

Tennessee Medical Laboratory Board Meeting

April 17, 2014

Minutes

Date: April 17, 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: 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.
Jason S. Nolan, MD, Pathologist Non Educator
Carla M. Davis, MD, Pathologist
Royce Joyner, MD, Pathologist Educator
Tereyo M. Cox, Medical Technologist, General

Members Absent: Jerry Lee Miller, MD Non-Pathologist Physician
VACANT: Citizen Representative
VACANT: Hospital Administrator
VACANT: Independent Lab Manager
VACANT: Medical Technologist Generalist

Staff Present: Lynda S. England, Medical Technologist Consultant, Director, TMLB
Jerry A. Gowen, Medical Technologist Consultant
Diona Layden, Assistant General Counsel, Advisory Attorney
Mollie Gass, Advisory Attorney, Office of General Consel
Julia Daniels, Medical Technologist Consultant/ Surveyor, East Tennessee Regional Office
Taylor Carpenter, Medical Technologist Consultant/Surveyor, East Tennessee Regional Office
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor, Middle 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: Karon Hathcoat, Medical Technologist Consultant/ Surveyor, West Tennessee Regional Office

CLIA Manager/Representative: Sandra Bogard, CLIA Manager

Presiding Officer: Cheryl Arnott, Chairman, TMLB

Call To Order: The meeting was called to order at 9:00 AM CST/CDT by Cheryl Arnott, Chairman, TMLB

Introductions of Board Members:

The Chairman recognized new and reappointed Board Members:
Jason S. Nolan, MD, Pathologist Non Educator (New)
Carla M. Davis, MD, Pathologist (New)
Royce Joyner, MD, Pathologist Educator (Reappointed)
Tereyo M. Cox, Medical Technologist, General (New)

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 15, 2014, Personnel & Education Committee minutes was made by: Dr. Joyner
Second: Ms. Kenwright

Motion approved

Full Board Meeting

A motion to approve the January 16, 2014, Board meeting minutes was made by: Ms. Kenwright
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, April 16, 2014.

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

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

Shirley Carr, MLT #12366, Monterey, TN., License Revoked for a period of no less than one year.

Motion to Accept: Ms. Dolsen
Second: Dr. Joyner
Abstention: Dr. Nolan

Bret A. Norrod, MT #21278, Maryville, TN., License Revoked for a period of no less than one year.

Motion to Accept: Dr. Joyner

Second: Ms. Walton

James W. Green, MT #12610, Talbot, TN., License Revoked for a period of no less than one year.

Motion to Accept: Ms. Dolsen

Second: Dr. Joyner

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 March 31, 2014, there was one (1) individual 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: Ms. Walton

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
Lisa Tittle,
Vanessa Crutcher
Discussion/Fee Reduction**

Financial reports are not reported at each meeting.

This agenda item was asked to be delayed until the July, 2014 meeting by the sponsor

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: Horizon Medical Center
Dickson, TN 37055**

Exemption to allow Licensed Registered Nurses, Licensed Practical Nurses and Licensed Paramedics to perform and report lactate analysis facility wide utilizing the i-STAT instrument and methodologies.

The Committee requested the instrument be recalibrated and the exemption request represented.

Motion to table until the July meeting: Ms. Kenwright

Second: Ms. Dolsen

Motion to table approved

**2: Williamson Med Center
Franklin, TN 37067**

(Ms. Walton recused herself)

Exemption to allow Radiology Technologist to perform and report creatinine testing events in the Computed Tomography unit (CT), Magnetic Resonance Imaging Unit (MRI) and the Outpatient Imaging Center (OIC) at this facility. The instrument and methodology used will be the Nova Stat Sensor.

Motion to approve exemption: Ms. Dolsen

Second: Dr. Joyner

Exemption approved

(Ms. Walton returned to the meeting)

**3. Tri-Star Ashland City Med
Center
313 N. Main Street
Ashland City, TN 37015**

Exemption to allow Licensed Registered Nurses to perform and report blood gasses, lactate and troponin analysis in the Emergency Department utilizing the i-STAT instrument and methodology.

Motion to approve exemption: Ms. Kenwright

Second: Ms. Dolsen

Exemption approved

**4. Tri-Star Centennial Medical
Center
2300 Patterson Street
Nashville, TN 37023**

Exemption to permit designated Registered Nurses and designated licensed Respiratory Therapists to perform and report Wescor Sweat Conductivity Screening Analysis utilizing the Nanoduct Sweat System. The designated personnel will be members of the Children's Hospital Staff.

Discussions and concerns regarding sensitivity, specificity, accuracy, correlation with reference method and a lack of

familiarity with the instrument resulted in the Committee requesting the sponsor to return with their request and respond to these unanswered concerns. A question also arose regarding the departure from the past norm of point of care testing in regards to urgency for procedure completion. Counsel pointed out that this was not a criteria required.

It is noted that the Cystic Fibrosis Foundation does not accept this procedure as definitive; however, the sponsor stressed that this is screening only and is not intended to be definitive.

The Committee requested the sponsor to present this request to the Respiratory Therapy Board for their input as to whether or not the performance of this test would be compatible with their scope of practice.

