

**Tennessee Medical Laboratory Board
October 17, 2019**

Minutes

Meeting Date: October 17, 2019

Time: 9:00 AM CDT

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

Members Present:

Patti J. Walton, MT-Hospital/Lab Mgr./Adm. Dir., Chair
Michael Johnson, MT-Medical Technologist Generalist
Board Vice-chair
LeeAnne Briggs, MT- Med. Technologist, Educator
Keisha Burnett, S.A.-Cytotechnologist
Mark A. Calarco, DO-Independent Lab Manager/Adm.
Tereyo M. Cox, MT-Medical-Technologist, General
Danielle Gibson, MD-Pathologist
Lynn Stewart-Citizen Representative
James A. Vaughn, MD-Pathologist Educator

Members Absent:

Carla M. Davis, MD-Pathologist
Gaye G. Jolly, MT-Hospital Administrator
Jon Parham, DO-Non-Pathologist Physician

Vacant Position: Medical Technologist Supervisor

Staff Present:

Sandra Bogard, MT Consultant, Director
Nina V. Smith, MT Consultant, Administrative Office
Kyonzte Hughes-Toombs, Deputy General OGC
Fowlen Anders, MT Consultant/Surveyor ETRO
Taylor Carpenter, MT Consultant/Surveyor ETRO
Debbie Haggard, MT Consultant/Surveyor WTRO
Susan Wilson, MT Consultant/Surveyor MTRO

Staff Absent: Karon Hathcoat, MT Consultant/Surveyor WTRO

CLIA Manager/Representative: Richard Carroll, Interim CLIA Manager

Presiding Officer: Patti Walton, MT, Chair

Call To Order:

The meeting was called to order at 9:05 am CDT by Board Chair Patti J. Walton.

Introduction of Board Members/Staff:

Board members and staff made their introductions to the audience and for the record. Roll call.

Quorum:

Nine board members were present which constitute a quorum.

Approve Minutes:

P & E Committee Meeting

A motion to approve the July 18, 2019 Personnel & Education Committee minutes was made by Dr. Vaughn.
Second: Mr. Johnson
Minutes: Approved.

Full Board Meeting

A motion to approve the July 19, 2019 Board minutes was made by Mr. Johnson.
Second: Dr. Vaughn
Board Minutes: Approved

Board Reports:

Ratification of Initial Determinations
P&E Committee Meeting:

Mr. Johnson reported the actions of the Personnel & Education Committee meeting, October 16, 2019.
Motion to ratify Committee actions by Ms. Burnett.
Second: Ms. Briggs
Report: Accepted as presented by Mr. Johnson.

Consent, Agreed, Compliance Orders, and Letters of Reprimand:

Consent Orders

No Consent Orders presented.

Agreed Orders

No Agreed Orders presented.

Compliance Orders

No Compliance Orders presented.

Letters of Reprimand

No Letters of Reprimand presented.

Presentations to the Board:

Tennessee Professional Peer Assistance Program (TNPAP)

Mr. Mike Harkreader, MS,RN,CARN
TNPAP Director

The statistical report for July 1, 2019-September 30, 2019 was presented by Ms. Rachel Talley.

Two (2) individuals were monitored during this time period with no new personnel additions for services and two (2) non-regulatory issues involved with treatment.

Motion to accept the TNPAP report by Mr. Johnson.
Second: Ms. Briggs
Report accepted as given.

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 session. Internet site: www.TNPAP.org

Financial Report Butch Jack Presentation/Discussion

Mr. Jack indicated he would send the report to the Board before the next meeting in January.

Investigations Report Lori L. Leonard Disciplinary Coordinator July-October 2019

Ms. Leonard's investigative report included the following:

Monitored Practitioners: (Jan. – Sept. 2019)

Four (4) suspensions, two (2) probation, one (1) currently under board order.

Investigative Licensed Laboratory Personnel: (Jan. – Sept. 2019)

Four(4) new complaints:
three (3) for drug allegation.
one (1) for mental impairment.

