

**Tennessee Medical Laboratory Board
October 28, 2022
Full Board Meeting
Minutes**

Meeting Date: October 28, 2022

Time: 9:01 am CDT

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-Gen.-Chairman
Jerry Barker, MT-Hospital Lab Mgr/Admin. Dir.
LeeAnne Briggs, MT- Med. Technologist, Educator
Danielle Gibson, MD-Pathologist
Jennifer Gidcomb, MT-Medical Technologist, General
Matthew Hardison, Ph.D., Independent Lab Mgr/Adm.
Chris Litle, MT-Medical Laboratory Supervisor
Andrew Stanton, CT-Cytotechnologist
James A. Vaughan, MD-Pathologist Educator

Vacant Positions: Non-Pathologist Physician
Pathologist

Members Absent: Gaye G. Jolly, MT-Hospital Administrator
Lynn Stewart, Citizen Representative

Staff Present: Sandra S. Bogard, MT Consultant, Director
Nina V. Smith, MT Consultant Administrative Office
Matt Gibbs, Deputy General Counsel
Mina Girgis, Board Administrator
Debbie Haggard, MT Consultant/Supervisor WTRO
Fowlen Anders, MT Consultant/Supervisor ETRO
Bobby Sommer, MT Consultant/Supervisor MTRO
Lori Reynolds, MT Consultant/Surveyor ETRO

Staff Absent: Richie Scruggs, MT Consultant/Surveyor WTRO

CLIA Manager/Representative: Tracy McLemore, MT CLIA Director

Introduction of Board Members: Board members and staff made their introductions to the audience.

Quorum: Nine (9) board members were present, which constituted a quorum.

Call To Order:

The meeting was called to order at 9:01 am CDT by Michael Johnson, the Board Chairman.

Presiding Officer:

Mr. Johnson conducted the meeting.

Approve Minutes:

P & E Committee Meeting

A motion to approve July 28, 2022, Personnel & Education Committee minutes was made by Mr. Barker.

Second: Ms. Gidcomb

The minutes were approved.

Full Board Meeting

A motion to approve July 29, 2022, Full Board meeting minutes was made by Mr. Stanton.

Second: Ms. Briggs

The Board minutes were approved.

Ratification of Initial Determinations
P & E Committee Meeting:

Ms. Briggs reported the actions of the Personnel & Education Committee meeting, October 27, 2022.

Motion to ratify Committee actions: Dr. Vaughan.

Second: Ms. Gidcomb

The report was accepted as presented by Ms. Briggs.

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

Nothing to present.

Presentations To The Board:

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

The statistical report for July 1, 2022-September 30, 2022, was presented by Ms. Teresa Phillips, Executive Director.

Zero (0) individuals were monitored during this period.

Motion to accept the TNPAP report: Ms. Gidcomb.

Second: Mr. Litle

The report was accepted as given.

Health Facilities Commission (HFC)
Caroline Tippens, Esq., C.H.C.
Director Licensure & Regulation

Ms. Tippens introduced the new CLIA Director, Tracy McLemore, MT, and the two new laboratory surveyors for the Middle Tennessee region, Mr. Bobby Sommer, MT, and Ms. Misty Rector, MT.

Ms. Tippens also discussed how they were addressing the survey backlog and indicated their willingness to work with the Board in collaboration and cooperation.

Investigations Report
Roger Knowlton
Disciplinary Intake Coordinator

Mr. Knowlton's investigative report included the following:

Monitored Practitioners (Personnel and Facilities):
(January-October 2022)

Investigative Licensed Laboratory Personnel: (2022)
Zero (0) new complaints
One (1) complaint closed
Zero (0) currently open

Investigative Licensed Laboratory Facilities: (2022)
Seven (7) new complaints:
Two (2) malpractice/negligence
Two (2) COVID
Three (3) unprofessional conduct
Nine (9) closed complaints:
Three (3) Insufficient evidence
Three (3) referred to OGC
Three (3) closed-warning letter
Five (5) currently open complaints

Motion to accept the report: Ms. Briggs.
Second: Mr. Barker

The investigations report was accepted as given.

