

Tennessee Medical Laboratory Board
April 29, 2021
Full Board Meeting
Minutes

Meeting Date: April 29, 2021

Time: 9:04 AM CST

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

Members Present:

Michael Johnson, MT-Med.Technologist Generalist/Chair
Paul Fleming, MT Supervisor, Board Vice-Chair
LeeAnne Briggs, MT- Med. Technologist, Educator
Mark A. Calarco, DO, Independent Lab Manager/Adm.
Tereyo M. Cox, MT-Medical-Technologist, General
Danielle Gibson, MD-Pathologist, Non-Educator
Gaye G. Jolly, MT-Hospital Administrator
James A. Vaughn, MD-Pathologist Educator

Vacant Positions: Previously appointed Board members continue to attend the meeting, for the following positions, until they are filled:
Hospital Laboratory Manager
Independent Laboratory Manager
Cytotechnologist
Medical Technologist
Non-Pathologist Physician

Members Absent: Keisha Burnett, S.A.-Cytotechnologist
Carla M. Davis, MD-Pathologist
Patti J. Walton, MT-Hospital/Lab Mgr./Adm. Director
Lynn Stewart, Citizen Representative

Staff Present: Sandra S. Bogard, MT Consultant, Director
Nina V. Smith, MT Consultant Administrative Office
Kyonzte Hughes-Toombs, Deputy General OGC
Mark Cole, Legal Counsel
Fowlen Anders, MT Consultant/Supervisor ETRO
Lori Reynolds, MT Consultant/Surveyor ETRO
Debbie Haggard, MT Consultant/Supervisor WTRO
Susan Wilson, MT Consultant/Supervisor MTRO
Susan Massey, MT Consultant/Surveyor MTRO

Staff Absent: All were present.

CLIA Manager/Representative:	Richard Carroll, CLIA Manager was absent.
Introduction of Board Members:	Board members and staff made their introductions to the audience.
Quorum:	Eight (8) board members were present which constitute a quorum.
Call To Order:	The meeting was called to order at 9:10 am CST by Mr. Michael Johnson the Board Chairman.
Presiding Officer:	The meeting was conducted by Mr. Johnson.
National Medical Laboratory Professional's Week	The Board Chairman recognized National Medical Laboratory Professional's Week that took place during April 18-24, 2021.
Approve Minutes:	
P & E Committee Meeting	A motion to approve the January 28, 2021 Personnel & Education Committee minutes was made by Ms. Briggs. Second: Dr. Calarco The minutes were approved.
Full Board Meeting	A motion to approve the January 29, 2021 Board minutes was made by Dr. Gibson. Second: Ms. Cox The Board minutes were approved.
Ratification Of Initial Determinations P & E Committee Meeting:	Ms. Briggs reported the actions of the Personnel & Education Committee meeting, April 28, 2021. Motion to ratify Committee actions: Dr. Vaughn Second: Mr. Fleming The report was accepted as presented by Ms. Briggs.
Contested Cases:	No contested cases were presented during this meeting.
Consent, Agreed, Compliance Orders, And Letters of Reprimand:	No consent, agreed, or compliance orders were presented during this meeting. No letters of reprimand were presented.

Presentations To The Board:

Tennessee Professional Peer Assistance Program (TNPAP)
Teresa Phillips, Acting Executive Director

The statistical report for July 1, 2020-March 31, 2021 was presented by Ms. Teresa Phillips, Acting Executive Director.

Zero (0) individuals were monitored during this period.

Motion to accept the TNPAP report: Ms. Briggs
Second: Dr. Gibson

The report was accepted as given.

Note: Review of TNPAP materials via the internet counts as clock hours toward continuing education credits.

A certificate of completion documenting the review of these materials can be completed at the end of the session. Internet site: www.TNPAP.org

Investigations Report
Lori L. Leonard
Disciplinary Coordinator

Ms. Leonard's investigative report included the following:

Monitored Practitioners (Personnel and Facilities): (2021)

Investigative Licensed Laboratory Personnel: (2021)
One new complaint:
 one for substance abuse.

Zero complaints closed.

Six currently monitored practitioners:
 two under board order.
 four suspended licenses.
 one expired license.

Investigative Licensed Laboratory Facilities: (2021)
Three new complaints:
 one for unlicensed practice.
 one for proficiency testing.
 one for diagnostic discrepancy.

Zero complaints closed.

Motion to Accept Report: Dr. Calarco
Second: Ms. Briggs

The investigations report was accepted as given.