Five (5) complaints closed:
one (1) closed for insufficient evidence.
one (1) closed and file sent to OGC.
two (2) closed with no action.

one (1) with letter of concern.

Investigative Licensed Facilities: (Jan. – Sept. 2019)

Two new complaints:

two (2) unprofessional conduct.

Five (5) complaints closed:

three (3) closed for insufficient evidence.

one (1) closed.

one (1) with letter of warning.

Motion to accept report by Dr. Calarco.

Second: Ms. Briggs.

The investigations report was accepted as given.

Point of Care Exemptions 1200-06-03-.16(1)

1. Cardiopulmonary Laboratory
907 E. Lamar Alexander Parkway
Maryville, TN 37804
Terry Beckmann, RRT
Director Cardiopulmonary Services

Request was to permit Credentialed Respiratory Therapists (ABG endorsed) to perform and report hemoximetry procedures (oxyhemoglobin, methemoglobin, and carboxyhemoglobin) on general patient population (hospital wide) utilizing the Avox 4000 system.

Motion: Mr. Johnson

Second: Dr. Calarco

The exemption request was approved.

2. Saint Francis Hospital
5959 Park Avenue
Memphis, TN 38119
Doretha Franklin, BS, M.Ed,
MT(ASCP)
Administrative Director, Laboratory
Kathy Crews, BS, MT(ASCP)
Laboratory Manager, Core Lab

The first request was to permit Registered Nurses in the Surgery Department to perform and report pH, PCO₂, PO₂, TCO₂, HCO₃, BE, Na, K, Ionized Ca, glucose, hematocrit, and hemoglobin testing on the CG8+ cartridge utilizing the i-STAT instrument and methodology.

Motion: Ms. Briggs

Second: Dr. Gibson

The exemption request was approved.

The second request was to permit Registered Nurses in the Surgery Department to perform and report ACT testing utilizing the Hemochron analyzer.

Motion: Dr. Calarco

Second: Mr. Johnson

The exemption request was approved.

Direct More than Three (3) Labs 1200-06-03-.13(5)

1. Danielle Gibson, MD, MBA
Medical Laboratory Director
PCA Southeast
1602 Hatcher Lane
Columbia, TN 38401

Dr. Gibson appeared before the board to request approval to direct a total of six (6) laboratories.

Dr. Gibson currently serves as a medical laboratory director for the following Tennessee licensed facilities:

- 1-PCA of Columbia, Inc.-1602 Hatcher Lane, Columbia, TN 38401
- 2-Consolidated Pathology(Covenant Pathology Services)-1802 Hayes St., Nashville, TN 37203
- 3- Industry Laboratory Diagnostic Partners (ILDLP), LLC(clinical lab)-8122 Sawyer Brown Rd., Suite 210, Nashville, TN 37221
- 4- Industry Laboratory Diagnostic Partners (ILDLP), LLC(esoteric lab)-8122 Sawyer Brown Rd., Suite 210, Nashville, TN 37221 (Application pending)
- 5-TriStar Horizon Medical Center-111Highway 70 East, Dickson, TN 37055 (Application pending)
- 6-TriStar Natchez ER-107 Natchez Park Dr., Dickson, TN 37055 (Application pending)

Motion: Dr. Calarco

Second: Dr. Vaughn

Abstained: Dr. Gibson recused herself from Board deliberation and voting.

The request for Dr. Gibson to direct six (6) laboratories was approved.

2. Albert C. Domm, MD
Medical Laboratory Director
PCA Southeast
1602 Hatcher Lane
Columbia, TN 38401

Dr. Domm appeared before the board to request approval to direct a total of four (4) laboratories.

Dr. Domm currently serves as a medical laboratory director for the following Tennessee licensed facilities:

- 1-Maury Regional Hospital dba Lewis Health Center-617 West Main St., Hohenwald, TN 38462
- 2-Houston County Community Hospital-5001 East Main Street, Erin, TN 37061
- 3-Decatur County General Hospital-969 Tennessee Avenue South, Parson, TN 38363
- 4-Henderson County Community Health Center-200 West Church St., Lexington, TN 38351 (Application pending)

Motion: Mr. Johnson

Second: Ms. Cox

Abstain: Dr. Gibson recused herself from Board deliberation and voting.

