## Tennessee Medical Laboratory Board October 27, 2023 Full Board Meeting Minutes

Meeting Date:	October 27, 2023
Time:	9:15 a.m. 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:	Jennifer Gidcomb, MT-Med. Technologist, GenChairman Jerry Barker, MT-Hospital Lab Mgr/Admin. Dir. Lee Anne Briggs, MT- Med. Technologist, Educator Danielle Gibson, MD-Pathologist Michael Johnson, MT-Medical Technologist-General Chris Litle, MT-Medical Laboratory Supervisor Andrew Stanton, CT-Cytotechnologist James A. Vaughan, MD-Pathologist Educator
Vacant Positions:	Citizen Representative Pathologist
Members Absent:	Penny Asbell, MD- Non-Pathologist Physician Marilyn (Buffy) Key, MT-Hospital Administrator Matthew Hardison, Ph.D., Independent Lab Mgr/Adm.
Staff Present:	Kyonzte Hughes-Toombs, Esq., Deputy Director Sandra S. Bogard, MT Consultant, Director (virtually) Nina V. Smith, MT Consultant Admin. Office (virtually) Ronda Webb-Stewart, Senior General 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/Supervisor MTRO
Staff Absent:	Lori Reynolds, MT Consultant/Surveyor ETRO
CLIA Manager/Representative:	Tracy McLemore, MT CLIA Director
Introduction of Board Members:	Board members and staff made their introductions to

the audience.

Quorum:

Eight (8) board members were present, which

constituted a quorum.

**Call To Order:** 

The meeting was called to order at 9:15 a.m. CDT by

Jennifer Gidcomb, the Board Chairman.

**Presiding Officer:** 

Ms. Gidcomb conducted the meeting.

**Approve Minutes:** 

P & E Committee Meeting

A motion to approve the July 18, 2023, Personnel & Education Committee minutes was made by

Mr. Barker. Second: Mr. Litle

The minutes were approved.

Full Board Meeting

A motion to approve the July 19, 2023, Full Board meeting minutes was made by Mr. Barker.

Second: Mr. Litle

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 26, 2023.

Motion to ratify Committee actions: Mr. Johnson.

Second: Dr. Gibson

The report was accepted as presented.

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

 Lab Plus, LLC Nashville, TN Consent Order Lab Plus, LLC, self-reported the following compliance updates:

- Licensed cytology supervisor has been in place and continues to be in place at least 30 hours per week.
- Cytologist's workload logs are completed daily and submitted for supervisor review weekly.
- Consolidated cytology processing to one campus and hired three (3) lab assistants for cytology processing.
- Error tracking systems were implemented: spreadsheet to track and trend errors, hospital

event reporting system (values line, 1-on-1s, department meetings)

• Systems are monitored regularly for cytology labeling errors.

Motion: Mr. Stanton Second: Ms. Briggs

The compliance report was accepted as given.

#### Presentations to the Board:

#### **Tennessee Professional Peer**

Assistance Program (TNPAP) Teresa Phillips, Executive Director The statistical report for July 1, 2023-September 30, 2023, was presented by Ms. Teresa Phillips, Executive Director.

Two (2) individuals were monitored during this period, with zero (0) referrals, two (20 agreements activated, and one (1) discharge.

Motion to accept the TNPAP report: Mr. Johnson. Second: Mr. Litle

The report was accepted as given.

**Investigations Report** 

Roger Knowlton
Disciplinary Intake Coordinator

Mr. Knowlton's investigative report included the following:

Monitored Practitioners (Personnel and Facilities): (January-October 2023)

Investigative Licensed Laboratory Personnel: (2023)

One (1) new complaint
Zero (0) complaints closed

One (1) currently open complaint

Investigative Licensed Laboratory Facilities: (2023)

Three (3) new complaints Two (2) closed complaints

Eight (8) currently open complaints

Investigative Licensed Laboratory Schools: (2023)

Zero (0) new complaints Zero (0) complaints closed

Zero (0) currently open complaints

Motion to accept the report: Mr. Litle.

Second: Ms. Briggs

The investigation report was accepted as given.

Financial Report Noranda French Fiscal Office Ms. French gave the Annual Fiscal Report, which compared the actual revenue and expenditures for the past three (3) years (FY2021, FY2022, FY2023). The values were compared with little change from year to year. She also presented information regarding the revenue sources for FY2023 that included the following fees: renewal, application, license, undefined ASC fee codes, penalty-late renewal, reinstatement, change (owner, director, & location, and unassigned amount.

Motion: Dr. Vaughan Second: Mr. Johnson.

The report was accepted as given.

**Legislative Update** 

Grayson Carter Legislative Liaison No report was given.

