

Tennessee Medical Laboratory Board Meeting

October 16, 2014

Minutes

Date: October 16, 2014

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: Stephanie Dolsen, Medical Technologist, Supervisor, Vice Chair
Kathleen Kenwright, Medical Technologist, Educator
Patti J. Walton, Hospital/Lab Manager/Adm. Dir.
Jason S. Nolan, MD, Pathologist Non Educator
Carla M. Davis, MD, Pathologist
Royce Joyner, MD, Pathologist Educator
Tereyo M. Cox, Medical Technologist, General
Jerry Lee Miller, MD Non-Pathologist Physician
Mark A. Calarco, DO Independent Lab Manager/Administrator

Members Absent: Cheryl Arnott, S.A.-Cytotechnologist, Chairman
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
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: Onezean Otey, Jr., 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: Stephanie Dolsen, Medical Technologist, Supervisor, Vice Chair

Call To Order: The meeting was called to order at 9:00 AM CST/CDT by Stephanie Dolsen, Medical Technologist, Supervisor, Vice Chair

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 July 17, 2014, Personnel & Education Committee minutes was made by:** Dr. Joyner
Second: Ms. Kenwright
Motion approved

Full Board Meeting **A motion to approve the July 18, 2014, Board meeting minutes was made by:** Dr. Miller
Second: Dr. Nolan
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, October 15, 2014.
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 Jeff C. Wagner, Medical Technologist - General
Madison, TN
License #21165
Violation of Continuing Education Requirements
License reprimanded, Must complete all delinquent continuing education and any other continuing education required by policy due to the delinquency, must pay actual and reasonable costs of prosecuting the case which is due within six (6) months from the issuance of the Assessment of Costs
Motion to accept Consent Order: Ms. Kenwright
Second: Dr. Joyner
Consent order accepted by the Board

Agreed Orders No Agreed Orders were presented

Compliance Orders No Orders of Compliance were presented

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 TnPAP presented the TNPap Report.

For the period July 1, 2013, through June 30, 2014, there was one (2) individuals being monitored. There were four (4) referrals, one (1) from an employer, two (2) referrals from the TDOH and one (1) self referral. The reasons for these referrals were due to an arrest/conviction or from a workplace positive UDS+. One individual declined services (TDOH Notified), One was evaluated and declined recommendations (TDOH Notified), One and was evaluated and monitoring was not recommended, and the other was in monitoring noncompliance (TDOH Notified). Those declining services or recommendations were reported to the Tennessee Department of Health, as indicated.

Move to accept the TnPAP report as presented: Dr. Davis

Second: Ms. Kenwright

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
Vanessa Crutcher
Discussion**

No Report. The year-end statistics have not been released.

(Ms. England, having made the financial report asked the chair to allow the Director's report, Tab S, to be given at this time. The chair recognized Ms. England to give the Director's report)

Board Director's Report

Ms. England gave a verbal report from the Director's Office. Ms. England also imparted information learned regarding the Ebola guidelines from a phone meeting with Commissioner Dreyzehner. Presently, there are no confirmed cases of Ebola Virus in Tennessee. General guidelines are the Central Point of Contact is the Tennessee Department of Health. Follow best practices guidelines and sentinel events protocol. Utilize PPE and use it correctly. Not using PPE is to be treated as a violation of laboratory practice and is to be addressed aggressively by the laboratory administration as well as the Medical Laboratory Board. Have POC needs addressed for Ebola before the need presents itself. Other information was given as far as presentation in the Emergency Department, symptomology and handling of the patient, but this was general information and not necessarily pertinent to medical laboratory practice or intervention. A webinar

to be conducted the next day was announced for those interested and in attendance. It is up to medical professionals to provide and act from factual information. There is no place for rumor, panic or other non-factual information or actions. Any direct testing of the Ebola Virus must be directed and approved by the TDOH and CDC.

Motion to accept Director's Report: Ms. Kenwright

Second: Dr. Nolan

Report accepted.

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

(The chair resumed the correct agenda order)

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: **Roane Medical Center
8045 Roane Med Ctr. Dr.
Harriman, TN 37748**

Requests a new exemption to allow Cardiac Catheterization Lab Registered Nurses to perform and report ACT levels using the Abbott I-Stat with an ACT Celite Cartridge in the Cardiac Catheterization Laboratory.

Motion to approve exemption: Ms. Walton

Second: Dr. Joyner

Exemption approved

2: **Jackson Madison County
General Hospital
Jackson, TN 38301**

(1) Exemption to allow State Licensed Perfusionist to perform and report heparin assays and heparin dose response assays, utilizing the Medtronic Hemostasis Management Plus Instrumentation, facility wide.