Financial Report
Matthew McSpadden
Fiscal Manager

Mr. McSpadden gave the Mid-Year Fiscal Report which compared the actual revenue and expenditures for the past three (3) years (FY2019, FY2020, FY2021 (actual) & FY2021 (projected)). The values were comparative with little change from year to year. Mr. McSpadden also presented three (3) different fiscal scenarios, to the Board, that discussed possible options to reduce the fee structure due to a surplus funds balance.

The Board requested copies of the scenarios for future review and requested that Mr. McSpadden returns in July to further discuss the fee structure options.

Motion: Dr. Vaughn
Second: Ms. Cox

The report was accepted as given.

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

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

- 1. Parkridge Medical Center Laboratory**
2333 McCallie Avenue
Chattanooga, TN 37404
Helen Richardson, Laboratory Admin. Director

The request was to permit licensed Perfusionists to perform electrolytes, ABG, tHgb, SO₂, glucose, lactic acid, and ionized calcium testing facility-wide utilizing the Siemens EPOC instrument and methodology.

Motion: Dr. Gibson
Second: Dr. Vaughn
Abstain: Mr. Fleming

The exemption request was approved with the Board Chairman voting.

- 2. TriStar StoneCrest Medical Center**
200 StoneCrest Boulevard
Smyrna, TN 37167
Marvin Wagster, Laboratory Admin. Director
Becky Bakalyar, Point-of-Care Lead
Blake Longmire, Manager Respiratory Therapy

The request to permit Respiratory Therapists (ABG endorsed) to perform pH/Blood Gas Analysis (pH, PCO₂, and PO₂) testing facility-wide utilizing the Siemens EPOC instrument and methodology.

Motion: Dr. Vaughn
Second: Ms. Briggs
Abstain: Mr. Fleming

The exemption request was approved with the Board Chairman voting.

- 3. Baptist Memorial Hospital Memphis**
6019 Walnut Grove Road
Memphis, TN 38120
Karen Clark, BS, MT(ASCP)SH - Point of Care
Supervisor

The request was to permit Perfusionists to perform heparin anticoagulation testing in the Surgery Department utilizing the Medtronic Hepcon HMS Plus instrument and methodology.

Motion: Dr. Gibson
Second: Mr. Fleming

The exemption request was approved.

- 4. Methodist Medical Center of Oak Ridge**
990 Oak Ridge Turnpike
Oak Ridge, TN 37830
Josh Huskey, MLS(ASCP)cm – Point-of-Care
Technical Specialist

The request was to permit Registered Nurses to perform lactate testing in the Emergency Department utilizing the Nova Biomedical Lactate Meter instrument and methodology.

Motion: Mr. Fleming
Second: Dr. Gibson

The exemption request was approved.

- 5. Methodist LeBonheur Healthcare-
Germantown Lab**
7691 Poplar Avenue
Germantown, TN 38138
Ariel Simpson, MLS(ASCP) - Point of Care
Coordinator

The request was to permit Licensed Practical Nurses, Licensed Registered Nurses, Registered Respiratory Therapists, Registered Cardiovascular Technologists to perform co-oximetry testing in the Cardiac Cath Lab utilizing the Avoximeter 4000 instrument and methodology.

Motion: Mr. Fleming
Second: Ms. Briggs

The exemption request was approved.

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

Thomas C. Watkins, DO, PhD, FCAP
Knoxville, TN

Dr. Watkins appeared before the Board to request approval to make quarterly lab director visits at two of the five labs that he is currently directing.

The two labs that he requested the exemption for include:

- MEDIC Regional Center-Crossville Center-96 Hayes Street, Crossville, TN 38555
- MEDIC Regional Center-Athens Center-213 E. Washington Ave, Suite 104, Athens, TN 37303

Motion: Ms. Briggs
Second: Dr. Calarco

The request was approved.

Discuss, Review, And Take Action, if Needed:

Discuss the Definition of Lab Surveillance Testing

After discussion, the Board adopted the CDC definition of surveillance testing which reads:

“Public health surveillance is intended to monitor population-level burden of disease, or to characterize the incidence and prevalence of disease. Surveillance testing is primarily used to gain information at a population level, rather than an individual level. Surveillance testing results are not reported back to the individual. As such, surveillance testing cannot be used, for an individual’s health care decision making or individual public health actions such as isolation or quarantine.”

Governor’s Executive Orders

Governor Lee’s Executive Order 77 & 80 were reviewed by the Board.

