Tennessee Medical Laboratory Board January 26, 2024 **Full Board Meeting** Minutes **Meeting Date:** January 26, 2024 Time: 9:05 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 Gidcomb, MT-Med. Technologist, Gen.-Chairman LeeAnne Briggs, MT- Med. Technologist, Educator Penny Asbell, MD- Non-Pathologist Physician Jerry Barker, MT-Hospital Lab Mgr/Admin. Dir. Danielle Gibson, MD-Pathologist Michael Johnson, MT-Medical Technologist-General Marilyn (Buffy) Key, MT-Hospital Administrator Chris Litle, MT-Medical Laboratory Supervisor Andrew Stanton, CT-Cytotechnologist James A. Vaughan, MD-Pathologist Educator Vacant Positions: **Citizen Representative** Pathologist Members Absent: Matthew Hardison, Ph.D., Independent Lab Mgr/Adm. Staff Present: Sandra S. Bogard, MT Consultant, Director Nina V. Smith, MT Consultant Administrative Office 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 Staff Absent: Kathy Dunn-McPhall, MT Consultant/Supervisor MTRO CLIA Manager/Representative: Tracy McLemore, MT CLIA Director-Absent 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 9:05 a.m. CST by Jennifer Gidcomb, the Board Chairman.			
Presiding Office	r:	Ms. Gidcomb conducted the meeting.			
Approve Minute	25:				
	P & E Committee Meeting	A motion to approve the October 26, 2023, Personnel & Education Committee minutes was made by Mr. Johnson. Second: Mr. Litle			
		The minutes were approved as written.			
I	Full Board Meeting	A motion to approve the October 27, 2023, Full Board meeting minutes was made by Mr. Litle. Second: Mr. Barker			
		The Board minutes were approved as written.			
	Ratification of Initial Determinations P & E Committee Meeting:	Ms. Gidcomb reported the actions of the Personnel & Education Committee meeting, January 25, 2024.			
		Motion to ratify Committee actions: Mr. Johnson. Second: Mr. Stanton			
		The report was accepted as presented by Ms. Gidcomb.			
Consent, Agreed Reprimand:	Consent, Agreed, Compliance Orders, and Letters of Reprimand:				
		Nothing to present.			
Presentations to	o the Board:				
A T	ennessee Professional Peer ssistance Program (TNPAP) eresa Phillips, Executive virector	The statistical report for July 1, 2023-December 31, 2023, was presented by Ms. Teresa Phillips, Executive Director. Two (2) individuals were monitored during this period,			
		one (1) regulatory and (1) one non-regulatory.			
		One (1) discharge - was monitored for noncompliance.			
		Motion to accept the TNPAP report: Mr. Litle. Second: Ms. Briggs			

Investigations Report

Disciplinary Intake Coordinator

Barbara Granum

The report was accepted as given.

Ms. Granum's investigative report included the following:

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

Investigative Licensed Laboratory Personnel: (2023) Four (4) new complaints

- One (1) falsification of records
- One (1) substance abuse
- One (1) malpractice/negligence
- One (1) unprofessional conduct

Two (2) complaints closed Two (2) currently open complaints

Investigative Licensed Laboratory Facilities: (2023) Nine (9) new complaints Seven (7) closed complaints

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

Six (6) currently open complaints

- One (1) proficiency testing
- One (1) unlicensed practice
- Seven (7) unprofessional conduct

Investigative Licensed Laboratory Schools: (2023) Zero (0) new complaints Zero (0) complaints closed Zero (0) currently open complaints

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

The investigation report was accepted as given.

No report was given.

Financial Report

Emily Goodwin Fiscal Director

Legislative Update

Grayson Carter Legislative Liaison No report was given.

> Surveyor Update Tracy McLemore, MT CLIA Director

In his absence, Mr. McLemore presented a written report to the Board regarding the surveyor workload. One East Tennessee surveyor resigned, and he has started the interview process.

Motion to accept the report: Mr. Johnson. Second: Dr. Vaughan

The report was accepted as given.

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

1. Baptist Memorial Hospital Laboratory Memphis, TN Karen Clark, BS, MT(ASCP)SH

POC Supervisor

The request was to permit Certified Registered Nurse Anesthetists (CRNAs) and Perfusionists to perform and report Sonic Estimation of Elasticity via Resonance (SEER) in Surgery utilizing HemoSonics Quantra Hemostasis Analyzer and methodology.

Motion: Dr. Gibson Second: Mr. Litle

The exemption request was approved.

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

Charles Bramlett, MD Columbia, TN Charles Bramlett, MD requested to direct the following six (6) laboratories:

- Maury Regional Medical Center-1224 Trotwood Ave., Columbia, TN 38401 (L2196)
- 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)
- Unity Medical Center-481 Interstate Drive, PO Box 1079, Manchester, TN 37349 (L2022)-New
- TriStar Summit Medical Center Lab-5556 Frist Boulevard, Hermitage, TN 37076 (L3255)

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

Discuss, Review, And Take Action, if Needed:

Review the memorandum regarding collection stations no longer using the one hub location and requiring licensure of all collection locations. The request for Dr. Bramlett to direct six (6) laboratories was approved.