Financial Report
Keeyona Love, MPS
Fiscal Manager

Ms. Love gave the Annual Fiscal Report, which compared the actual revenue and expenditures for the past three (3) years (FY2020, FY2021, FY2022). The values were compared with little change from year to year. She also presented information regarding the revenue sources for FY2022 that included the following fees: renewal, civil penalty, case cost assessment, unassigned cash, penalty-late renewal, reinstatement, return check fee, state regulatory fee, application, licensure, and undefined ASC feed codes.

Motion: Dr. Vaughan
Second: Ms. Gidcomb

Legislative Update

Olivia Spears, Esq.
Legislative Liaison

The report was accepted as given.

No report was given.

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

1. Tristar Centennial Medical Center

Nashville, TN
Mollie Wynn, MT-POC/QA Coordinator
Molly Cassady, MLT-POC Lead Tech

The first request is to permit Core Staff Registered Nurses (RNs) and Charge Nurses (RNs) to perform and report Ruptured Membrane Test (ROM) in the Women's Obstetrics Emergency Room and 6th Floor Maternal Special Care Unit utilizing the ROM Plus methodology.

Motion: Dr. Gibson
Second: Mr. Stanton

The exemption request was approved.

2. MidSouth Transplant Foundation

Cordova, TN
Kylie Peck, BS, MS, MT(ASCP), CHT, CHS(ABHI)
HLA Lab Technologist

The request was to permit Emergency Medical Technicians, Paramedics, International Medical Graduates, Certified Procurement Transplant Coordinators, Certified Respiratory Therapists (CRT) ABG-endorsed, Organ Donor Coordinators, Clinical Response Coordinators, Surgical Technicians, Director of Clinical Operations-Organ, and Manager of Organ Recovery to perform and report sodium, potassium, chloride, BUN, ionized calcium, glucose, creatinine, pH, pCO₂, pO₂, TCO₂, and lactate on brain dead patients awaiting the donation process at multiple hospital locations throughout Tennessee utilizing the Abbott i-STAT instrument and methodology.

The Board indicated that the testing personnel must meet the CLIA requirements for moderately complex testing, and the exemption is limited to organ procurement on brain-dead patients.

Motion: Dr. Hardison
Second: Mr. Litle

The exemption request was approved.

3. Saint Francis Hospital Memphis

Memphis, TN
Ricky Tucker, MT

The request was to permit Registered Respiratory Therapists (RRT) and Certified Respiratory Therapists (CRT) to perform and report sodium, potassium,

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chloride, ionized calcium, glucose, lactic acid, pH, pCO₂, pO₂, HCO₃, BE, tHB, O₂HB, COHB, METHB in the ICU, NICU, Emergency Department, Catheterization Lab, and hospital-wide utilizing the Siemens RAPIDPoint 500e Blood Gas instrument and methodology.

Motion: Ms. Briggs
Second: Ms. Gidcomb

The exemption request was approved.

- 4. Cookeville Regional Medical Center**
Cookeville, TN
Tammy McCoy, MA, BS, MLS(ASCP)
POC Supervisor/ABG Technical Supervisor

The request was to permit Licensed Perfusionists, Registered Nurses, Licensed Practical Nurses, Certified Radiological Technologists, and Respiratory Therapists to perform and report sodium, potassium, chloride, ionized calcium, ionized magnesium, glucose, BUN, creatinine, hematocrit, hemoglobin, lactate, pH, pCO₂, pO₂, sO₂, and Co-Oximetry campus-wide utilizing the Nova Prime Plus instrument and methodology.

Motion: Dr. Vaughan
Second: Dr. Gibson

The exemption request was approved.

- 5. Parkwest Medical Center**
Knoxville, TN
Mark Trujillo, RT-Manager Respiratory Care

To permit licensed Registered Respiratory Therapists (RRTs) and Certified Respiratory Therapists (CRTs) to perform and report oxygen saturation (O₂sat), oxygen content (CaO₂), and total hemoglobin (tHb) in the Cardiac Catheterization Lab utilizing the AVOXimeter 1000E instrument and methodology.

Motion: Ms. Briggs
Second: Dr. Gibson

The exemption request was approved.

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

Nothing to present.