Discuss Point of Care Testing Models
HCA HealthCare
Free Standing Emergency Department
Kelli Riggins, AVP-Laboratory Services HCA
Laura Medley-Director of Laboratory Services

HCA Healthcare proposed a Free Standing Emergency Department (FSED) model in which nursing staff performs moderately complex testing. They are proposing not to have a medical technologist or laboratory supervisor present when testing is being performed.

At this point, HCA Healthcare does not have three (3) months of laboratory data. They are developing a plan about the set-up and the diagnostic testing which they would like to share with the Board at their next meeting in July.

The Board requested that they complete an exemption packet and define where within the facility testing will occur.

Also, a request was made for a legal opinion regarding if the Board has the authority to grant an exemption to personnel performing testing within a FSED.

No motion was needed.

Update on Task Force to Discuss Digital Imaging and Remote Work

An email was sent to all interested task force participants notifying them that the meeting will take place in person on July 27, 2021.

No motion was needed.

Discuss Transcutaneous Testing

The Board discussed transcutaneous testing and determined that they are unable to regulate this methodology at this time.

No motion was needed.

Review And Discuss The Licensure Of Medical Laboratory Directors:

1. Ping Zou, PhD
Brentwood, TN 37027
Director: Molecular Diagnostics

Dr. Zou received her MD degree at Zhengzhou University in Zhengzhou, China in 1998.

She received her Ph.D. in Biophysics from Peking University Health Sciences Center, Beijing, China in 2003.

Dr. Zou is certified by the American Board of Bioanalysis (ABB) in Molecular Diagnostics through Dec. 31, 2021.

She received her postdoctoral fellowship training at Ovation Fertility in Nashville, TN from 2016-present.

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

Motion: Dr. Gibson
Second: Dr. Vaughn

The license was approved.

Reports/Requests:

Board Director's Report

Sandra Bogard, MS, MT(ASCP) QLC ^{cm}

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

The website continues to be updated daily/or as needed.

Staffing updates:

- New East TN Surveyor, Lori Reynolds, started on March 22, 2021.
- New Vacancy West TN Surveyor, Francena Kennedy resigned.

Board meeting dates for 2021 were presented.

Six (6) Board vacancies:

Board terms that expired in December:

- Hospital Laboratory Manager-Ms. Patti Walton
- Independent Laboratory Manager-Dr. Mark Calarco
- Cytotechnologist-Dr. Keisha Burnett
- Medical Technologist-Ms. Tereyo Cox

Board members that resigned:

- Jon Parham, DO Non-Pathologist Physician, Effective March 1, 2021
- Paul Fleming, MT Supervisor, Effective April 30, 2021

The continued attendance by these Board Members, pending new appointments, is greatly appreciated.

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

Motion to approve the report as given: Dr. Calarco
Second: Ms. Briggs

The report was accepted as given.

Board Attorney Report
Kyontzé Hughes-Toombs
Deputy General Counsel

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

One (1) open case is currently in the Office of General Counsel.

The personnel rule revisions are in an internal review.

The Governor's Executive Order #77 has been amended. However, it still includes the suspension of previously discussed Medical Laboratory Board rules and/or statutes. It is effective through May 31, 2021. The Executive Order allowing remote meetings has expired.

The Policy Statement on Esoteric Labs performing SARS-CoV-2 testing was presented and revised. After "...allow esoteric laboratories to..." the words "begin performing" were added. Also, before "The laboratories must notify..." the word "However" was added.

Motion to accept the esoteric lab policy statement as revised: Dr. Calarco
Second: Dr. Gibson

The motion was approved.

The policy statement on Mobile Laboratories was presented to the Board.

Motion to accept the policy statement as written:

Ms. Briggs

Second: Dr. Calarco

The motion was approved.

Motion to accept the Office of General Counsel Report as given: Dr. Gibson

Second: Dr. Calarco

The report was accepted as given.