Surveyor Update Tracy McLemore, MT CLIA Director Mr. McLemore presented a verbal report to the Board regarding the surveyor workload. One new surveyor, Kathy Dunn-McPhall, was hired. Her training is expected to be completed in January.

No motion was needed.

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

## TriStar NorthCrest Medical Center Springfield, TN Doug Worshaw, MT Administrative Laboratory Director

The request was to permit Registered Nurses and Radiologic Technologists to perform and report Activated Clotting Time (ACT) in the Cath Lab utilizing the GEM Hemochron 100 instrument and methodology.

Motion: Dr. Vaughan Second: Mr. Barker

The exemption request was approved.

 Fort Loudon Medical Center Lenoir City, TN Melissa C. Wright, MT(ASCP) Laboratory Manager The request was to permit Respiratory Therapists to perform and report Lactate testing in the Emergency Department utilizing the Nova Biomedical Lactate Meter instrument and methodology.

Motion: Mr. Johnson

Second: Mr. Litle

The exemption request was approved.

#### 3. TriStar Skyline Medical Center Laboratory

Nashville, TN John Daniels, MT Administrative Laboratory Director The request was to permit Radiologic Technologists to perform and report Creatinine testing in the Radiology Department utilizing the Abbott i-STAT instrument and methodology.

Motion: Mr. Barker Second: Dr. Gibson

The exemption request was approved.

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

Albert C. Domm, MD Columbia, TN Albert C. Domm, MD, requested to direct four (4) laboratories.

Dr. Domm requested to direct the following four (4) laboratories:

- Houston County Community Hospital-5001 East Main St, Erin, TN 37061 (L2014)
- Henderson County Community Health Center-200 West Church St, Lexington, TN 38351 (L2000)
- MyGenetx Laboratory, LLC dba LifeTime Sciences-4037 Rural Plains Circle, Ste 150, Franklin, TN (L4224)
- Macon Community Hospital-305 W. Locust St, Lafayette, TN 37083 (L1978)-NEW

Motion: Mr. Litle Second: Mr. Stanton Recused: Dr. Gibson

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

Charles Bramlett, MD Columbia, TN Charles Bramlett, MD, requested to direct four (4) laboratories.

Dr. Bramlett requested to direct the following laboratories with the POL and collection station not needing Board approval:

Ave., Columbia, TN 38401 (L2196)
• Spectrum Pain Clinic-820 B Airpark Center Dr.,

Maury Regional Medical Center-1224 Trotwood

- Spectrum Pain Clinic-820 B Airpark Center Dr., Nashville, TN 37217-Physician's Office Lab (POL)
- Lab Corp of America-1400 Donelson Pike, #B10, Nashville, TN 37127 (L2327)-Collection Station
- Southern Blood Services-1114 17th Avenue South, Suite 104, Nashville, TN 37212 (L538)
- TriStar Mt Juliet ER-100 Wilfong Parkway, Mount Juliet, TN 37122 (L4402)
- TriStar Summit Medical Center Lab-5556 Frist Boulevard, Hermitage, TN 37076 (L3255)

Motion: Mr. Barker Second: Mr. Stanton Recused: Dr. Gibson

The request for Dr. Bramlett to direct the above laboratories was approved with the chairman voting.

Alexander Thurman, MD, requested to direct

Dr. Thurman requested to direct the following five (5) laboratories:

- Southern TN Regional Health System (STRHS) Lawrenceburg-1607 South Locust Avenue, Box 847, Lawrenceburg TN 38464 (L2023)-NEW
- Southern TN Regional Health System (STRHS) Pulaski-1265 E College St, Pulaski, TN 38478 (L2255)-NEW
- Ariana Diagnostics, LLC, 658 Grassmere Park # 104, Nashville, TN 37211(L4484)
- Resolve Molecular Diagnostics-E, 357 Riverside Dr., Suite 204, Franklin, TN 37064 (L4366)
- Phase 2 Laboratory, LLC, 5225 Harding Place, Nashville, TN 37217 (L4438)

Motion: Mr. Johnson Second: Mr. Litle Recused: Dr. Gibson

The request for Dr. Thurman to direct five (5) laboratories was approved with the chairman voting.

**Alexander Thurman, MD** Columbia, TN

#### Discuss, Review, And Take Action, if Needed:

Discuss if mobile PET/CT Imaging glucose testing needs a state mobile lab license. Kay Kassel, MS, CNMT, NMTCB(RS) Alliance Healthcare Services

The Board discussed the PET/CT Imaging Units and the glucose testing they perform. Based on that discussion, the Board determined that mobile PET/CT Imaging glucose testing did require a state laboratory license in Tennessee. They requested that the mobile units apply for a mobile laboratory license using the corporate office as the home base. Along with the application, it was requested that a listing of the different locations the mobile unit will be testing be provided.

Motion: Dr. Vaughan Second: Mr. Barker

The motion was approved.

