

**Tennessee Medical Laboratory Board
January 27, 2023
Full Board Meeting
Minutes**

Meeting Date: January 27, 2023

Time: 9:06 am CST

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:

Jennifer Gidcomb, MT-Med. Technologist, Gen.-Chairman
Jerry Barker, MT-Hospital Lab Mgr/Admin. Dir.
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
Hospital Administrator
Non-Pathologist Physician
Pathologist

Members Absent:

LeeAnne Briggs, MT- Med. Technologist, Educator
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
Bobby Sommer, MT Consultant/Supervisor MTRO
Lori Reynolds, MT Consultant/Surveyor ETRO
Richie Scruggs, MT Consultant/Surveyor WTRO
Misty Rector, MT Consultant/Surveyor MTRO

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:

Seven (7) board members were present, which constituted a quorum.

Call To Order:

The meeting was called to order at 9:06 am CST by Jennifer Gidcomb, the Board Chairman.

Presiding Officer:

Ms. Gidcomb conducted the meeting.

Approve Minutes:

P & E Committee Meeting

A motion to approve October 27, 2022, Personnel & Education Committee minutes was made by Mr. Johnson.

Second: Mr. Barker

The minutes were approved with the chairman voting.

Full Board Meeting

A motion to approve October 28, 2022, Full Board meeting minutes was made by Dr. Gibson.

Second: Mr. Litle

The Board minutes were approved with the chairman voting.

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

Dr. Vaughan reported the actions of the Personnel & Education Committee meeting, January 26, 2023.

Motion to ratify Committee actions: Mr. Johnson.

Second: Mr. Stanton

The report was accepted as presented by Dr. Vaughan 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, 2022-December 31, 2022, was presented by Ms. Teresa Phillips, Executive Director.

Zero (0) individuals were monitored during this period.

Motion to accept the TNPAP report: Dr. Vaughan.

Second: Dr. Gibson

Investigations Report

Roger Knowlton
Disciplinary Intake Coordinator

The report was accepted as given with the chairman voting.

Mr. Knowlton's investigative report included the following:

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

Investigative Licensed Laboratory Personnel: (2022)

Two (2) new complaints:

One (1) Substance abuse

One (1) Outside investigative scope

Three (3) complaints closed:

Two (2) were referred to OGC

One (1) was closed

Zero (0) currently open complaints

Investigative Licensed Laboratory Facilities: (2022)

Seven (7) new complaints:

Two (2) malpractice/negligence

Two (2) COVID

Three (3) unprofessional conduct

Eleven (11) closed complaints:

Three (3) Insufficient evidence

Three (3) were referred to OGC

Two (2) complaints closed

Three (3) closed-warning letter

Three (3) currently open complaints

Motion to accept the report: Ms. Litle.

Second: Mr. Barker

The investigations report was accepted as given with the chairman voting.

Financial Report

Keeyona Love, MPS
Fiscal Manager

No report was given.

Legislative Update

Olivia Spears, Esq.
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 and introduced the new Middle Tennessee surveyor, Misty Rector.

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

- 1. Regional One Extended Care Hospital**
Memphis, TN
Robert Farmer, RRT-Clinical Director

The first request is to permit Registered Respiratory Therapists (RRT) and Certified Respiratory Therapists (CRT) to perform and report pH, pCO₂, and pO₂ on the 2nd and 4th floors of the Turner Tower utilizing the Epop Meter instrument and methodology.

Motion: Mr. Litle
Second: Mr. Johnson

The exemption request was approved with the chairman voting, provided the facility submits a revised request removing the chemistry analytes and the hematocrit.

- 2. Parkridge Medical Center Laboratory**
Chattanooga, TN
Barbara Roberts, MT(ASCP)
POC Coordinator

The request was to permit Radiology Technologists, CT Technologists, MRI Technologists, and Registered Nurses to perform and report whole blood creatinine and calculated GFR in the Imaging Department and the Emergency Department utilizing the Nova StatSensor Creatinine Meter instrument and methodology.

Motion: Dr. Gibson
Second: Dr. Vaughan

The exemption request was approved with the chairman voting.

- 3. Baptist Memorial Hospital-Memphis**
Memphis, TN
Karen Clark, BS, MT(ASCP)SH
POC Supervisor

The request was to permit Licensed Practical Nurses to perform and report PT/INR, Hematocrit, Sodium, Potassium, Chloride, BUN, Glucose, Creatinine, ionized Calcium, and TCO₂ in the Outpatient Cath Lab, Pre/Post Cath Lab, and Cath Lab utilizing the Abbott i-STAT instrument and methodology.

Motion: Dr. Gibson
Second: Mr. Stanton

The exemption request was approved with the chairman voting.