Discuss, Review, And Take Action, if Needed:

Discussion of regulation change regarding the release of tissue samples to providers.

Dr. Stephen Schleicher, CMO, and Brad Lampley, Esq. with Tennessee Oncology, requested that the Board consider changing their regulations to allow for the timely release of a patient's original biopsy tissue sample to the providers that are responsible for the treatment. After discussion, the Board decided to refer this issue to the Task Force for further discussion and rule revision.

Discuss the need for a laboratory facility license.

The Board tabled any action on this inquiry until the January 2023 Board meeting when the Task Force can provide recommendations.

The Board reviewed a question concerning physical rehabilitation hospitals and if they are viewed as physician office laboratories or subject to the Medical Laboratory Board's regulations.

The Board decided to refer this question to the Task Force for review and possible regulation change.

The Board tabled any action on this inquiry until the January 2023 Board meeting when the Task Force can provide recommendations.

Discuss collection station licensure.

Beth Hawes, VP of Operations with ETHOS Laboratories in Kentucky, requested clarification from the Board if they need to obtain collection station licenses in Tennessee. ETHOS Laboratories has staff located in physician office laboratories in Tennessee that collect specimens and send them to their out-of-state lab. The Board discussed if each location needed a Tennessee collection station license.

After discussion, The Board decided to refer this question to the Task Force for review and possible regulation change. Also, the pending collection station applications will be on hold while continuing operations until the January 2023 Board meeting.

The Board tabled any action on this inquiry until the January 2023 Board meeting when the Task Force can provide recommendations.

Motion: Ms. Gidcomb
Second: Mr. Barker

The motion to table the request was approved.

Discuss if the collection of research samples requires a collection station license.

After discussion, the Board decided that the collection of research samples in a collection station is not under the purview of the Medical Laboratory Act.

No motion was needed.

Clarification of Board policy pertaining to waived testing.

The following question was presented to the Board for clarification:

If a facility has multiple waived testing instruments that test for the same analyte, i.e., glucometers, does the lab need to validate each instrument or only one?

After discussion, the Board decided that only one waived testing instrument would need to be validated if they were all using the same method.

No motion was needed.

Discussion if a laboratory that only performs H&E and special stains need a state license.

The Board discussed if a laboratory that only performs H&E and special stains would need a state laboratory license even if pathologists do not read slides on the premises.

After discussion, the Board decided that the laboratory did need a state license and the appropriate modifier for the license is histopathology.

Motion: Ms. Gidcomb
Second: Mr. Stanton

The motion was approved.

Clarification of Board guidance pertaining to remote lab work.

The following questions were presented to the Board for clarification:

1. If pathologists read slides at different hospitals, do they need different facility licenses at each location or one license for the pathology group?

After discussion, the Board decided that reading glass or digital slides by pathologists does not require an additional lab license except for the license for the pathology group. If the pathologists perform fine needle aspirations (FNA) at different locations, a lab license is required at each site where the FNA is performed.

2. Does the reading of glass slides apply to the Remote Work Policy or only digital images?

After discussion, the Board decided that the Remote Work Policy needs to be revised to include the reading of glass slides by pathologists. The glass slides, along with the pathology records, need to be maintained by the main histology laboratory that is licensed. In addition, cytology maintenance records for the

microscopes should be housed in the licensed central laboratory and retrievable upon request.

No motion was needed. The Remote Work Policy was amended based on Board guidance and clarification.

Discuss Remote Survey Policy Statement.

The Board reviewed the Remote Survey Policy Statement and made the following revisions:

- The onsite review was interpreted to include the review of documents by electronic means.
- Removed the term "moderately complex."
- Removed the phrase "with verified poor performance."
- The Board decided not to limit the remote survey process to two years but that it could not be used for the same laboratory for consecutive surveys.

Motion: Ms. Gidcomb

Second: Ms. Briggs

The motion to accept the policy revisions was approved.

CLEAR Board Member Training

The Board discussed the Board member training offered by the Council on Licensure, Enforcement, and Regulation (CLEAR). They decided that they were not interested in the training.

No motion was needed.

ASCP Conference

The Board discussed the possibility of Board members and staff attending the American Society for Clinical Pathology (ASCP) Annual Conference in 2023. The decision was tabled until the January meeting awaiting clarification from staff regarding the State's travel policy.