The request for Dr. Domm to direct four (4) laboratories was approved.

3. Paul DiGiovanni, MD
Medical Laboratory Director
PathGroup
1010 AirPark Center Drive, Suite M
Nashville, TN 37217

Ms. Sharon Buher, representing Dr. DiGiovanni, appeared before the board to request the approval for him to direct a total of five (5) laboratories.

Dr. DiGiovanni currently serves as a medical laboratory director for the following Tennessee licensed facilities:

- 1-PathGroup Southern Hills, Pathology Dept.-391
Wallace Road, Nashville, TN 37211
- 2-TriStar Southern Hills Medical Center Laboratory-391
Wallace Road, Nashville, TN 37211
- 3-DCI Laboratory-2917 Foster Creighton Drive, Nashville,
TN 37204
- 4-PathGroup TriStar Summit, Pathology Dept.-5655 Frist
Blvd., Nashville, TN 37076 (Application pending)
- 5-TriStar Summit Medical Center Laboratory-5655 Frist
Blvd., Nashville, TN 37076 (Application pending)

Motion: Dr. Gibson

Second: Ms. Briggs

The request for Dr. DiGiovanni to direct five (5) laboratories was approved.

4. Julie Lemmon, MD
Medical Laboratory Director
PathGroup
1010 AirPark Center Drive, Suite M
Nashville, TN 37217

Dr. Lemmon appeared before the board to request approval to direct a total of five (5) laboratories.

Dr. Lemmon currently serves as a medical laboratory director for the following Tennessee licensed facilities:

- 1-PathGroup Sumner Regional, Pathology Dept.-555
Hartsville Pike, Gallatin, TN 37066
- 2-Sumner Regional Medical Center laboratory-555
Hartsville Pike, Gallatin, TN 37066
- 3-Sumner Station Emergency Department-225 Big
Station Camp Blvd., Gallatin, TN 37066
- 4-PathGroup TriStar Hendersonville Hospital, Pathology
Dept.-355 New Shackle Island Road, Hendersonville, TN
37075 (Application pending)
- 5-TriStar Hendersonville Hospital Laboratory-355 New
Shackle Island Road, Hendersonville, TN 37075
(Application pending)

Motion: Dr. Vaughn

Second: Dr. Calarco

Abstain: Mr. Johnson recused himself from Board deliberation and voting.

The request for Dr. Lemmon to direct five (5) laboratories was approved.

Discuss, review, and take action, if needed:

Vanderbilt University Medical Center
dba Vanderbilt Health One Hundred
Oaks Mohs Micrographic Surgical Lab
719 Thompson Lane, Suite 26300,
Room 28173, Nashville, TN 37228

Vanderbilt Health One Hundred Oaks Mohs Micrographic Surgical Lab submitted an applicant for an initial laboratory license to perform Mohs testing. Dr. William G. Stebbins applied to be the laboratory director of that facility.

During discussions it was determined that if a lab director applicant has a one (1) year Fellowship in Mohs Surgery and is boarded in Dermatology then these credentials are acceptable to direct a Mohs laboratory. If the director applicant does not obtain a one (1) year Fellowship in Mohs surgery or boarding in Dermatology then he would need to appear before the Board to determine if his qualifications to direct a Mohs lab are acceptable. The Board indicated that Dr. Stebbins met the qualifications to direct a Mohs laboratory.

No action was needed by the board.

Baptist Memorial Health Care
Hospitals
Outpatient Clinics
Medical Groups of Physicians

A second discussion took place, involving a request from Baptist Memorial Health Care, for clarification concerning their recent restructuring and if these changes would result in the need for a State laboratory license for any of their locations. The Board requested that a representative, from Baptist Memorial Health Care, appear before them at the January meeting. The Board also requested that the presentation include visual diagrams of the restructuring for clarification.

