

**Tennessee Medical Laboratory Board
January 24, 2025
Full Board Meeting
Minutes**

Meeting Date:	January 24, 2025
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 Michael Johnson, MT-Medical Technologist-General Marilyn (Buffy) Key, MT-Hospital Administrator
Vacant Positions:	Pathologist
Members Absent:	Penny Asbell, MD- Non-Pathologist Physician Matthew Hardison, Ph.D., Independent Lab Mgr/Adm. Andrew Stanton, CT-Cytotechnologist
Staff Present:	Kyonztè Hughes-Toombs, Esq., MBA, CHC, Interim Director Nina V. Smith, MT Consultant Administrative Office Matt Gibbs, Deputy General Counsel Mina Girgis, Board Administrator Debbie Haggard, MT Consultant/Supervisor WTRO Fowlen Ivey, 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:

Nine (9) 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 Chairperson.

Presiding Officer:

Chair Chandler conducted the meeting.

Approve Minutes:

P & E Committee Meeting

A motion to approve the October 24, 2024, Personnel & Education Committee minutes was made by Dr. Vaughan.
Second: Mr. Litle

The minutes were approved as written with the Chairperson voting.

Full Board Meeting

A motion to approve the October 25, 2024, Full Board meeting minutes was made by Mr. Litle.
Second: Ms. Briggs

The Board minutes were approved as written with the Chairperson 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. Vaughan.
Second: Mr. Johnson

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

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

One consent order, *David Fugate*, was presented by Kertyssa Tia Smalls, Senior Associate Counsel.

Motion to ratify Consent Order: Mr. Barker
Second: Dr. Gibson

Presentations to the Board:

**Tennessee Professional Peer
Assistance Program (TNPAP)**

Teresa Phillips, Executive
Director

The statistical report for July 1, 2024-December 31, 2024, was presented by Ms. Teresa Phillips, Executive Director.

One (1) individual was monitored during this period.

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

The report was accepted as given with the Chairperson voting.

Investigations Report
Barbara Granum
Intake Coordinator

Ms. Granum's investigative report included the following:

Medical Laboratory Board (2024)

Twenty-four (24) closed complaints

- Eight (8) insufficient evidence
- Three (3) referred to OGC
- Six (6) no action
- Five (5) Letter of Concern
- Two (2) Letter of Warning

Twenty-three (23) new complaints

- One (1) proficiency testing
- Two (2) specimen handling
- One (1) facility transfusion fatality
- Two (2) substance abuse
- One (1) unlicensed practice
- Ten (10) unprofessional conduct
- Three (3) CE violations
- Two (2) outside of OIV's investigative scope
- One (1) environment

Investigations of Licensed Laboratory Personnel: (2024)

Five (5) complaints closed

- One (1) transferred to OGC
- One (1) no action
- One (1) Letter of Concern
- Two (2) Letter of Warning

Seven (7) new complaints

- Two (2) substance abuse

- Two (2) unprofessional conduct
- Three (3) CE violations

Investigations of Licensed Laboratory Facilities (2024)

Nineteen (19) complaints closed

- Eight (8) insufficient evidence
- Two (2) transferred to OGC
- Five (5) no action
- Four (4) Letter of Concern

Sixteen (16) new complaints

- One (1) proficiency testing
- Two (2) specimen handling
- One (1) facility transfusion fatality
- Eight (8) unprofessional conduct
- One (1) unlicensed practice
- Two (2) outside of OIV's scope
- One (1) environment

Investigative Licensed Laboratory Schools: (2024)

Zero (0) new or closed complaints.

No new complaints overall for 2025.

Motion to accept the report: Mr. Litle.

Second: Mr. Barker

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

Financial Report

Emily Godwin
Fiscal Director

No report was presented.

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. The CLIA backlog is nearly finished. The state backlog in East TN persists.

Motion to accept the report: Dr. Gibson.

Second: Mr. Litle

The report was accepted as given with the Chairperson voting.

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

1. Regional One Health

Memphis, TN

Kevin McHugh, MS, MLS(ASCP)^{CM}SC^{CM}

Manager, Laboratory Quality

The request was to permit the facility to change its Fern testing from waived to nonwaived testing and to add midwives and nurse practitioners to the testing personnel as well as making the exemption facility wide instead of just Labor & Delivery.

Motion: Mr. Johnson

Second: Mr. Barker

The exemption request was approved with the Chairperson voting.

2. Holston Valley Medical Center

Kingsport, TN

La Donna Compton, MT(ASCP)

Lead Point of Care Coordinator

The request was to permit anesthesiologists, CRNAs, RNs, respiratory therapists, certified clinical perfusionists (CCP), and LPNs to perform alternate site testing in the cardiovascular Operating Room, Cardiac Intensive Care Unit, Surgery Department, and Cardiac Catheterization Laboratory using the Gem Premier 5000.

Motion: Ms. Briggs

Second: Mr. Johnson

The exemption request was approved with the Chairperson voting.