Motion to table until the July, 2014, meeting to allow time for the presentation to be heard by the Respiratory Therapy Board and for the sponsor to address the concerns noted: Ms. Kenwright
Second: Ms. Walton

Motion to table approved

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

Nothing to Present

*The Chair called for a fifteen (15) break at 10:25A
The Chair called the meeting back to order at 10:40A*

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

**Patient Access to Laboratory
Reports**

Federal Rules preempt any State Statute regarding patient access to their laboratory reports. The Committee did not see any conflict with the requirement thus there was discussion only and NO ACTION taken.

**Buccal Swab Testing in TN Rite
Aid Pharmacies
Mindy Locke, PharmD
Rite Aid Corporation Field
Clinical Services Manager**

Information Only: This is a nationwide study between Rite Aid Pharmacies and the pharmaceutical company manufacturing Plavix regarding adsorption studies. NO ACTION NECESSARY

**Genome Expressions, Inc.
Memphis, TN 38105
Esoteric Laboratory Director
Qualifications/Initial License
Approval**

Dr. Richard D. Childress and Dr. Kivyen H. Patel presented an outline of the work being performed at Genome Expressions, Inc. and their qualifications and interactions. The purpose of this discussion is to allow the Board to compare Dr. Childress' qualifications as potential medical director with the existing guidelines for Medical Directors

Testing in esoteric areas is growing and the present guidelines do not necessarily address the qualifications for medical directors of same.

After discussion it was decided that this topic needed more research by General Counsel and reported back at the July meeting.

Move to Table until the July, 2014 meeting: Ms. Kenwright

Second: Dr. Joyner

Motion to table approved.

**Board Advisory Opinion
Employee Status Via
TCA§68-29-101
Rules Governing Med Lab
Personnel 1200-06-01-.21(2)(a)
Mark A. Ison
Sherrard & Roe, PLC**

Topic explores what type of employee/employer relationships may exist in harmony with the Statutes and Rules of the Medical Laboratory Act; specifically, is employee leasing and independent contracting allowable under the "Act.?"

The advisory opinion suggests that the terms, "Employee," "Employ," and "Employment," in reference to medical laboratory professionals and other laboratory personnel should be interpreted as inclusive of independent contractor and employee leasing arrangements so long as a medical laboratory supervises and remains in control (to the extent permitted by law) of the professional services performed by such personnel.

Move to approve advisory letter as written: Ms. Walton

Second: Dr. Joyner

Advisory letter approved

**Rules and Regs. Governing
Medical Laboratories
Rule 1200-06-03-.08(1)(b)(4)(ii)
TCA§§68-29-121(a)(b)
Necessity of authorized
signature on lab request**

Question is regarding what is acceptable to the Board in regard to written requisitions with suitable identifiers of authorized person requesting testing?

Consensus of opinion was that there must be adequate identifiers on the requisition to determine who requested the test(s), who to notify or report and for billing purposes but not necessarily a signature.

Discussion only no action taken.

**Addiction Labs of America
Brentwood, TN 37027
Director of Toxicology
Mark Calarco, DO**

Upon discussion it was learned that Addiction Labs of America performs toxicology laboratory determinations solely upon their own patients and does not accept specimens from outside sources. With this information it was determined that they were more closely defined as a Physician's Office Laboratory and not a reference laboratory; thus, Dr. Calarco need not qualify as a director under the Tennessee Medical Laboratory Act nor is Addiction Labs of America need a license to operate.

Discussion only no action taken.

The Chair called for a fifteen (15) break at 11:55A

The Chair called the meeting back to order at 12:10P

ADDITIONS/DELETIONS TO THE BOARD'S WAIVED TEST LIST

No additions or Deletions to the Board's waived test list.

RECEIVE REPORTS AND /OR REQUESTS:

Board Director's Report

Ms. England gave a verbal report.

The dates for the 2014 Board Meetings are listed with one important date change to place on calendar. The July meeting will be held on Thursday and Friday, rather than Wednesday and Thursday.

There are new Board appointments; however, there are still vacancies that need to be filled.

A brief statistical report followed.

Motion to accept Director's Report: Ms. Walton

Second: Dr. Joyner

Report accepted.

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

Reinstatement of License

Nothing to present and No action by the Board is required.

Office of General Counsel's Report:

Ms. Gass reported that three (3) consent orders were presented leaving no open cases.

There will be a rule making hearing during the July meeting regarding the Esoteric Laboratory rules.

Ms. Gass reiterated that the P&E Committee authorized a rules re-write task force and that would be established.

Regarding legislative updates; two bills, one regarding patient access to laboratory determinations (HHS rules effectively closed this bill) and the prohibition of out of state laboratories soliciting referrals (no outcome as of report)

Motion to accept General Counsel's Report: Dr. Joyner

Second: Ms. Dolsen

Report accepted.

Investigative Report

Medical Laboratory Board
Office of Investigations

Ms. England gave a verbal report of one open complaint.