No motion was needed.

Review and Discuss the Licensure of Medical Laboratory Directors:

1. Shu-Ling Fan, Ph.D.
Franklin, TN
Director – Clinical Chemistry

Dr. Fan received her B.S. degree in Medical Technology at the National Cheng Kung University in Tainan, Taiwan, in 1998.

She received her M.S. degree in Clinical Laboratory Science from the University of Buffalo in Buffalo, New York, in 2000.

Dr. Fan received her Ph.D. in Clinical Chemistry from Cleveland State University in Cleveland, OH, in 2005.

She was certified by the American Board of Clinical Chemistry (ABCC) as a Clinical Chemist in 2009.

Dr. Fan received her post-doctoral fellowship training at John Hopkins Medical Institute Department of Pathology in Baltimore, MD, from 2005-2007.

She is seeking licensure as a Director of Clinical Chemistry.

Motion: Dr. Hardison
Second: Mr. Stanton

The license was approved.

2. Lijun Wang, Ph.D.
Chicago, IL
Director of Molecular Diagnostics

Dr. Wang received his M.D. degree in Clinical Medicine from Binzhou Medical College in China in 1991.

He received her Ph.D. in Neurology from Peking University Health Science Center in China in 1999.

Dr. Wang was certified by the American Board of Medical Genetics and Genomics (ABMGG), Diplomate Clinical Molecular Genetics and Genomics, in 2017.

He was a fellow of the American College of Medical Genetics and Genomics (ACMG) in 2017.

Dr. Wang received his post-doctoral fellowship training at the Clinical Molecular Genetics, Division of Human Genetics in Cincinnati Children's Hospital Medical Center in Ohio from 2014-2016.

He is seeking licensure as a Director of Molecular Diagnostics.

Motion: Dr. Gibson
Second: Mr. Barker

The license was approved.

3. Amal Aly, Ph.D.
Wayne, NJ
Director of Cytogenetics

Dr. Wang received her M.D. degree in OB/GYN from Al-Azhar University in Cairo, Egypt, in 1997.

She received her Ph.D. in Cell and Molecular Pharmacology from Rutgers University in Newark, NJ, in 2011.

Dr. Aly was certified by the American Board of Medical Genetics and Genomics (ABMGG), Clinical Cytogenetics and Genomics in 2017.

She received her post-doctoral fellowship training at the University of Medicine and Dentistry of New Jersey, The Cancer Institute of NJ from 2011-2012.

She is seeking licensure as a Director of Cytogenetics.

Motion: Ms. Gidcomb.

Second: Mr. Stanton

The license was approved.

4. Kendall Bryant, Ph.D.
Portland, OR
Director of Microbiology

Dr. Bryant received his B.S. degree in Biology at UT Chattanooga in Chattanooga, TN, in 2003.

He received his Ph.D. in Microbiology from the University of Nebraska Medical Center in Omaha, NE, in 2008.

Dr. Bryant was certified by the American Board of Medical Microbiology (ABMM) in 2012 and expires on Dec. 31, 2024.

He received his post-doctoral fellowship training in CPEP Clinical Microbiology at the University of Nebraska Medical Center in Omaha, NE, from 2010-2012.

He is seeking licensure as a Director of Microbiology.

Motion: Dr. Gibson

Second: Ms. Briggs

The license was approved.

Reports/Requests:

Board Director's Report

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

The report included statistical data concerning laboratory personnel, facilities, training programs licensure, and health fair/health screening events during the Third Quarter of 2022.

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

Staffing updates:

New Middle TN surveyors:

- Robert “Bobby” Sommer, MT Supervisor – Started 10/17/22.
- Misty Rector, MT-Starts 11/14/22.

Board meeting dates for 2023 and 2024 were presented.

No new Board Members have been appointed.

Vacancies on the Board:

- Pathologist – Dr. Kieffer resigned due to moving out of state.
- Non-Pathologist Physician
- Hospital Administrator
- Citizen Member

Continue to work on the collaborative database between CEDEP (Communicable and Environmental Diseases and Emergency Preparedness) and the Medical Laboratory Board. The Board Director is currently working with a Project Manager on the design components of the database.