Motion to approve exemption: Dr. Miller

Second: Ms. Kenwright

Exemption approved

(2) Request for an extension to a previous exemption to allow State Licensed Perfusionist to perform and report activated clotting times (ACT) assays, utilizing the Medtronic ACT Plus and whole blood samples, facility wide.

Motion to approve exemption: Dr. Nolan

Second: Ms. Walton

Exemption Extension approved

3. **Methodist Medical Center
Oak Ridge, TN 37830**

Exemption to allow licensed Respiratory Therapists to perform and report pH analysis of plural fluid using the ABL Radiometer 800.

Move to send exemption request to the table. On return the exemption request should address whether the ABL 800 has the correct module to perform pH on body fluids and that correlations are conducted using plural fluid utilizing a pH meter for those measurements. Ms. Walton

Second: Dr. Joyner

Move to send to the table approved

**4. Vanderbilt University
Medical Center
Nashville, TN 37232**

(1) Request modification to previous exemption to approve instrument change from the IL GEM 3000 to the IL GEM Premier 4000 for all existing VUMC IL GEM 3000 Point of Care (POC) exemptions.

Move to approve modification: Dr. Davis

Second: Dr. Joyner

Modification approved.

(2) Request exemption to allow Licensed Respiratory Therapists and Technicians (both ABG Endorsed) to perform and report IL GEM Premier 4000 testing procedures in any POC testing location previously approved.

Move to approve exemption: Dr. Nolan

Second: Ms. Walton

Exemption approved.

(3) Request modification to previous exemption allowing Registered Nurses to perform and report INR point of care testing procedures in the VUMC Emergency Department utilizing the Roche CoaguChek XL Pro System. The extent of this modification is a location extension on the exemption granted January, 2013.

Move to approve modification: Ms. Kenwright

Second: Dr. Davis

Modification approved.

Ms. England asked that Tab 17, Section Q #D be addressed at this time since representatives from Vanderbilt were present at the podium.

Q17D: Letter from Dr. Pampee Young requesting Board determination whether individuals performing processing consisting of storing, shipping and thawing of hematopoietic stem cell products are required to be licensed under the Tennessee Medical Laboratory Act.

Move to affirm that the described individuals must be licensed:

Ms. Kenwright

Second: Dr. Joyner

Affirmation of Licensure approved

5. Tri-Star Southern Hills

(1) Request exemption to allow Registered Nurses to perform and report lactate levels, utilizing the Abbott i-STAT, in the Emergency

Nashville, TN 37211

Department

Motion to approve exemption: Ms. Kenwright

Second: Dr. Nolen

Exemption approved

(2) Request modification to previous exemption to approve instrument change for the performance of O2 Saturations in the Catheterization Laboratory by Registered Nurses from the Abbott i-STAT to the AVOX . There were no correlation studies submitted.

Motion to send exemption request to the table until such time as correlation studies are ready to submit: Ms. Kenwright

Second: Dr. Joyner

Move to send to the table approved

6. **Tri-Star Stone Crest
Smyrna, TN 37167**

Request exemption to allow Registered Nurses to perform and report lactate levels, utilizing the Abbott i-STAT, in the Emergency Department and the ICU.

Motion to approve exemption: Dr. Calarco

Second: Ms. Walton

Exemption approved

7. **Region One Health
Memphis, TN 38103**

(1) Requesting modification of previous exemption to allow Respiratory Therapists (ABG endorsed) to perform and report pH, pCO₂, pO₂, TC0₂, O₂ Saturation, BE, Lactate, Na, K, Glucose, and Ionized Calcium utilizing the GEM 4000 rather than the GEM 3000, an instrument change, facility wide

Move to approve modification: Ms. Walton

Second: Dr. Joyner

Modification approved.

(2) Request name change from EMT to MCT. This Board has no such authority and suggests Region One Health Care to present this request to the EMT Board.

Move to suggest change in venue: Dr. Davis

Second: Dr. Joyner

Move to change venue approved.

(3) Request modification of previous exemption granted July, 2014, for Registered Nurses, Licensed Practical Nurses, Paramedics (EMT), Radiology Technicians, and Respiratory Therapists (ABG Endorsed) to perform and report lactate levels, utilizing the Abbott i-STAT, facility wide.

Move to approve modification: Dr. Nolan

Second: Dr. Calarco

Modification approved.

**8. Methodist LeBonheur
Hospital
Germantown, TN 38138**

(Dr. Joyner recused himself from the meeting)

Request for an extension to allow Licensed Perfusionist, to perform and report Activated Clotting Time (ACT) analysis, facility wide, utilizing the Medtronic HMS Hepcon Hemostasis Management System.

