training Program:** The American Board of Clinical Chemistry requires candidates to document at least five (5) years, full time/equivalent part time, diverse professional experience in clinical chemistry. Applicant may elaborate.

**Certification:** Diplomate of the American Board of Bioanalysis (ABB) 10/17/2014 as a BCLD with an expiration date of December 31, 2015.

**File Status:** All other qualifying documents are present in the file

**Motion to approve license:** Ms. Dolsen

**Second:** Dr. Davis

**License approved**

**RECEIVE REPORTS AND /OR  
REQUESTS:**

**Board Director's Report**

Ms. England gave her report covering October 1, 2014 thru December 31, 2014.

She pointed out the Board Dates now published. Dr. Miller has indicated he will no longer be able to serve the Board and will not accept reappointment.

A statistical report was given.

**Motion to accept Director's report:** Ms. Kenwright

**Second:** Dr. Calarco

**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: Ms. Gass**

There is one open case in OGC.

The rules rewrite for Medical Laboratory Personnel are being discussed. If completed they will be forward to internal review.

The legislature is in session; however, there are no Bills affecting the Medical Laboratory Board as of the present date.

**Motion to accept Counsel's report:** Ms. Walton

**Second:** Ms. Cox

**Report accepted**

**Regional Surveyors Reports**  
Complaint Investigations and proficiency testing (East, West and Middle TN)

**ETRO Report**  
**Taylor Carpenter**

East TN Regional Office: Taylor Carpenter for the fourth quarter of 2014.

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 fourth quarter of 2014.

Unsatisfactory/Unsuccessful Proficiency Testing: One (1)

Complaint Investigations: Zero (0)

**WTRO Report**  
**Mary Hamblen**

West TN Regional Office: Mary Hamblen for the fourth quarter of 2014.

First unsuccessful occurrence of PT: Zero (0)

Complaint Investigations: Zero (0)

**Move to accept regional surveyor's reports as presented:**

Ms. Kenwright

**Second:** Ms. Dolsen

**Reports accepted**

**Board Ratification of Laboratory  
Initial License:**

**Genome Explorations, Inc**  
**654 Jefferson Avenue**  
**Memphis, TN 38105**

Application/licensure is denied based upon TCA§68-29-126(12).

This motion came about by conversation of the history of this application and that Genome Exploration, Inc had not continued to keep the office up to date as to their progress towards the direction given by this board. They have been given ample time to produce a director of the laboratory which meets requirements in Rule 1200-06-01 and different ways to achieve this requirement. Since the last meeting, there has been no communication from GE and it is the opinion of the board that the

application is not moving forward; thus, after working with this laboratory more than a year, it is time to make a decision and that decision is to deny the application thus the license to Genome Explorations. If they take issue with this decision, then they have avenues to challenge. If they so choose, they can make reapplication for a license in the future.

Move that Initial License be denied: Ms. Walton

Second: Dr. Davis

Initial License denied.

**Atherotech**  
113 North Main Street  
Bulls Gap, TN 37701

**Medical Director:** Mark R. Davenport, MD  
Physician

**Specialties:** Collection Station

**Surveyor:** Julia Daniels  
Consultant 2/Surveyor ETRO

Move to approve license: Dr. Calarco

Second: Ms. Cox

Licenses Approved

**Insight Diagnostics, LLC**  
357 Riverside Drive STE 1004  
Franklin, TN 37064

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

**Specialties:** Toxicology & Molecular  
Diagnostics; Related  
Pharmacogenetics; Esoteric  
Testing Procedures

**Surveyor:** Richard Carroll  
Consultant 1/Surveyor MTRO

Move to approve license pending CAP: Ms. Walton

Second: Dr. Davis

Licenses Approved Pending CAP

**OTHER BUSINESS:**

**Election of Officers:**

The Election for Officers of the Tennessee Medical Laboratory Board was held. Rules require the election of a chairman and a vice chairman for the year 2015.

The name of the current chairman, Cheryl Arnott, was nominated

by Ms. Cox and seconded by Ms. Dolsen. Ms. Arnott accepted the nomination. No other nominees were presented and Ms. Arnott was elected by acclamation.

The name of the current vice-chairman, Ms. Dolsen, was nominated by Ms. Kenwright and seconded by Dr. Calarco. Ms. Dolsen accepted the nomination. No other nominees were presented and Ms. Arnott was elected by acclamation

**Statement of Next Meeting**

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

**Record of Adjournment**

With no further business to discuss, the meeting was adjourned at 1:20 PM CST/CDT on a motion properly presented by Dr. Davis and seconded by Ms. Kenwright. The motion to adjourn was unanimously approved.

by Ms. Cox and seconded by Ms. Dolsen. Ms. Arnott accepted the nomination. No other nominees were presented and Ms. Arnott was elected by acclamation.

The name of the current vice-chairman, Ms. Dolsen, was nominated by Ms. Kenwright and seconded by Dr. Calarco. Ms. Dolsen accepted the nomination. No other nominees were presented and Ms. Arnott was elected by acclamation

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