

**Tennessee Medical Laboratory Board
October 25, 2024
Full Board Meeting
Minutes**

Meeting Date: October 25, 2024

Time: 9:00 a.m. CST

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:

Jennifer Chandler, MT-Med. Technologist General-Chair
Jerry Barker, MT-Hosp Lab Mgr/Admin. Dir.-Vice-Chair
LeeAnne Briggs, MT- Med. Technologist Educator
Danielle Gibson, MD-Pathologist
Chris Litle, MT-Medical Laboratory Supervisor
James A. Vaughan, MD-Pathologist Educator
Diana Varela-Citizen

Vacant Positions: Pathologist

Members Absent:

Penny Asbell, MD- Non-Pathologist Physician
Matthew Hardison, Ph.D., Independent Lab Mgr/Adm.
Michael Johnson, MT-Medical Technologist-General
Marilyn (Buffy) Key, MT-Hospital Administrator
Andrew Stanton, CT-Cytotechnologist

Staff Present:

Sandra S. Bogard, MT Consultant, Director
Nina V. Smith, MT Consultant Administrative Office
Kertyssa Tia Smalls, Senior Associate Counsel
Mina Girgis, Board Administrator
Debbie Haggard, MT Consultant/Supervisor WTRO
Fowlen Anders, MT Consultant/Supervisor ETRO
Robert Sommer, MT Consultant/Supervisor MTRO
Misty Rector, MT Consultant/Surveyor WTRO
Kathy Dunn-McPhall, MT Consultant/Surveyor MTRO
Pam Frederick, MT Consultant/Surveyor ETRO

Staff Absent: None

CLIA Manager/Representative: Tracy McLemore, MT CLIA Director

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

Quorum:

Ten (10) board members were present, which constituted a quorum.

Call To Order:

The meeting was called to order at 9:00 a.m. CDT by Jennifer Chandler, the Board Chairman.

Presiding Officer:

Mrs. Chandler conducted the meeting.

Approve Minutes:

P & E Committee Meeting

A motion to approve the August 2, 2024, Personnel & Education Committee minutes was made by Dr. Vaughan.

Second: Ms. Briggs

The minutes were approved as written with the Chairman voting.

Full Board Meeting

A motion to approve the August 2, 2024, Full Board meeting minutes was made by Mr. Barker.

Second: Mr. Litle

The Board minutes were approved as written with the Chairman voting.

**Ratification of Initial Determinations
P & E Committee Meeting:**

Ms. Briggs reported the actions of the Personnel & Education Committee meeting, October 24, 2024.

Motion to ratify Committee actions: Dr. Gibson.

Second: Dr. Vaughan

The report was accepted as presented by Ms. Briggs, with the Chairman voting.

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, 2024-September 30, 2024, was presented by Ms. Teresa Phillips, Executive Director.

One (1) individual was monitored during this period, one (1) regulatory.

Investigations Report
Amy Bozzelli
Complaint Coordinator

Motion to accept the TNPAP report: Ms. Briggs.
Second: Mr. Litle

The report was accepted as given with the Chairman voting.

Ms. Bozzelli's investigative report included the following:

Monitored Practitioners (Facilities): (January-Oct. 2024)

Investigative Licensed Laboratory Facilities: (2024)

Four (4) new complaints

Eight (8) closed complaints

- Two (2) insufficient evidence
- Two (2) closed letter of concern
- Three (3) closed
- One (1) referred to OGC

Four (4) currently open complaints

Investigative Licensed Laboratory Personnel: (2024)

Three (3) currently open complaints

Investigative Licensed Laboratory Schools: (2024)

Zero (0) currently open complaints

Motion to accept the report: Mr. Vaughan.

Second: Dr. Gibson

The investigation report was accepted as given with the Chairman voting.

Financial Report
Emily Godwin
Fiscal Director

Ms. Godwin presented the preliminary FY2024 Fiscal Report (Jan 1, 2024-June 30, 2024), which compared the actual revenue and expenditures for the past three (3) years (FY2022, FY2023, FY2024(to date)). The values were compared with little change between FY2022 and FY2023. Fiscal year 2024 (to date) showed an increase of \$328,276.43 in total expenditures compared to FY2023. She also presented information regarding the expenditure sources for all three years, which included the following: salaries, travel, printing, maintenance/repairs, professional services, supplies/materials, grants, computer-related issues, and state professional services.

Motion: Dr. Vaughan

Second: Ms. Briggs

The report was accepted as given with the Chairman voting.