Motion to approve exemption: Ms. Walton

Second: Dr. Calarco

Motion approved

(Dr. Joyner returned to the meeting)

*The chairman called for a ten (10) minute break at 10:50AM
The chairman called the meeting back into session at 11:00AM*

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

CSL Plasma Inc. requested Dr. Lewis R. Hagood be allowed to direct a fourth (4th) laboratory within the CSL Facilities.

Move to allow directorship at fourth (4th) laboratory: Dr. Nolan

Second: Ms. Walton

Abstain: Dr. Calarco

Directorship approved.

Tab 18, Section R, Investigations Report taken out of agenda order

**Investigative Report
Medical Laboratory Board
Office of Investigations**

Nichelle Dorroh, Office of Investigations, gave a verbal report. There is one (1) case active and is being investigated. All monitoring is up to date and current.

Motion to accept Investigations Report: Dr. Joyner

Second: Ms. Kenwright

Report accepted

Tab 25, Section Y, Director Approval taken out of agenda order

**Review and Approve Medical
Laboratory Directors**

**Jonathan E. Schmitz, MD-Ph.D
Director-Microbiology
Antioch, TN 37013**

Application: Director – Microbiology

Degree: Awarded the Bachelor of Science, 2002, Concentration on Chemistry, Princeton University, Princeton, NJ, Affiliated with the Tri-Institutional M.D.- Ph.D program in biomedical sciences, Ph.D awarded in the biological sciences with a concentration of bacterial pathogenesis and immunology by Rockefeller University, New York and Awarded the M.D. in May, 2012, Weill Cornell Medical College of Cornell University, New York.

Training Program: Clinical Fellowship in Microbiology, Vanderbilt University Medical Center 2012-2014.

Certification: American College of Microbiology, Medical and Public Health Microbiology, August, 2014

Mark P. Borgman, Ph.D
Director-Chemistry
Floyds Knobs, IN

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

Motion to approve license: Dr. Miller

Second: Dr. Joyner

License approved

Application: Director – Chemistry

Degree: Bachelor’s degree in Medical Technology, Michigan State University, Michigan, 2004; Ph.D awarded in Pharmaceutical Sciences, University of Maryland, Baltimore, MD, 2009.

Training Program: ComACC-Accredited Clinical Chemistry Fellowship, July 2009 to June, 2011, University of Louisville, Louisville, KY.

Certification: American Board of Clinical Chemistry, 9/10/13 until 12/31/2014 (Active Status). ABCC Certification does not have an expiration date.

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

Motion to approve license: Dr. Nolan

Second: Dr. Miller

License approved

The Chairman resumed original agenda order Tab 17, Section Q

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

Review of guidelines for director licensing per T.C.A. §68-29-138 esoteric laboratories

Since no specific guidelines for director qualifications for esoteric laboratories exists and since it is evident this determination for Genome Expressions has consumed an inordinate amount of time with little progress, it is necessary to make decisions to decide this question to an.

First the laboratory must be classified, then personnel must be classified. Ms. Gass, read to the Board, Definitions and/or descriptions, of what determines the workings of an Esoteric, Clinical and Research Laboratory. Within these definitions, the Board should determine where Genome Expressions, fits.

Ms. Gass also touched upon one other pathway to resolve the dilemma of classification and that being the filing of a declaratory order.

The laboratory cannot be licensed without a director. It appears that Dr. Patel would qualify to sit for the boarding exam in molecular genetics and may qualify for a temporary license, which in turn may allow for the licensing of the laboratory.

Motion to approve plan of action: Dr. Davis

Second: Dr. Joyner

Plan of action approved

Discuss direct to consumer access from out of State laboratories

This is concerning research being conducted, Tennessee included, regarding the permissibility of direct to consumer (direct access) laboratory testing. Specifically is a laboratory not located or operating in Tennessee allowed to perform such testing.

Move that direct to consumer testing from out of state laboratories is not allowed: Dr. Nolan

Second: Ms. Kenwright

Motion approved

Discuss non-licensed laboratory personnel entering patient results into the LIS after review by licensed lab personnel.

After discussion, it was determined that a clerk or "Unlicensed laboratory personnel" may enter laboratory results into the LIS so long as licensed laboratory personnel review and release those results. This is compatible with earlier determinations made by this Board. The reporting of laboratory determinations is expressly written into the Responsibilities and Duties of testing personnel Rule 1200-06-01-.22(2)(a-b-c)(18-8-18)

Move that a clerk or "Unlicensed laboratory personnel" may enter laboratory results into the LIS so long as licensed laboratory personnel review and release those results: Ms. Walton

Second: Dr. Davis

Motion approved

REINSTATEMENT OF LICENSES

None

ADDITIONS/DELETIONS TO THE BOARD'S WAIVED TEST LIST

None

RECEIVE REPORTS AND /OR REQUESTS:

Board Director's Report

Previously reported

Office of General Counsel's Report:

Ms. Gass reported that One (1) open case in OGC. This was presented earlier to the Board by Consent Order.