- 4. Arlington Freestanding Emergency Department and Medical Office Building**
Arlington, TN
Karen Clark, BS, MT(ASCP)SH

The first exemption request was to permit Registered Nurses to perform and report Vaginal pH in the Emergency Department utilizing the Nitrazine Amniotest

POC Supervisor

Swabs (moderate complexity) instrument and methodology.

The second request was to permit Radiology Technologists to perform and report Creatinine (moderate complexity based on collection method) in the Emergency Department Radiology Imaging Department utilizing the Abbott i-STAT instrument and methodology.

The third request was to permit licensed Respiratory Therapists to perform and report pH, pCo₂, pO₂, tHb, O₂Hb, COHB, MetHb, BE, and HCO₃ in the main FSED Laboratory utilizing the Gem Premier 5000 instrument and methodology.

After review, the Board did not see an issue with the three exemption requests. Since the facility does not have a temporary license, the final evaluation of the POCT exemption requests was tabled until the April Board meeting.

No vote was taken.

- 5. Kindred Hospital**
Chattanooga, TN
Rhsea Parrott, RRT, BS
Director Respiratory Care Department

To permit licensed Respiratory Therapists (RRTs and CRTs) to perform and report Sodium, Potassium, Chloride, Lactate, and ionized Calcium in the Respiratory Department utilizing the Nova Stat Profile Prime ABG Instrument.

Motion: Dr. Gibson
Second: Dr. Vaughan

The exemption request was approved with the chairman voting.

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.

The Board could not act on this request because one Board member had to recuse themselves which resulted in the Board not having a quorum. The Board's Administrative Office will administratively review the request, and the final vote will be tabled until the April Board meeting.

The Board also indicated that it was permissible for laboratory directors to present their requests to direct more than three (3) labs virtually over the phone.

Discuss, Review, And Take Action, if Needed:

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

Tennessee Oncology

PathGroup

Vanderbilt-Ingram Cancer Center

Tennessee Oncology-

Dr. Natalie Dickson, President TN Oncology, 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.

They proposed the following draft language:

“With regard to anatomic pathology, and subject to requirements or standards in federal law, a treating physician has the right to obtain a sample of a patient’s tissue sufficient to conduct any requested additional testing to aid in management or treatment decisions and/or select the laboratory which will receive a sample of a patient’s specimen. A tissue sample should be released from the pathology laboratory that received and/or has control of the respective sample/tissue block within two business days of the request being received by the laboratory, provided the pathologist has signed and approved the final diagnosis.”

PathGroup-

Dr. Pranil Chandra, Sr. Vice President PathGroup, and Dr. Michelle Shiller with PathGroup requested that the Board consider the proposed language below regarding the timely release of the patient’s original biopsy tissue sample to the providers:

“With regards to anatomic pathology, and subject to requirements or standards in federal law regarding specimen custody, as also may be specified by other organizations such as CAP, a treating physician may request to obtain a recut sample of a patient’s tissue, if such sample is available beyond what is necessary for completeness of the diagnostic record, to aide in management or treatment decisions. If the treating physician determines that a comparable test is not available locally, the tissue sample should be released from the pathology laboratory that received and/or has control of the respective sample/tissue block within two business days of the request being received by the

laboratory, provided the pathologist has signed and approved the final diagnosis and the treating provider has agreed to the appropriate custodial care of the specimen. Ultimately, testing decisions need to be made through consultation and collaboration between the laboratory and treating clinician.”

Vanderbilt-Ingram Cancer Center-

Dr. Ben Ho Park, Director Vanderbilt-Ingram Cancer Center, expressed his support of the proposed regulatory language by Tennessee Oncology regarding the timely release of a patient's original biopsy tissue sample to the providers that are responsible for the treatment.

The Board deferred the discussion of the regulatory change to the Task Force. The debate will continue at the April Board meeting with recommendations from the Task Force.

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 in Tennessee's physician office laboratories 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 that collection facilities that perform indirect specimen collection and meet the following criteria will not need to obtain a Tennessee collection station license:

- The specimen is self-collected by the patient
- No patient manipulation of the sample occurs

ETHOS Laboratories was instructed to request a refund for their initial collection station application if they meet the indirect specimen collection criteria.

Motion: Mr. Litle

Second: Dr. Vaughan

The motion was approved with the chairman voting.

Discuss exemption request for director visits.

In July 2017, the Medical Laboratory Board exempted the American Red Cross from the Rules Governing Medical Laboratories requirements in Tennessee,

specifically at 1200-06-01-.20 and 1200-06-03-.14 for two of their fixed-site blood donor centers located in Murfreesboro, and Johnson City, which only performs a waived hemoglobin test. The exemption required, at a minimum, an onsite visit by the lab director every six (6) months.