No action was taken by the Board.

Break:

Board members and staff took a break and reconvened at 10:30a.m. followed by roll call.

Professional Meeting Attendance

After a discussion regarding the importance of education and training the Board decided to send board staff, surveyors and Board members to various professional

trainings and conferences.

The approved trainings included:

Clinical Laboratory Management Association (CLMA)
March 29-31, 2020 Louisville, KY
(Including conference expenses, travel, lodging, and membership)

Attending: Sandra Bogard, Director MLB
Tereyo M. Cox, Board Member

Federation of Associations of Regulatory Boards (FARB)
January 23-26, 2020 Colorado Springs, CO
(Including conference expenses, travel & lodging)

Attending: Sandra Bogard, Director MLB
Kyonzte Hughes-Toombs, Board A
John Tidwell, Director HRB
Lynn Stewart, Board Member

The Council on Licensure, Enforcement and Regulation
(CLEAR) March 17-19, 2020 Raleigh, NC
National Certified Investigator & Inspector Training-Basic

Attending: Karon Hathcoat, WT Supervisor
Debbie Haggard, WT Surveyor
Vacant, MT Supervisor
Susan Wilson, MT Surveyor
Taylor Carpenter, ET Supervisor
Fowlen Anders, ET Surveyor

CLEAR Introduction to Regulatory Governance for Board
Members(online agency subscription up to 10 users)
Participating: Ten Board Members

Discussions concerning attendance at the CLEAR Annual
Educational Conference and the American Society for
Clinical Pathology (ASCP) Annual Conference were
tabled until the January meeting.

Motion: Mr. Johnson

Second: Ms. Cox

The training requests were approved.

Licensure of out-of-state
laboratories

The topic of licensing out-of-state laboratories that
perform testing on Tennessee residents was discussed
by the Board.

No action was taken by the Board.

CLIA Exemption Status

The possibility of becoming a CLIA-exempt state was discussed by the Board. A request was made of the Board Director to research the exemption process and report back to the Board and present her findings at the January meeting.

No action was taken by the Board.

Point-of-Care (POCT) Exemption Request Procedure

A lengthy discussion pursued regarding the Board's desire to offer laboratories the option of presenting their laboratory exemption requests via a remote option like telephone or WebEx in lieu of traveling to Nashville and presenting in person. The Board determined that if a laboratory has a new POCT instrument, methodology, location, personnel, or department, not already approved in the State of Tennessee, the exemption request needs to be in person. Also, if the laboratory is requesting their first POCT exemption they must also present in person before the Board. All other requests can be presented to the Board by a remote option.

An information sheet titled, "Guidelines for Point-of-Care Testing (POCT) Exemption Requests" was reviewed and revised by the Board. This information sheet will be distributed to laboratories wanting to request an exemption.

Review and Discuss Licensure of Medical Laboratory Director

Alice Layton, Ph.D.
Knoxville, TN 37922

Dr. Layton received her BS degree in Biology from the University of Virginia, Charlottesville in 1981, her M.S. degree in Botany & Plant Pathology in 1983 and her Ph.D. in Biochemistry in 1987 from Purdue University in Lafayette, Indiana.

She received five (5) years of on-the-job training, 2014-2019, at Molecular Pathology Laboratory Network, Inc.

Dr. Layton is certified by the American Board of Bioanalysis (ABB) in Molecular Diagnostics which expires on December 31, 2019.

Dr. Layton is seeking licensure as a Director of Molecular Diagnostics.

Motion: Dr. Calarco
Second: Mr. Johnson

Reports/Requests

Board Director's Report

Sandra S. Bogard, MS, MT(ASCP) QLC

License Approved.

The report included statistical data concerning the licensure of laboratory personnel, facilities, training programs licensure and health fair/health screening events.

Motion to approve report as given by Mr. Johnson.
Second: Ms. Burnett

Report accepted as given.

A copy of this report is kept on file in the administrative office.