3. Johnson City Medical Center

Johnson City, TN

Jennifer Miears, MT

Clinical Lab Educator

The request was to permit Registered Nurses to perform and result Creatinine on patients in the JCMC Cardiac Stress Lab using the Abbott istat analyzer. This exemption adds a new location to the facility's current exemption.

Motion: Mr. Barker

Second: Mr. Litle

The exemption request was approved with the Chairperson voting.

4. Vanderbilt University Medical Center

Nashville, TN

Lauren Wieronski, MLS(ASCP)^{CM}

Diagnostic Laboratory Team Leader

The request was to upgrade from the facility's current Gem 5000 exemption to the Gem 7000. There is no change in personnel or location from the previous exemption.

Josh Mawyer, MPH, MLS(ASCP)^{CM}

Motion: Mr. Barker

Technical Specialist, Point of Care Testing

Second: Dr. Gibson

The exemption request was approved with the
Chairperson voting.

**5. Vanderbilt – Tullahoma Harton
Hospital**

Tullahoma, TN

Lauren Wieronski, MLS(ASCP)^{CM}

Diagnostic Laboratory Team Leader

Josh Mawyer, MPH, MLS(ASCP)^{CM}

Technical Specialist, Point of Care Testing

The request was to upgrade from the facility's current
Gem 5000 exemption to the Gem 7000. There is no
change in personnel or location from the previous
exemption.

Motion: Dr. Vaughan

Second: Mr. Litle

The exemption request was approved with the
Chairperson voting.

**6. Vanderbilt – Wilson County Hospital
Lebanon, TN**

Lauren Wieronski, MLS(ASCP)^{CM}

Diagnostic Laboratory Team Leader

Josh Mawyer, MPH, MLS(ASCP)^{CM}

Technical Specialist, Point of Care Testing

The request was to upgrade from the facility's current
Gem 5000 exemption to the Gem 7000. There is no
change in personnel or location from the previous
exemption.

Motion: Dr. Gibson

Second: Ms. Briggs

The exemption request was approved with the
Chairperson voting.

**7. Vanderbilt – Bedford County Hospital
Shelbyville, TN**

Lauren Wieronski, MLS(ASCP)^{CM}

Diagnostic Laboratory Team Leader

Josh Mawyer, MPH, MLS(ASCP)^{CM}

Technical Specialist, Point of Care Testing

The request was to upgrade from the facility's current
Gem 5000 exemption to the Gem 7000. There is no
change in personnel or location from the previous
exemption.

Motion: Mr. Johnson

Second: Mr. Litle

The exemption request was approved with the
Chairperson voting.

**8. Vanderbilt – Tullahoma-Harton Hospital
Tullahoma, TN**

Lauren Wieronski, MLS(ASCP)^{CM}

Diagnostic Laboratory Team Leader

Josh Mawyer, MPH, MLS(ASCP)^{CM}

Technical Specialist, Point of Care Testing

The request was to upgrade from the facility's current IL
Hemochron Signature Elite to the IL GEM Hemochron
100. Testing personnel include RNs, Certified Anesthesia
Technicians, Licensed Certified Perfusionists, ECMO
Specialists, and Interventional Technicians. The
locations include the operating room, radiology,
cardiovascular intensive care unit, and the cardiac
catheterization laboratory.

Motion: Mr. Litle

Second: Mr. Barker

The exemption request was approved with the Chairperson voting.

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

1. Eugene G. Fong, MD
Nashville, TN

Eugene G. Fong, MD requested to direct the following four (4) laboratories:

Parkridge East Camp Jordan Free Standing ER Lab -
License# 4505
495 Camp Jordan Pkwy
East Ridge, TN 37412

Parkridge Medical Center Blood Gas Laboratory –
License #21
2333 McCallie Avenue
Chattanooga, TN 37404-3285

Parkridge Soddy Daisy ER Laboratory – License #4517
9402 Reco Drive
Soddy Daisy, TN 37379

Parkridge West Hospital – License #2180
1000 HWY 28
Jasper, TN 37347

Motion: Mr. Johnson
Second: Mr. Litle

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

Discuss, Review, And Take Action, if Needed:

Discuss licensure of collection station hubs.

Keith C. Dennen, an attorney with Phelps Dunbar LLP, representing LabCorp, asked the Board for clarification of a memo issued by the Board on whether licensed laboratories must also have a separate license for their collection station hubs. The Board clarified that collection stations owned and operated by a licensed Tennessee laboratory do not need a separate medical laboratory license, which is in line with state statutory law. Deputy General Counsel Matt Gibbs stated that he

would work with Mr. Dennen on the best method to publicly disseminate the Board's clarification.

Motion to revise memo to reflect the language of the statute: Dr. Gibson

Second: Mr. Johnson

Mr. Barker asked whether the phlebotomists working in the collection station are employees of the collection station or the licensed laboratory in order to determine who should be supervising the phlebotomists. Mr. Gibbs stated that he could research the issue and bring the information back at another meeting.

Discuss the definition of rural and implications for one director supervising 5 rural hospital laboratories.