The American Red Cross is opening a new blood donor center with a limited test menu at 91 Seaboard Lane, Brentwood, TN 37027, and is requesting the six (6) month director exemption for the new location.

After discussion, the Board members decided to authorize the exemption for the lab director to perform onsite visits every six (6) months to the Brentwood location. The Board also indicated that future sites seeking the same exemption must appear before the Board.

Motion: Mr. Stanton
Second: Mr. Baker

The motion was approved with the chairman voting.

Discuss Mobile Laboratory Policy Statement

The following question was presented to the Board for clarification:

If a mobile lab wants to perform testing at a long-term care facility, do they need to follow the Board's Mobile Lab Policy, or is a long-term care facility seen as a physician's office lab?

After discussion, the Board decided that mobile labs must affiliate with a state-licensed lab to perform testing in Tennessee. If the lab testing is performed outside of the vehicle, then it must pursue licensure as a state-licensed laboratory.

No motion was needed.

Discussion ASCP Conference Attendance

The Board discussed who wanted to attend the 2023 Annual ASCP Conference in Long Beach, California. The Board was informed that three (3) Board members and one (1) staff member can attend conferences without approval from the Commissioner of Health. Additional Board members and staff attendance will require a justification to be submitted.

Six (6) board members and two (2) staff members indicated they would like to participate in the conference. The Board decided to approve the request for everyone that wanted to attend the ASCP Conference and to have a justification submitted for Commissioner approval.

Motion: Mr. Johnson

Second: Mr. Barker

The motion was approved with the chairman voting.

Discuss Remote Work Policy

Based on the Board's Remote Work Policy, the following questions were presented to the Board for clarification:

1. Does reading cytogenetics digital images and reporting final patient results at a home office fall under the purview of the main laboratory, or does it require a separate laboratory license?

After discussion, the Board decided that reading cytogenetics digital images does not require an additional lab license, provided the final report indicates the main state-licensed laboratory location.

2. Do the final reports need to reflect the exact location the slides or digital images were read or the main laboratory address?

After discussion, the Board decided that the final patient report needs to reflect the address of the main state-licensed laboratory.

3. Are all laboratory specialties included in the Board's Remote Work Policy?

After discussion, the Board decided that the intent of the Remote Work Policy was to include all laboratory specialties.

Remote Work Policy will be revised to include the reading of cytogenetics digital images does not require an additional lab license provided the final report indicates the main state-licensed laboratory location, all final patient reports need to reflect the address of the main state-licensed laboratory, and the intent of the Remote Work Policy was to include all laboratory specialties.

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

The Board requested that their Remote Work Policy be converted into a policy statement.

Review and Discuss the Licensure of Medical Laboratory Directors:

1. Helen Fernandes, PhD.
Wayne, NJ 07470
Director- Molecular Diagnostics

Dr. Fernandes received her Ph.D. in Biophysics from the University of Mumbai in Mumbai, India in 1978.

She was certified by the American Board of Bioanalysis (ABB) in the category HCLD Molecular Diagnostics in 2001, expiring on 12/31/2023.

Dr. Fernandes received her post-doctoral fellowship training at the University of Medicine and Dentistry of NJ, New Jersey Medical School, 1985-1988. Director of Molecular Diagnostics Laboratory for Pathology Department in 1995-2013

She is seeking licensure as a Director of Molecular Diagnostics.

Motion: Mr. Stanton
Second: Mr. Johnson

The license was approved with the chairman voting.

2. Catherine Williams, Ph.D.
Fairview, TN 37062
Director- Breath Analysis

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

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

Dr. Williams received her Ph.D. in Oceanography from University of Southampton in Southampton, UK in China in 1999.

There is no national certification available for Breath Testing.

She received his post-doctoral training at Cairn Diagnostics, Brentwood, TN performing gastric emptying breath analysis from 2008-2021.

Dr. Williams wants to qualify under Rule 1200-06-01-.20(1)(e) which states:

(e) Hold an earned doctoral degree from an accredited college/university and, in the opinion of the Board, have appropriate work experience in a subspecialty for which there is no national certification. If boarding is available in a closely related field, that boarding must be sought. These individuals must obtain national boarding in the subspecialty when it becomes available.

She is seeking licensure as a Director of Breath Analysis.

Motion: Mr. Johnson

Second: Mr. Stanton

The license was approved with the chairman voting.

3. Daniel Ramon, Ph.D.
Nashville, TN 37215
Director- Histocompatibility.

Dr. Ramon received his B.S./M.S. degrees in Biochemistry from National University of San Luis, San Luis, Argentina in 1993.

He received his Ph.D. in Biochemistry from National University of San Luis, San Luis, Argentina in 2005.