The Board discussed the memorandum that will notify collection stations that they can no longer use the one hub location and that all collection stations must be state-licensed.

Motion: Mr. Litle Second: Mr. Barker

The memorandum was approved for mailing.

Review the memorandum regarding respiratory therapy departments performing arterial blood gas testing to request a point-ofcare exemption unless they have a separate laboratory license.

respiratory therapy departments that they will need to request a point-of-care exemption if they perform arterial blood gas testing. Respiratory therapy departments with their own laboratory licenses are an exception to this decision. They would not need to request a point-of-care exemption.

The Board discussed the memorandum that will notify

Motion: Mr. Barker Second: Mr. Litle

The memorandum was approved for mailing.

After discussing the differences between public and private laboratories, it was determined that, based on the statute change, all state-licensed laboratories, whether privately or publicly owned, are not required to employ state-licensed testing personnel.

No motion was needed.

The Board discussed Rule 1200-06-03-.21 Renewal of Laboratory License. They decided to revise the rule to only require the signature of the medical laboratory's owner or director on the facility renewal form. It was also decided that a roster of all personnel currently employed in the laboratory would not be required upon renewal.

Motion: Mr. Barker Second: Mr. Stanton

The motion was approved.

Discuss the definitions of public and private laboratories.

Discuss red-line rule revisions regarding 1200-06-03-.21 Renewal of Laboratory License Rules Governing Medical Laboratories. Discuss red-line rule revision regarding 1200-06-02-.01 Rules Governing Training Programs for Medical Laboratory Personnel.

Discuss red-line rule revision regarding 1200-06-02-.07 Rules Governing Training

Programs for Medical Laboratory

The Board discussed Rule 1200-06-02-.01 Rules Governing Training Programs for Medical Laboratory Personnel. It was decided to revise Rule 1200-06-02-.01(4)(a) Initial Training Program Application Fee to make it non-refundable.

Motion: Dr. Vaughan Second: Dr. Gibson

The motion was approved.

The Board discussed Rule 1200-06-02-.07 Rules Governing Training Programs for Medical Laboratory Personnel. It was decided that section C should be added for Cytology Training Programs.

Motion: Mr. Johnson Second: Mr. Litle

The motion was approved.

Review and Discuss the Licensure of Medical Laboratory Directors:

Personnel.

1. Catherine Williams, Ph.D. Brentwood, TN 37027 Director-Breath Analysis Dr. Williams received her Ph.D. in Oceanography from the University of Southampton, Southampton, UK in 1999.

She received her M.S. degree in Oceanography from the University of Southampton, Southampton, UK in 1994.

Dr. Williams received her B.S. degree in Chemistry from the University of Sheffield, Sheffield, UK in 1992.

She is currently licensed as a Director-Breath Analysis.

Dr. Williams received an exemption from the Medical Laboratory Board to become a director without national certification at the January 2023 Board meeting.

She is currently a director of Cairn Diagnostics Laboratory in Brentwood, TN.

Dr. Williams is requesting an exemption to Rule 1200-06-01-.20(1)(c). She does not have certification in Chemistry or Endocrinology but has work experience in the field of Chemistry. National certification is available through the American Board of Bioanalysis (ABB), the American Board of Clinical Chemistry (ABCC), the

National Registry of Certified Chemists (NRCC), and the American Board of Internal Medicine (ABIM).

She is seeking licensure as a Director of Chemistry (limited to HCG Pregnancy).

After discussion, the Board decided to extend the coverage of the specialty of Director-Breath Testing to include the oversight of qualitative HCG serum testing. Based on their decision, an exemption request was not necessary.

Motion: Mr. Litle Second: Dr. Gibson

The motion was approved.

Reports/Requests:

Board Director's Report				
Sandra Bogard, MS, MT(ASCP) QLC $^{\mbox{cm}}$				

The report included statistical data concerning laboratory personnel, facilities, training programs licensure, and health fair/health screening events during the Fourth Quarter of 2023.

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

Staffing updates:

• Lori Reynolds, East Tennessee laboratory surveyor, resigned.

Board meeting dates for 2023 and 2024 were presented.

Vacancies on the Board:

- Pathologist
- Citizen Member

Board positions that expired on December 31, 2023:

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

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-December 2023 (completed biennial & initial surveys only): West TN – 41 surveys Middle TN – 23 surveys East TN – 50 surveys

January-December 2023 (completed all survey types): West TN – 75 surveys Middle TN – 47 surveys East TN – 72 surveys

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

Motion to approve the report with a correction to the July meeting date: Dr. Vaughan. Second: Mr. Litle

The report was accepted with the revision.