Reinstatement of License

No licenses were presented for reinstatement this quarter.

Additions/Deletions

Board's Waived Test List

No requests for additions or deletions presented during this meeting.

Board Attorney Report

Kyonzte Hughes-Toombs
Deputy General Counsel

Counsel Hughes-Toombs gave her report for the past quarter:

One open case is currently in the Office of General Counsel.

The re-write of the Rules Governing Medical Laboratory Personnel 1200-06-01 are still under internal review.

Motion to accept report as given by Ms. Briggs.
Second: Ms. Cox
Report accepted as given.

Regional Surveyors Reports:

Complaint Investigations

Proficiency Testing Events

Regional Offices:

East, Middle, West Tennessee

ETRO Report-

Taylor Carpenter, MT
Consultant/Surveyor

East TN Regional Office: July 1-September 30, 2019
Complaint Investigations: One (in process)
Unsuccessful Proficiency Testing: Zero

MTRO Report- Susan
Wilson, MT
Consultant/Surveyor

Middle TN Regional Office: July 1-September 30, 2019
Complaint Investigations: One
Unsuccessful Proficiency Testing: Two
-First Occurrence(two in a row or two out of three
unsatisfactory scores): One
-Second occurrence (three in a row or three out of
five unsatisfactory scores): One

WTRO Report-
Debbie Haggard, MT
Consultant/Surveyor

West TN Regional Office: July 1-September 30, 2019
Complaint Investigations: Zero
Unsuccessful Proficiency Testing : Two
-First Occurrence(two in a row or two out of three
unsatisfactory scores): Two

Motion to accept regional surveyor reports by Mr.
Johnson.

Second: Dr. Vaughn

Surveyor reports accepted as presented.

Board Ratifications Initial Facility Applications

1. IDL Acquisition Co., LLC
357 Riverside Drive, Ste 1001
Franklin, TN 37064
(esoteric lab)

Specialties: Esoteric Molecular Diagnostics

Laboratory Director: Pamela T. Osborne, MD
ABP/Anatomic-Clinical Pathology

Surveyor: Richard Carroll, MT Consultant II/MTRO

Motion: Mr. Johnson
Second: Dr. Gibson
License approved.

2. Tennessee Oncology HMS,
LLC
4488 Carothers Parkway
Suite 320
Franklin, TN 37076

Specialty: General Immunology

Laboratory Director: Douglas Kingma, MD
ABP/Anatomic Pathology &
Pathology-Hematology
Fellow Molecular Genetic Pathology

Surveyor: Susan Wilson, MT Consultant I/MTRO

Motion: Dr. Calarco
Second: Ms. Briggs
License approved.

Other Business/Discussion

CE Broker Update

Ms. Nina Smith updated the Board on the status of the CE Broker contract. The company plans on beginning their beta testing on November 18, 2019 and have everything finalized and ready for use by licensees early next year. CE Broker is a company that provides a service to assist licensed personnel to track their continuing education. This information was sent to all licensees via email.

SharePoint Site

Ms. Sandra Bogard presented to the Board a new SharePoint site that will be available for use by the Board members. She demonstrated the basic functionality of the site.

Discussion Regarding Lab Personnel Lapsed License Policy

The Board discussed its current laboratory personnel lapsed license policy which states:

Practicing medical technology on a lapsed (expired) license or permit **for less than three (3) months** shall remit renewal fee and reinstatement (penalty fee).

Practicing medical technology on a lapsed (expired) license or permit **for three (3) months or longer** shall remit renewal fee, reinstatement (penalty) fee, and a civil penalty of \$100 per month for each month practicing on a lapsed license or permit.

Adjournment:

The next meeting will be January 29, 2020.

The beginning time is scheduled for 9 AM CST in the Iris Conference Room, Ground Floor, Metro Center Complex 665 Mainstream Drive Nashville, TN.

With no further business to discuss, the meeting was adjourned at 12:33 pm CDT.

Motion to adjourn: Mr. Johnson

Second: Ms. Briggs