Deputy General Counsel, Matt Gibbs, gave a presentation on the definition of the word "rural" in Public Chapter 1046 using the definition from Health Resources and Services Administration (HRSA), which is referenced in the public chapter. The Board adopted HRSA's definition of rural. The 30-hour supervision rule cannot be realistically applied to a director supervising/directing 5 rural hospital laboratories. The board will need to change its rule according to Mr. Gibbs.

Motion to adopt statutory language referencing HRSA's definition of "rural": Mr. Barker

Second: Dr. Vaughan

Discussion of whether Tristar Centennial Parthenon Pavilion Psychiatric Hospital needs a separate laboratory license to perform waived testing.

The Board decided that a laboratory license is not necessary for waived-only testing.

Motion that Tristar does not need a laboratory license to conduct solely waived testing: Mr. Johnson

Second: Mr. Little

Review and Discuss the Licensure of Medical Laboratory Directors:

Nothing to present.

Reports/Requests:

Board Director's Report

Kyonzte Hughes-Toombs, Esq., MBA, CHC

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

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

Staffing updates:

Ms. Hughes-Toombs is currently serving as the interim board director until a replacement is hired.

Board members were reminded of the 2025 meeting dates.

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

Interim Director Hughes-Toombs thanked those board members whose terms have expired for continuing to attend meetings, so that the Board can conduct its business.

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

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

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

West TN – 58 surveys

Middle TN – 56 surveys

East TN – 46 surveys

January-December 2024 (completed all survey types):

West TN – 89 surveys
Middle TN – 82 surveys
East TN – 57 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 Chairperson voting.

Board Attorney Report
Matthew Gibbs
Deputy General Counsel

Deputy General Counsel Matthew Gibbs gave his Office of General Counsel report for the Fourth Quarter of 2024:

- The Conflict-of-Interest Policy was reviewed with the Board members.
- Three (3) open cases.
- OCG is completing its internal review of the Medical Laboratory Board Rules. Mr. Gibbs anticipates having a rulemaking hearing this year.

Disciplinary Report
Matthew Gibbs
Deputy General Counsel

Deputy General Counsel Matthew Gibbs gave the Disciplinary Report for the Fourth 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. Barker.
Second: Dr. Gibson

The reports were accepted as given with the Chairperson voting.

Regional Surveyor Reports:
Complaint Investigations
Proficiency Testing Events
Regional Offices:

East, Middle, and West TN

ETRO Report: 4th Quarter
Fowlen Ivey, MT
Consultant/Surveyor

East Tennessee Regional Office –Fourth Quarter 2024:

Complaint Investigations: One (1)

Unsuccessful Proficiency Testing: One (1)

- 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: Zero (0)

MTRO Report: 4th Quarter
Robert Sommer, MT
Consultant/Surveyor

Middle Tennessee Regional Office–Fourth Quarter 2024:

Complaint Investigations: One (1)

Unsuccessful Proficiency Testing: One (1)

- 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: Zero (0)

WTRO Report: 4th Quarter
Debbie Haggard, MT
Consultant/Surveyor

West Tennessee Regional Office –Fourth Quarter 2024:

Complaint Investigations: Two (2)

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 4th Quarter reports of the East, West, and Middle TN regions: Mr. Litle
Second: Mr. Barker

The reports were accepted as presented with the Chairperson voting.

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

Nothing to present.

Board Ratifications Initial Facility Applications:

**1. American National Red Cross -
Hendersonville**
Hendersonville, TN

Blood Donor Center

Specialties: Hemoglobin (waived)

Medical Laboratory Director: Caroline Miller, M.D.

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

**2. Meharry Medical College
Consolidated Laboratories**
Nashville, TN

Clinical Laboratory

Specialty: Hematology, Diagnostic Immunology, Syphilis
Serology, Routine Chemistry, Urinalysis, Endocrinology,
Toxicology

Medical Laboratory Director: Ellen Cleland, MD
Family Medicine

Surveyor: Robert Sommer, MT Consultant/Surveyor/
MTRO

3. Quest Diagnostics – Bristol, TN
Bristol, TN

Collection Station

Medical Laboratory Director: Kristin Pierce, M.D.

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

4. Quest Diagnostics – Lebanon, TN
Lebanon, TN

Collection Station

Medical Laboratory Director: Andrew Young, M.D.

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

**5. Laboratory Corporation of
America – Blount County**
Alcoa, TN

Clinical Laboratory

Specialty: Hematology, Routine Clinical

Medical Laboratory Director: Elizabeth Hubbard, M.D.

Surveyor: Fowlen Ivey, MT Consultant/Surveyor/ETRO

Motion to approve all five (5) initial licenses: Mr. Johnson

Second: Ms. Briggs

The licenses were approved with the Chairperson voting.

Other Business:

No other business was presented.

Public Comment:

None.

Adjournment:

The meeting was adjourned at 10:35 a.m. CST with no further business to discuss.

Motion to adjourn: Mr. Barker.

Second: Mr. Lytle

The meeting was adjourned with the Chairperson voting.