Legislative Update

Holt Whitt
Assistant Commissioner of Legislative
Affairs

No report was presented.

Surveyor Update
Tracy McLemore, MT
CLIA Director

Mr. McLemore presented a written report to the Board regarding the surveyor workload.

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

The report was accepted as given with the Chairman voting.

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

1. Erlanger East Laboratory

Chattanooga, TN
Rita Stewart, MLT-Lab Support Services
Coordinator

The request was to permit Registered Nurses, Nurse Practitioners, and Midwives in the OBED to perform and report rupture of membranes test to detect amniotic fluid utilizing the ROM Plus System.

Motion: Dr. Gibson
Second: Mr. Litle

The exemption request was approved with the Chairman voting.

2. Baroness Erlanger Hospital Laboratory

Chattanooga, TN
Rita Stewart, MLT-Lab Support Services
Coordinator

The request was to permit Registered Nurses, Nurse Practitioners, and Midwives in the OBED to perform and report rupture of membranes test to detect amniotic fluid utilizing the ROM Plus System.

Motion: Ms. Briggs
Second: Mr. Barker

The exemption request was approved with the Chairman voting.

3. Methodist Medical Center of Oak Ridge

Oak Ridge, TN
Joshua Huskey, MLS(ASCP)-Point of Care
Coordinator

The request was to permit Registered Nurses in the Cardiovascular Intensive Care (CVSU)/Acute Care Unit to perform and report the Activated Clotting Times (ACT) test utilizing the Werfen Hemochron instrument.

Motion: Mr. Litle
Second: Ms. Briggs

The exemption request was approved with the Chairman voting.

- 4. Parkridge Medical Center**
Chattanooga, TN
Jessie Buntin MSM, MLS(ASCP)-Market Point
of Care Coordinator

The request was to permit Registered Nurses (RN) in the Operating Room (OR) to perform and report Sodium, Potassium, Glucose, Hematocrit, Hemoglobin, pH, pO₂, ionized Calcium, and Lactic Acid testing utilizing the EPOC Blood Analysis System and methodology.

Motion: Mr. Barker
Second: Dr. Vaughan

The exemption request was approved with the Chairman voting.

- 5. Lab Plus, LLC - Saint Thomas Midtown**
Nashville, TN
LaKisha Prowell, MT(ASCP)-Laboratory
Operations Manager

The request was to permit Registered Respiratory Therapists (RRT) and Certified Respiratory Technicians (CRT) to perform and report Arterial Blood Gas Testing (pH, pO₂, pCO₂, TCO₂, HCO₃, BE, and sO₂) facility-wide utilizing the Abbott i-STAT instrument and methodology.

Motion: Ms. Briggs
Second: Dr. Gibson

The exemption request was approved with the Chairman voting.

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

- 1. Frances L. Cate, MD**
Nashville, TN

Frances L. Cate, MD requested to direct the following four (4) laboratories:

- TriStar Centennial Medical Center Laboratory-2300 Patterson Street, Nashville, TN 37203 (L3262)
- TriStar Centennial Med Ctr NICU Resp Bld Gas Lab-2221 Murphy Ave, 7th Flr, Nashville, TN 37203 (L2205)
- PathGroup Labs, LLC dba Jackson, TN-28 Medical Center Drive, Jackson, TN 38301-(L4520-pending)-Initial license pending ratification
- Bellevue Free Standing Emergency Room- Nashville, TN (application pending)-NEW

Motion: Dr. Gibson
Second: Dr. Vaughan

The request for Dr. Cate to direct four (4) laboratories was approved with the Chairman voting.

2. Gregory A. Stancel, MD
Kingsport, TN

Gregory A. Stancel, MD requested to direct the following four (4) laboratories:

- Hancock County Hospital-1519 Main Street, Sneedville, TN 37869-(L4095)
- Hawkins County Memorial Hospital-851 Locust Street, Rogersville, TN 37857-(L2035)
- Hawkins County ABG Laboratory-851 Locust Street, Rogersville, TN 37857-(L4085)
- Holston Valley Medical Center-Point of Care-130 W. Ravine Rd, Kingsport 37660-(L4086)-NEW

Motion: Dr. Vaughan
Second: Dr. Gibson

The request for Dr. Stancel to direct four (4) laboratories was approved with the Chairman voting.

Discuss, Review, And Take Action, if Needed:

Discuss the possibility of decreasing the frequency of laboratory director onsite visits to blood donor centers.