Dr. Ramon was certified by the American Board of Bioanalysis (ABB) in the category of HCLD Diagnostic Immunology in 2009, expiring on 12/31/2023.

He was also certified by the American College of Histocompatibility and Immunogenetics (ACHI) in 2009, expiring on 12/31/2024.

Dr. Ramon received his post-doctoral fellowship training at the Histocompatibility Clinical Laboratory at Northwestern University, Feinberg School of Medicine from, 2006-2010.

He is seeking licensure as a Director of Histocompatibility and Immunogenetics.

Motion: Dr. Vaughan

Second: Dr. Gibson

The license was approved 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 Fourth Quarter of 2022.

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

Staffing updates:

- No changes during this quarter.

Board meeting dates for 2023 and 2024 were presented.

No new Board Members have been appointed.

Vacancies on the Board:

- Pathologist
- Non-Pathologist Physician
- Hospital Administrator
- Citizen Member

The Personnel, Laboratory Facility, and Training Program regulations are currently under review by a Task Force.

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.

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

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

Second: Dr. Vaughan

Absent: Mr. Johnson

The report was accepted as given with the chairman voting.

Board Attorney Report

Ronda Webb-Stewart

Senior Associate General Counsel

Senior Associate General Counsel Ronda Webb-Stewart gave her Office of General Counsel report for the Fourth 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.
- Currently, OCG is assisting the Task Force in completing the review and rewrite of the Medical Laboratory Board Rules.

Motion to accept the Office of General Counsel Report as given: Mr. Johnson.

Second: Mr. Stanton

The report was accepted as given with the chairman voting.

Disciplinary Report

Ronda Webb-Stewart
Senior Associate General Counsel

Senior Associate General Counsel Ronda Webb-Stewart gave the Disciplinary Report for the Fourth 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. Gibson.

Second: Mr. Litle

The report was accepted as given with the chairman voting.

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 2022:

Complaint Investigations: Two (2) - unsubstantiated

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: 4th Quarter

Middle Tennessee Regional Office—Fourth Quarter 2022:
Complaint Investigations:

Unsuccessful Proficiency Testing: Five (5)

- First Occurrence (two in a row or two out of three unsatisfactory scores: Five (5))
- 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 2022:

Complaint Investigations: Zero (0)

Unsuccessful Proficiency Testing: Four (4)

- 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 reports as given: Mr. Johnson.
Second: Mr. Litle

Reports were accepted as given with the chairman voting.

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

Nothing to present.

Board Ratifications Initial Facility Applications:

1. **Wellness of Middle Tennessee, LLC
Dba Any Lab Test Now
Murfreesboro, TN**

Specialties: Collection Station

Laboratory Director: Deborah Kondis, MD

Surveyor: Fowlen Anders, MT Consultant II/ETRO

Motion: Dr. Gibson
Second: Mr. Stanton

The license was approved with the chairman voting.

Other Business/Discussion:

Task Force Report

Ms. Gidcomb presented a verbal report summarizing the proposed regulation changes of the December 6, 2022, and January 26, 2023, Task Force meetings. The Task Force will meet again before the next meeting of the Medical Laboratory Board. The red-line version of the Personnel regulations will be sent to the Board members in the next few weeks.

Motion: Dr. Vaughan
Second: Mr. Johnson

The report was accepted as presented with the chairman voting.

New Lapsed License Policy

The Board reviewed the new Lapsed License Policy with recent revisions. A request was made to add the word "not" in section 5B. of the document between "amount" and "to."

Motion: Mr. Johnson
Second: Mr. Stanton

The new policy was approved with the chairman voting.

Special Analyst National Certification Policy

The Board reviewed the Special Analyst National Certification Policy pursuant to Rule 1200-06-01-.22(f)1(ii).

Motion: Mr. Johnson
Second: Mr. Litle

The policy was retired with the chairman voting.

Arterial Blood Gas Policy

The Board reviewed the Arterial Blood Gas Policy pursuant to Rule 1200-06-01-.22(g).

Motion: Mr. Litle
Second: Dr. Gibson

The policy was retired with the chairman voting.

FISH (Fluorescence in Situ Hybridization) Policy

The Board reviewed the FISH (Fluorescence in Situ Hybridization) Policy.

Motion: Mr. Johnson
Second: Mr. Stanton

The policy was retired with the chairman voting.

New Remote Survey Policy

The Board reviewed the new Remote Survey Policy with recent revisions.

Motion: Mr. Stanton
Second: Mr. Litle

The new policy was approved with the chairman voting.

Adjournment:

With no further business to discuss, the meeting was adjourned at 3:05 pm CST.

Motion to adjourn: Dr. Vaughan.
Second: Mr. Litle

The meeting was adjourned with the chairman voting.