Motion to accept the investigations report: Ms. Walton

Second: Dr. Joyner

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: Julia Daniels for the first quarter of 2014.
Unsatisfactory/ Unsuccessful Proficiency Testing: Three (3) all with acceptable plans of correction.
Complaint Investigations: Zero (0)

**MTRO Report
Onezean Otey**

Middle TN Regional Office: Onezean Otey for the first quarter of 2014.
Unsatisfactory/Unsuccessful Proficiency Testing: Zero (0)
Complaint Investigations: Zero (0)

**WTRO Report
Mary Hamblen**

West TN Regional Office: Karon Hathcoat for the first quarter of 2014.
First unsuccessful occurrence of PT: Three (3)
There were no second occurrences: Zero (0)
Complaint Investigations: Zero (0)

Move to accept regional surveyor's reports as presented:

Dr. Joyner

Second: Ms. Dolsen

Reports accepted

**Board Ratification of Laboratory
Initial License:**

**Pioneer Community Hospital of
Scott County
Oneida, TN 37841**

Medical Director:

Timothy J. Collins, M.D.
Anatomic/Clinical Pathology

Specialties:

Bacteriology, Mycology,
Parasitology, Virology,
Hematology, General
Immunology, Clinical Chemistry,
Urinalysis, Endocrinology,
Toxicology, ABO Group & Rh
Type, Antibody Detection,
Transfusion, Compatibility
Testing, pH & Blood Gasses

Surveyor:

Julia Daniels
Consultant 2/Surveyor ETRO

Move to approve license: Ms. Walton

Second: Dr. Joyner

Abstain: Dr. Nolen

License Approved

Your Choice Labs, LLC
124 Old Gray Station Road
Gray, TN 37615

Medical Director: Bruce D. Boggs, M.D.

Specialties: Collection Station

Surveyor: Taylor Carpenter
Consultant 1/Surveyor ETRO

Move to approve license: Dr. Joyner

Second: Ms. Walton

License Approved

**Artherotech Diagnostic
Laboratory**
5515 Edmondson Pike, STE 115
Nashville, TN 37212

Medical Director: Aladraine. E. Sands, M.D.

Specialties: Collection Station

Surveyor: Onzean Otey
Consultant 2/Surveyor MTRO

Move to approve license: Ms. Dolsen

Second: Ms. Walton

Licenses Approved

**Blood Assurance Donor Station
Johnson City**
1 Professional Park Dr. STE 14
Johnson City, TN 37604

Medical Director: Elizabeth Culler, M.D.

Specialties: Blood Donor Center

Surveyor: Julia Daniels
Consultant 2/Surveyor ETRO

Move to approve license: Ms. Kenwright

Second: Ms. Walton

Licenses Approved

Integralabs MDG, INC.
2203 McKinley Road, STE 120
Johnson City, TN 37604

Medical Director: James W. Denham, MD
American Board of Pathology
Anatomic/Clinical Pathology

Specialties: General Immunology &
Histopathology

Surveyor: Taylor Carpenter
Consultant I/Surveyor ETRO

Move to approve license: Ms. Kenwright

Second: Dr. Joyner

Licenses Approved

Review and Approve Medical Laboratory Directors

Marc J. Rumpler, Ph.D
Gainesville, FL 32653

Application: Director – Toxicology.

Degree: Awarded the Bachelor of Science, 2001, Toxicology, Northeastern University, Boston, MA, Awarded the Master of Science, 2008, Forensic Toxicology, University of Florida, Gainesville, FL, Awarded the Ph.D, 2012, Toxicology, University of Florida, Gainesville, FL.

Training Program: University of Florida, Clinical and Forensic Toxicology, May, 2012 until August, 2013.

Certification: National Registry of Certified Chemists in Toxicology

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

Move to approve license: Ms. Dolsen

Second: Dr. Joyner

License approved

Richard S. Steece, Ph.D
Mt. Juliet, TN 37122

Application: Director - PHLD

Degree: Awarded the Bachelor of Science, Biology, South Dakota State University, Brookings, South Dakota; Awarded the Master of Science, Microbiology, South Dakota State University, Brookings, South Dakota; Ph.D awarded in Biology, University of New Mexico, Albuquerque, 16 December 1989.

Training Program: Plan I: Applicants must possess an earned doctorate and complete a minimum of three (3) years of experience, as defined.

Certification: American College of Microbiology, Diplomate, July 1, 1999. Requires recertification. Next recertification date is December 31, 2014.

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

Move to approve license: Ms. Walton

Second: Ms. Dolsen

License approved

OTHER BUSINESS:

There was an inquiry regarding the retention time for extracted DNA for DNA and genomic testing. Storage requirements depends upon the test ie. Genetics vs. cancer vs. engrachment studies. At present, molecular labs store samples as long as they have space in their freezers. CAP is in the process of addressing this but there are no rules, presently. CLIA states the specimen must be kept until the final report is released but there are no other stipulations

as to retention time. In lieu of no statutory requirements, at this time, retention is left to the discretion of the laboratory in accordance with their accreditation agency.

Statement of Next Meeting

The next Board Meeting will be July 18, 2014, 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 12:45PM CST/CDT on a motion properly presented by Dr. Joyner and seconded by Ms. Walton The motion to adjourn was unanimously approved.