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

Motion to approve the report as given: Dr. Vaughan.

Second: Ms. Briggs

Absent: Mr. Litle

The report was accepted as given.

Deputy General Counsel Matt Gibbs gave his Office of General Counsel report for the Third Quarter of 2022:

- The Conflict-of-Interest Policy was reviewed with the Board members.
- Two (2) open cases are currently in the Office of General Counsel.
- A Remote Survey Policy draft was presented to the Board for review.

Board Attorney Report
Matt Gibbs
Deputy General Counsel

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

Second: Mr. Stanton

Absent: Ms. Gidcomb

The report was accepted as given.

Disciplinary Report

Matt Gibbs

Deputy General Counsel

Deputy General Counsel Matt Gibbs gave the Disciplinary Report for the Third Quarter of 2022:

- Seven (7) licensees are being monitored.
- Two (2) with terms of reprimand.
- Five (5) with terms of suspension.

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

Second: Ms. Briggs

Absent: Ms. Gidcomb

The report was accepted as given.

Regional Surveyor Reports:

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

ETRO Report: 3rd Quarter
Fowlen Anders, MT
Consultant/Surveyor

East Tennessee Regional Office –Third Quarter 2022:

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: 3rd Quarter

Middle Tennessee Regional Office–Third Quarter 2022:

No report was given.

WTRO Report: 3rd Quarter
Debbie Haggard, MT
Consultant/Surveyor

West Tennessee Regional Office –Third Quarter 2022:

Complaint Investigations: One (1)-substantiated)

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: Dr. Gibson.
Second: Dr. Hardison

Reports were accepted as given.

Addition/Deletions to the Board's Health Screening Test List:

Nothing to present.

Board Ratifications Initial Facility Applications:

1. Biomat USA, Inc.
Murfreesboro, TN

Specialties: Plasmapheresis Center (Spun Hematocrit & Total Serum Protein)

Laboratory Director: Samori O. Cummings, M.D.
American Board of Pediatrics

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Ms. Briggs
Second: Mr. Litle
Absent: Ms. Gidcomb

The license was approved.

2. Laboratory Corporation of America Holdings
Memphis, TN

Specialty: Hematology

Laboratory Director: Pamela T. Osborne, M.D.
Anatomic/Clinical Pathology

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Mr. Hardison
Second: Mr. Barker
Absent: Ms. Gidcomb

The license was approved.

3. Kingsport PSC-Walgreens
Kingsport, TN

Specialty: Collection Station

Laboratory Director: Kelly H. Coches, D.O.

Surveyor: Fowlen Anders, MT Consultant II/ETRO

Motion: Dr. Gibson
Second: Mr. Stanton
Absent: Ms. Gidcomb

The license was approved.

Other Business/Discussion:

Task Force Report

Mr. Johnson presented a verbal report summarizing the proposed regulation changes of the October 8, 2022, Task Force meeting.

After discussion, the Board decided to rescind the Lapsed License Policy.

Motion: Ms. Briggs
Second: Dr. Gibson
Absent: Ms. Gidcomb

The policy was rescinded.

The Board decided to adopt the Board of Optometry Lapsed License Policy with revisions as their new policy.

Motion: Dr. Hardison.
Second: Mr. Stanton
Absent: Ms. Gidcomb

The new policy was approved.

Election of Chairman-Full Board

The nomination for Full Board Chairman was Ms. Gidcomb.

Motion: Ms. Briggs.
Second: Dr. Vaughan

The nomination was approved.

Election of Vice-Chairman- Full Board

The nomination for Full Board Vice-Chairman was Mr. Barker.

Motion: Ms. Gidcomb.
Second: Mr. Stanton

The nomination was approved.

Election of P&E Committee Chairman

The nomination for P & E Committee Chairman was Ms. Briggs.

Motion: Ms. Gidcomb.
Second: Mr. Barker

The nomination was approved.

Adjournment:

With no further business to discuss, the meeting was adjourned at 2:19 pm CDT.

Motion to adjourn: Mr. Litle.
Second: Ms. Briggs
Absent: Ms. Gidcomb

The meeting was adjourned.