Personnel rules rewrite was briefly discussed and will go out to all Board members once newest entries have been made. Board is asked to review and be ready to discuss at the January Board meeting.

Motion to accept General Counsel's Report: Ms. Kenwright

Second: Dr. Joyner

Report accepted.

Investigative Report

Previously reported

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 third quarter of 2014.

Unsatisfactory/ Unsuccessful Proficiency Testing: Two (2) all with acceptable plans of correction.

Complaint Investigations: One (1)

**MTRO Report
Richard Carroll**

Middle TN Regional Office: Richard Carroll for the third quarter of 2014.

Unsatisfactory/Unsuccessful Proficiency Testing: Two (2) all with acceptable plans of correction.

Complaint Investigations: Zero (0)

**WTRO Report
Mary Hamblen**

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

First unsuccessful occurrence of PT: Four (4) all with acceptable plans of correction.

There were no second occurrences: One (1)

Complaint Investigations: Zero (0)

Move to accept regional surveyor's reports as presented:

Dr. Joyner

Second: Ms. Kenwright

Reports accepted

Board Ratification of Laboratory Initial License:

**American Toxicology Lab
414 E. Watauga Ave
Johnson City, TN 37064**

Medical Director: Richard Knapp, MD.
Anatomic/Clinical Pathology

Specialties: Toxicology

Surveyor: Julia Daniels
Consultant 2/Surveyor ETRO

Move to approve license: Ms. Kenwright

Second: Ms. Walton

License Approved

Genome Explorations, Inc

Move to send to the Table: Ms. Kenwright

Second: Dr. Joyner

**654 Jefferson Avenue
Memphis, TN 38105**

Sent to the table

**Medical Center West
11808 Kingston PK. Ste. 130
Knoxville, TN 37934**

Medical Director: Joseph P. McDonnell, Ph.D
Director-Chemistry

Specialties: Collection Station

Surveyor: Julia Daniels
Consultant 2/Surveyor ETRO

Move to approve license: Ms. Kenwright

Second: Ms. Walton

Licenses Approved

**Discover Diagnostics
702 S. Illinois Ave. Ste B-104
Oak Ridge, TN 37830**

Medical Director: Jamshed U. Haq, MD.
Anatomic/Clinical Pathology

Specialties: Clinical Chemistry, Toxicology

Surveyor: Julia Daniels
Consultant 2/Surveyor ETRO

Move to approve license: Ms. Kenwright

Second: Dr. Joyner

Licenses Approved

**Recovery Associates of
Mosheim
65 Payne Road
Mosheim, TN 37818**

Medical Director: Tony Yost, MD
Family Medicine

Specialties: Collection Station

Surveyor: Julia Daniels
Consultant 2/Surveyor ETRO

Move to approve license: Ms. Kenwright

Second: Dr. Davis

Licenses Approved

Diatech Oncology, LLC

Medical Director: Allan Hallquist, MD.
Anatomic/Clinical Pathology

405 Duke Drive, Ste. 240
Franklin, TN 37067

Specialties: Esoteric Testing Procedures
Flow Cytometry, Molecular
Diagnostics

Surveyor: Onzean Otey
Consultant 2/Surveyor MTRO

Move to approve license contingent upon a letter of inspection from the CAP within six (6) months: Ms. Walton

Second: Dr. Nolan

Licenses Approved

**Associated Pathologists, LLC
D/b/a Pathgroup- Cleveland
2305 Chambliss Avenue
Cleveland, TN 37830**

Medical Director: J. Ross Slemmer, MD.
Anatomic/Clinical Pathology
Cytopathology

Specialties: Oral Pathology
Non-Gyn Cytopathology

Surveyor: Taylor Carpenter
Consultant 1/Surveyor ETRO

Move to approve license: Ms. Walton

Second: Dr. Joyner

Licenses Approved

**Review and Approve Medical
Laboratory Directors**

Previously approved

OTHER BUSINESS:

Elections for Officers of the Board and of the P&E Committee will take place in January.

Ms. England asked the Board in regard to Esoteric Laboratory Licensing, should she require that an applicant have scheduled a CAP Accreditation survey prior to bringing to the Board. The Board responded in the affirmative.

Statement of Next Meeting

The next Board Meeting will be January 15, 2015, and will begin at

9AM CST/CDT in the Iris Conference Rood, Ground Floor,
Metrocenter Complex, 665 Mainstream Drive, Nashville, TN 37243

Record of Adjournment

With no further business to discuss, the meeting was adjourned at 1:30 PM CST/CDT on a motion properly presented by Ms. Kenwright and seconded by Ms. Walton The motion to adjourn was unanimously approved.