Discuss out-of-state licensed military personnel.

The Board Attorney, Ronda Webb-Stewart, made a presentation to the Board regarding the revisions to the Service Member Civil Relief Act, which protects servicemembers and their spouses. The revision will allow service members and their spouses who possess a professional license to work under that license in any state when they relocate. There will be some requirements, i.e., being under military orders and registering with Tennessee. The final guidance is still under revision.

No motion was needed.

Discuss the credentials of Point-of-Care Coordinators.

After discussion, the Board determined that the Pointof-Care Coordinator needs to be licensed at the level that corresponds with the duties they perform. If they perform supervisory duties, they must be licensed as a supervisor. If not, they will not need a supervisor's license.

Note: CLIA requires a bachelor's degree for oversight of non-waived testing.

No motion was needed.

# Review and Discuss the Licensure of Medical Laboratory Directors:

 Joe Wiencek, Ph.D Nashville, TN 37205 Director- Molecular Diagnostics Dr. Wiencek received his Ph.D. in Clinical Chemistry from Cleveland State University, Cleveland, OH in 2015.

He was certified by the American Board of Clinical Chemistry.

Dr. Wiencek received his post-doctoral fellowship training at Vanderbilt University from 2015-2017.

He requests an exemption to Rule 1200-06-01-.20(1)(c). He does not have certification in Hematology, but he has work experience in the Hematology specialty.

#### Hematology work experience:

- Scientific Co-Director of the Core Hematology Lab at the University of Virginia from 2018-2019.
- CLIA Lab Director over Point-of-Care testing at the University of Virginia from 2019-2020.
- CLIA Lab Director of three (3) additional labs in Virginia.
- CLIA lab Director of Vanderbilt Health Belle Meade Diagnostic Laboratory from 2021-2023.

National certification is available through the American Board of Bioanalysis (ABB).

He is seeking licensure as a Director of Hematology.

Motion: Mr. Johnson Second: Mr. Litle Recused: Mr. Stanton

The exemption request was approved based on work experience with the chairman voting.

# 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 2023.

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

#### Staffing updates:

 New Middle Tennessee laboratory surveyor, Kathy Dunn-McPhall.

Board meeting dates for 2023 and 2024 were presented.

No new Board Members appointments.

Vacancies on the Board:

- Pathologist
- Citizen Member

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

2023 State Licensure Surveyor Workload Targets: West TN – 40 surveys Middle TN – 35 surveys East TN – 50 surveys

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

The target survey workload is 2-3 state-licensed laboratory surveys per fully trained surveyor per month.

January-September 2023 (completed biennial & initial surveys only):

West TN – 32 surveys Middle TN – 17 surveys East TN – 44 surveys

January-September 2023 (completed all survey types): West TN-50 surveys Middle TN-32 surveys East TN-51 surveys

On July 17, 2023, the Department of Health conducted a virtual board member training for all Health Related Boards. A recorded version of the presentation is available for any Board members who could not attend.

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

Motion to approve the report as given: Mr. Johnson. Second: Ms. Briggs

The report was accepted as given.

Senior Associate General Counsel Ronda Webb-Stewart gave her Office of General Counsel report for the Third Quarter of 2023:

**Board Attorney Report** Ronda Webb-Stewart Senior Associate General Counsel

- The Conflict-of-Interest Policy was reviewed with the Board members.
- One (1) open case in the Office of Investigations (OGC).
- OGC is completing its internal review of the Medical Laboratory Board Rules.

#### **Disciplinary Report**

Ronda Webb-Stewart Senior Associate General Counsel Senior Associate General Counsel Ronda Webb-Stewart gave the Disciplinary Report for the Third Quarter of 2023:

Six (6) licensees are being monitored:

- Two (2) with terms of reprimand.
- One (1) on probation.
- Three (3) with terms of 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.

#### **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 2023:

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 Robert Sommer, MT Consultant/Surveyor Middle Tennessee Regional Office-Third Quarter 2023:

Complaint Investigations: One (1)

Unsuccessful Proficiency Testing: One (1)

- 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: One (1)

#### WTRO Report: 3rd Quarter

Debbie Haggard, MT Consultant/Surveyor

West Tennessee Regional Office –Third Quarter 2023:

Complaint Investigations: Zero (0)

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)

Motion to accept the reports as given: Mr. Stanton.

Second: Mr. Litle

Reports were accepted as given.

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

Nothing to present.

Board Ratifications Initial Facility Applications:

 National American Red Cross-Brentwood

Brentwood, TN

**Blood Donor Center** 

Specialties: Hemoglobin

Medical Laboratory Director: Pampee Young, MD

ABP/Clinical Pathology

Surveyors: Robert Sommer, MT Consultant/MTRO

Motion: Mr. Johnson Second: Ms. Briggs

The license was approved.