Regional Surveyor Reports:

Complaint Investigations
Proficiency Testing Events
Regional Offices:
East, Middle, West TN

ETRO Report: 1st Quarter
Fowlen Anders, MT
Consultant/Surveyor

East Tennessee Regional Office –First Quarter 2021

Complaint Investigations: Zero (0)

Unsuccessful Proficiency Testing: Zero (0)

- First Occurrence (two in a row or two out of three unsatisfactory scores: Zero (0))
- Second Occurrence (three in a row or three out of five unsatisfactory scores: Zero (0))

MTRO Report: 1st Quarter
Susan Wilson, MT
Consultant/Surveyor

Middle Tennessee Regional Office –First Quarter 2021

Complaint Investigations: One (1)

Unsuccessful Proficiency Testing: Two (2)

- First Occurrence (two in a row or two out of three unsatisfactory scores: One (1))
- Second Occurrence (three in a row or three out of five unsatisfactory scores: One (1))

WTRO Report: 1st Quarter
Debbie Haggard, MT
Consultant/Surveyor

West Tennessee Regional Office –First Quarter 2021

Complaint Investigations: Zero (0)

Unsuccessful Proficiency Testing: Zero (0)

- First Occurrence (two in a row or two out of three unsatisfactory scores: Zero (0))
- Second Occurrence (three in a row or three out of five unsatisfactory scores: Zero (0))

Motion to accept the reports as given: Ms. Briggs
Second: Mr. Fleming

Reports were accepted as given.

Board Ratifications Initial Facility Applications:

- 1. ADMA BioCenters Georgia, Inc.**
1412 Sevierville Road
Maryville, TN 37804

Specialties: Spun Hematocrit
Total Serum Protein

Laboratory Director: Nancy L. Witherspoon, DO
Geriatric Medicine

Surveyor: Fowlen Anders, MT Consultant II/ETRO

Motion: Dr. Vaughn
Second: Mr. Fleming

The license was approved.

- 2. Associated Pathologist, LLC dba Pathgroup**
601 Grassmere Park
Nashville, TN 37211

Specialties: Molecular Diagnostics

Laboratory Director: Pranil K. Chandra, DO
Clinical & Anatomic Pathology

Surveyor: Susan Wilson, MT Consultant II/MTRO

Motion: Ms. Briggs
Second: Dr. Gibson

The license was approved.

- 3. BioReference Lab, Inc @ Tennessee GYN**
9330 Park West Boulevard, Suite 409
Knoxville, TN 38017

Specialties: Collection Station

Laboratory Director: Ariana Citabria Holley, MD
Clinical & Anatomic Pathology

Surveyor: Fowlen Anders, MT Consultant II/ETRO

Motion: Dr. Calarco
Second: Mr. Fleming
Abstain: Ms. Jolly

The license was approved with the Board Chairman

4. Octapharma Plasma, Inc.
7124 Winchester Road
Memphis, TN 38125

voting.

Specialties: Spun Hematocrit
Total Serum Protein

Laboratory Director: Marshall Goren, MD

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Ms. Briggs
Second: Dr. Vaughn

The license was approved.

5. PhaseTwo Labs, LLC
5225 Harding Place
Nashville, TN 37217

Specialties: Molecular Diagnostics

Laboratory Director: Jeff Wisotzkey, PhD

Surveyor: Susan Wilson, MT Consultant II/MTRO

Motion: Mr. Fleming
Second: Ms. Cox

The license was approved.

**6. Sewanee Molecular Diagnostics
Laboratory-Esoteric Lab**
735 University Avenue
Sewanee, TN 37383

Specialties: Esoteric-Molecular Diagnostics

Laboratory Director: Daniel Snyder, DO
Clinical & Anatomic Pathology

Surveyor: Susan Wilson, MT Consultant II/MTRO

Motion: Dr. Vaughn
Second: Mr. Fleming

The license was approved.

**7. West Tennessee Regional Blood
Center dba Lifeline Blood Svc**
1130 Highway 51, Suite 19 & 20
Dyersburg, TN 38024

Specialties: Hemoglobin

Laboratory Director: Paul Jeffrey Sims, MD
Clinical & Anatomic Pathology
Blood Bank/Transfusion Medicine

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Dr. Gibson
Second: Ms. Briggs

The license was approved.

8. Vanderbilt Health Belle Meade
6002 Highway 100, #1307
Nashville, TN 37205

Specialties: Microbiology
Hematology
Urinalysis
Routine Chemistry
UCG Pregnancy Test

Laboratory Director: Ridas Juskevicius, MD
Clinical & Anatomic Pathology

Surveyor: Susan Wilson, MT Consultant II/MTRO

Motion: Dr. Calarco
Second: Dr. Gibson

The license was approved.

Other Business/Discussion:

Nothing to present.

Adjournment:

With no further business to discuss, the meeting was adjourned at 12:43 pm CDT.

Motion to adjourn: Ms. Briggs
Second: Dr. Calarco

The meeting was adjourned.