Vitalant
Salima Shaikh, MD-Medical Director
Northeast and South Divisions
Stephanie Stenshoel-Regulatory Compliance Manager

Discuss if a hospital needs a separate laboratory license to perform waived testing.

TriStar Centennial Parthenon Pavilion
Psychiatric Hospital
Mollie Wynn, MT-Laboratory QA & POC Coordinator

The Board discussed Vitalant's request to decrease the laboratory director's on-site visits to every six (6) months. The new law 68-29-116, which allows laboratory directors to monitor laboratory personnel remotely, was also discussed.

After the discussion, Dr. Shaikh decided to withdraw the request.

No motion was needed.

The Board clarified its rules and determined that a hospital that only performs waived testing could submit a Waived Testing Notification form to the Board's Administrative Office. The Board's Attorney will request information from Health Facilities Commission regarding hospital compliance before a final decision can be rendered.

This decision was tabled until the January 2025 Board meeting.

Discuss Public Chapter 1046.

After discussion, it was decided to table this discussion until the January 2025 Board meeting.

Review and Discuss the Licensure of Medical Laboratory Directors:

Nothing to present.

Reports/Requests:

Board Director's Report

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

The report included statistical data concerning laboratory personnel, facilities, training programs, and health fair/health screening events during the Third Quarter of 2024.

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

Staffing updates:

Ms. Bogard announced to the Board that she will be retiring from State government and will not be at the next Board meeting.

Board meeting dates for 2025 were presented.

Vacancies on the Board:

- Pathologist

Board positions that expired on December 31, 2023:

- Chris Litle-Medical Laboratory Supervisor
- Michael Johnson-Medical Technologist Generalists

Board positions that will expire on December 31, 2024:

- Andrew Stanton-Cytotechnologist
- Jennifer Chandler-Medical Technologist
- Jerry Barker-Hospital Laboratory Manager/Administrative Director

The Personnel, Laboratory Facility, and Training Program regulations are currently awaiting Rulemaking Hearings.

2024 State Licensure Surveyor Workload Targets:

West TN – 59 surveys
Middle TN – 52 surveys
East TN – 40 surveys

Each region will be incorporating the remote survey process along with onsite surveys.

The target survey workload is three (3) state-licensed laboratory surveys per fully trained surveyor per month.

January-September 2024 (completed biennial, initial, & complaint surveys only):

West TN – 49 surveys

Middle TN – 37 surveys

East TN – 30 surveys

January-September 2024 (completed all survey types):

West TN – 74 surveys

Middle TN – 55 surveys

East TN – 38 surveys

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

Motion to approve the report: Ms. Briggs.

Second: Dr. Gibson

The report was accepted with the Chairman voting.

Board Attorney Report

Kertyssa Tia Smalls
Senior Associate Counsel

Senior Associate Counsel Kertyssa Tia Smalls gave her Office of General Counsel report for the Third Quarter of 2024:

- The Conflict-of-Interest Policy was reviewed with the Board members.
- Two (2) open cases.
- OCG is completing its internal review of the Medical Laboratory Board Rules.

Disciplinary Report

Kertyssa Tia Smalls
Senior Associate Counsel

Senior Associate Counsel Kertyssa Tia Smalls gave the Disciplinary Report for the Third Quarter of 2024:

Four (4) licensees are being monitored.

- Two (2) with terms of reprimand.
- One (1) on probation.
- One (1) on suspension.

Motion to accept the Office of General Counsel Report and the Disciplinary Report as given: Mr. Litle.
Second: Mr. Barker

The reports were accepted as given with the Chairman voting.

Regional Surveyor Reports:

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

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

East Tennessee Regional Office –Third Quarter 2024:

Complaint Investigations: One (1)

Unsuccessful Proficiency Testing: Two (2)

- First Occurrence (two in a row or two out of three) unsatisfactory scores: Two (2)
- Second Occurrence (three in a row or three out of five) unsatisfactory scores: Zero (0)

Motion to accept the report:
Mr. Litle.
Second: Mr. Barker

The report was accepted as presented with the Chairman voting.

MTRO Report: 3rd Quarter
Robert Sommer, MT
Consultant/Surveyor

Middle Tennessee Regional Office–Third Quarter 2024:

Complaint Investigations: Two (2)

Unsuccessful Proficiency Testing: One (1)

- First Occurrence (two in a row or two out of three) unsatisfactory scores: Four (4)
- Second Occurrence (three in a row or three out of five) unsatisfactory scores: Zero (0)

Motion to accept the report:
Mr. Barker.
Second: Mr. Litle

The report was accepted as presented with the Chairman voting.