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

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

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

Six (6) licensees are being monitored.

- Two (2) with terms of reprimand with \$20,556.81 in fines and fees.
- One (1) on probation.

Board Attorney Report

Ronda Webb-Stewart Senior Associate General Counsel

Disciplinary Report

Ronda Webb-Stewart Senior Associate General Counsel

• Three (3) are on suspension with \$2,012.96 in fines and fees.

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

The reports were accepted as given.

Regional Surveyor Reports:

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

ETRO Report: 4th Quarter

Fowlen Anders, MT Consultant/Surveyor East Tennessee Regional Office –Fourth Quarter 2023: (Revised)

Complaint Investigations: One (1)

Unsuccessful Proficiency Testing: Zero (0)

- 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)

Middle Tennessee Regional Office–Fourth Quarter 2023:

Complaint Investigations: Two (2)

Unsuccessful Proficiency Testing: Four (4))

- 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)

West Tennessee Regional Office –Fourth Quarter 2023:

Complaint Investigations: Zero (0)

Unsuccessful Proficiency Testing: Zero (0)

- 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

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

Knoxville, TN

Motion to accept the reports with a revision: Mr. Johnson. Second: Dr. Gibson Reports were accepted with a revision. Addition/Deletions to the Board's Health Screening Test List: Nothing to present. **Board Ratifications Initial Facility Applications:** 1. East Tennessee Pathology Jefferson Anatomic Laboratory Memorial Jefferson City, TN Specialties: Histopathology & Oral Pathology Medical Laboratory Director: William Beuerlein, D.O. ABP/Clinical Pathology, Anatomic Pathology Surveyor: Lori Reynolds, MT-Consultant/Surveyor/ETRO 2. East Tennessee Pathology North Anatomic Laboratory Knoxville Powell, TN Specialties: Pathology, Histopathology, Oral Pathology, Cytology Medical Laboratory Director: Lauren Chiles, MD ABP/Anatomic Pathology, Clinical Pathology Surveyors: Fowlen Ivey, MT-Consultant/Surveyor/ETRO 3. East Tennessee Pathology Anatomic Laboratory **Sweetwater Hospital** Sweetwater, TN Specialties: Histopathology & Oral Pathology Medical Laboratory Director: Frank J. Beuerlein, MD ABP/Clinical Pathology & Anatomic Pathology Surveyors: Fowlen Ivey, MT-Consultant/Surveyor/ETRO 4. East Tennessee Pathology Turkey Anatomic Laboratory **Creek Medical Center**

Cytology

Specialties: Pathology, Histopathology, Oral Pathology,

		Medical Laboratory Director: William Beuerlein, D.O. ABP/Clinical Pathology, Anatomic Pathology
		Surveyor: Fowlen Ivey, MT-Consultant/Surveyor/ETRO
5.	Razor Genomics Nashville, TN	Clinical & Anatomic Laboratory
		Specialties: Pathology, Molecular Diagnostics & Molecular Pathology
		Medical Laboratory Director: Wenjiang Chu, M.D. ABP/Clinical Pathology, Anatomic Pathology
		Surveyor: Robert Sommer, MT Consultant/MTRO
6.	Camp Jordan Freestanding Emergency	Clinical Laboratory
	Department Chattanooga, TN	Specialties: Bacteriology (limited), Virology (limited), Hematology, General Immunology, Clinical Chemistry, Transfusion Services (limited to Emergency Release only), and Arterial Blood Gases & pH
		Medical Laboratory Director: Eugene Fong, M.D. ABP/Clinical Pathology
		Surveyor: Lori Reynolds, MT-Consultant/Surveyor/ETRO
7.	James A. Henry, M.D., LLC Loudon, TN	Anatomic Laboratory
		Specialty: Histopathology
		Medical Laboratory Director: James Henry, M.D. ABP/Clinical Pathology, Anatomic Pathology
		Surveyor: Fowlen Ivey, MT-Consultant/Surveyor/ETRO
8.	Laboratory Corporation of America Holdings	Anatomic Laboratory
	Memphis, TN	Specialty: Cytology
		Medical Laboratory Director: Steven Wang, M.D. ABP/Clinical Pathology, Anatomic Pathology, Cytopathology, Hematology
		Surveyor: Debbie Haggard, MT Consultant/WTRO

	After discussion, the Board decided to ratify the eight (8) laboratories listed above since they had no deficiencies cited during their initial inspection.
	Motion: Mr. Litle Second: Mr. Stanton
	The licenses were approved.
Other Business/Discussion:	
Other Business:	No other business was presented.
New Business:	No new business was presented.
Public Comment:	No public comments.
Adjournment:	The meeting was adjourned at 11:33 a.m. CST with no further business to discuss.
	Motion to adjourn: Mr. Litle. Second: Ms. Briggs
	The meeting was adjourned.