2. Laboratory Corporation of America

Holdings

Jamestown, TN

**Clinical Laboratory** 

Specialties: Hematology, General Immunology, ABO Group & Rh Type, Clinical Chemistry, Transfusion Services, Arterial Blood Gases & pH, Influenza Screen, KOH & Wet Prep, RSV, Strep A Antigen, and SARS-CoV2.

Medical Laboratory Director: James W. Vaughan, MD ABP/Anatomic Pathology, Clinical Pathology, & Hematology

Surveyor: Fowlen Anders, MT Consultant/Surveyor/ETRO

Motion: Mr. Johnson Second: Mr. Litle Recused: Dr. Vaughan

The license was approved with the chairman voting.

## 3. Blood Assurance, Inc.-West End dba OurCel Solutions

Nashville, TN

**Blood Donor Center** 

Specialty: Hemoglobin

Medical Laboratory Director: Elizabeth Culler, MD ABP/Clinical Pathology & Transfusion Medicine Surveyor: Robert Sommer, MT Consultant/MTRO

Motion: Mr. Johnson Second: Dr. Gibson

The license was approved.

**Anatomic Laboratory** 

# 4. PCA Southeast Summit Campus dba Opus Pathology

Hermitage, TN

Specialties: Histopathology & Cytopathology

Medical Laboratory Director: Estelle MD

ABP/Anatomic, Cytopathology & Neuropathology

Surveyors: Robert Sommer, MT Consultant/MTRO

Motion: Mr. Johnson Second: Dr. Vaughan Recused: Dr. Gibson

The licenses were approved with the chairman voting.

# 5. Select Specialty Hospital-West Tennessee, LLC

Jackson, TN

Clinical Laboratory

Specialties: Chemistry and Blood Gases & pH

Medical Laboratory Director: Ashley Porter, M

Surveyor: Robert Sommer, MT Consultant/MTRO

Motion: Dr. Vaughan Second: Mr. Stanton Recused: Mr. Barker

The license was approved with the chairman voting.

#### 6. Morristown-Hamblen West

Morristown, TN

**Clinical Laboratory** 

Specialties: Bacteriology-limited, Virology-limited, General Immunology, Clinical Chemistry, pH & Blood Gases, Transfusion Services, and Hematology.

Medical Laboratory Director: Kent M. McGinley, MD

Surveyor: Lori Reynolds, MT Consultant/ETRO

Motion: Mr. Johnson Second: Ms. Briggs

The license was approved.

### 7. Memphis Pathology Laboratory dba AEL-Pathology Laboratory

Memphis, TN

Anatomic Laboratory

Specialties: Histopathology & Cytopathology

Medical Laboratory Director: Holly Pierce, MD

Surveyor: Debbie Haggard, MT Consultant/WTRO

Motion: Dr. Gibson Second: Mr. Stanton

The license was approved.

# 8. Laboratory Corporation of America

Holdings

Memphis, TN

**Collection Station** 

Medical Laboratory Director: Pamela T. Osborne, MD

Surveyor: Misty Rector, MT Consultant/WTRO

Motion: Mr. Litle

Second: Dr. Vaughan

The license was approved.

9. BioTek America, LLC dba Freedom Plasma

Clarksville, TN

Plasma Donor Center

Specialties: Routine Chemistry and Hematocrit (spun)

Medical Laboratory Director: Michael Dao, MD

Surveyor: Debbie Haggard, MT Consultant/WTRO

Motion: Mr. Stanton Second: Mr. Litle

The license was approved.

10. OPUS Pathology Memphis Campus

Cordova, TN

**Anatomic Laboratory** 

Specialty: Cytopathology

Medical Laboratory Director: Estelle May, MD

Surveyor: Debbie Haggard, MT Consultant/WTRO

Motion: Mr. Litle Second: Mr. Johnson Recused: Dr. Gibson

The license was approved with the chairman voting.

Other Business/Discussion:

Election of Chairman-Full Board

The nomination for Full Board Chairman was Ms.

Gidcomb.

Motion: Mr. Johnson. Second: Mr. Stanton

The nomination was approved.

Election of Vice-Chairman- Full Board

The nomination for Full Board Vice-Chairman was Mr.

Barker.

Motion: Mr. Litle. Second: Mr. Johnson

The nomination was approved.

Election of P&E Committee Chairman The nomination for P & E Committee Chairman was Ms.

Briggs.

Motion: Ms. Gidcomb. Second: Dr. Vaughan

The nomination was approved.

**New Business:** No new business was presented.

Public Comment: No public comments.

Adjournment: With no further business to discuss, the meeting was

adjourned at 11:51 a.m. CDT.

Motion to adjourn: Mr. Litle.

Second: Dr. Gibson

The meeting was adjourned.