WTRO Report: 3rd Quarter
Debbie Haggard, MT

West Tennessee Regional Office –Third Quarter 2024:

Consultant/Surveyor

Complaint Investigations: One (1)-Two (2) allegations

Unsuccessful Proficiency Testing: Zero (0)

- First Occurrence (two in a row or two out of three) unsatisfactory scores: Four (4)
- Second Occurrence (three in a row or three out of five) unsatisfactory scores: Zero (0)

Motion to accept the report:

Mr. Litle.

Second: Dr. Gibson

The report was accepted as presented with the Chairman voting.

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

Nothing to present.

Board Ratifications Initial Facility Applications:

- 1. Cellular Therapy Laboratory**
Knoxville, TN 37920

Clinical Laboratory

Specialties: General Immunology & Hematology.

Medical Laboratory Director: Ramon Hartage, M.D.
ABP/Clinical Pathology/Blood Bank Transfusion Medicine

Surveyor: Fowlen Ivey, MT-Consultant/Surveyor/ETRO

- 2. Biolife Plasma Services, LP**
Chattanooga, TN 37421

Blood Donor Center

Specialty: Spun Hematocrit & Total Serum Protein

Medical Laboratory Director: Ellen Cleland, MD
Family Medicine

Surveyor: Robert Sommer, MT Consultant/Surveyor/
MTRO

After discussion, the Board decided to ratify the two (2) laboratories listed above since they had no deficiencies cited during their initial inspection.

Motion: Dr. Gibson

Second: Mr. Litle

The licenses were approved with the Chairman voting.

3. Shelton Diagnostics, Inc.
Nashville, TN 37221

Clinical Laboratory

Specialties: Microbiology, Chemistry, Urinalysis,
Toxicology, and Hematology

Medical Laboratory Director: Hao H. Ho, MD
ABP/Clinical Pathology/Anatomic Pathology/Molecular
Genetic

Surveyor: Robert Sommer, MT-Consultant/Surveyor/
MTRO

Motion: Dr. Vaughan
Second: Ms. Briggs

The license was approved with the Chairman voting.

4. Accurate Testing and Wellness, Inc.
Nashville, TN 37214

Collection Station

Specialties: operates as a collection station.

Medical Laboratory Director: Kirk Roberts, MD

Surveyor: Robert Sommer, MT-Consultant/Surveyor/
MTRO

Motion: Mr. Baker
Second: Mr. Litle

The license was approved with the Chairman voting.

5. PathGroup Labs, LLC dba Jackson TN
Jackson, TN

Clinical Laboratory

Specialty: Hematology (Limited) and Urinalysis

Medical Laboratory Director: Frances Cate, MD
ABP/Anatomic Pathology/Clinical Pathology

Surveyor: Misty Rector, MT Consultant/Surveyor/WTRO

Motion: Mr. Litle
Second: Ms. Briggs

The license was approved with the Chairman voting.

6. Natera-Nashville Patient Service Center
Nashville, TN 37203

Collection Station

Specialties: operates as a collection station.

Medical Laboratory Director: Jennifer Keen-Kim, Ph.D.
Director-Molecular Diagnostics
Director-Clinical Cytogenetics & Molecular Genetic

Surveyor: Robert Sommer, MT Consultant/Surveyor/
MTRO

Motion: Mr. Litle
Second: Dr. Gibson

The license was approved with the Chairman voting.

Other Business:

No other business was presented.

New Business:

Election of Chairman-Full Board

The nomination for Full Board Chairman was Ms. Chandler.

Motion: Mr. Barker.
Second: Ms. Briggs

The nomination was approved.

Election of Vice-Chairman- Full Board

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

Motion: Ms. Briggs.
Second: Mr. Litle

The nomination was approved.

Election of P&E Committee Chairman

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

Motion: Dr. Vaughan.
Second: Mr. Litle

The nomination was approved.

Public Comment:

Mr. Keith C. Dennen, with Phelps Dunbar LLP, representing LabCorp, addressed the Board regarding

the Collection Station Licensure Memorandum dated February 12, 2024. He requested that the Board consider sending a follow-up memorandum extending the collection station deadline past the December 31, 2024 deadline.

Adjournment:

The meeting was adjourned at 10:50 a.m. CST with no further business to discuss.

Motion to adjourn: Mr. Barker.

Second: Ms. Briggs

The meeting was adjourned with the Chairman voting.