

**Tennessee Medical Laboratory Board**  
**October 28, 2021**  
**Full Board Meeting**  
**Minutes**

**Meeting Date:** October 28, 2021

**Time:** 9:04 am CDT

**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:**

Michael Johnson, MT-Med.Technologist Generalist/Chair  
Jerry Barker, MT-Hospital Laboratory Mger/Admin. Dir.  
LeeAnne Briggs, MT- Med. Technologist, Educator  
Carla M. Davis, MD-Pathologist  
Danielle Gibson, MD-Pathologist, Non-Educator  
Jennifer Gidcomb, MT-Medical Technologist, General  
Matthew Hardison, Ph.D., Independent Lab Mger/Adm.  
Andrew Stanton, CT-Cytotechnologist  
James A. Vaughn, MD-Pathologist Educator

**Vacant Positions:** Non-Pathologist Physician  
Medical Technologist Supervisor

**Members Absent:** Gaye G. Jolly, MT-Hospital Administrator  
Lynn Stewart, Citizen Representative

**Staff Present:** Sandra S. Bogard, MT Consultant, Director  
Nina V. Smith, MT Consultant Administrative Office  
Mark Cole, Senior Associate Counsel  
Debbie Haggard, MT Consultant/Supervisor WTRO  
Richie Scruggs, MT Consultant/Surveyor WTRO

**Staff Absent:** Fowlen Anders, MT Consultant/Supervisor ETRO  
Lori Reynolds, MT Consultant/Surveyor ETRO  
Susan Massey, MT Consultant/Surveyor MTRO

**CLIA Manager/Representative:** Susan Wilson, interim CLIA Manager

**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 9:07 am CST by Mr. Michael Johnson, the Board Chairman.

**Presiding Officer:**

Mr. Johnson conducted the meeting.

**Recognized New Board Members**

No new board members at this meeting.

**Approve Minutes:**

P & E Committee Meeting

A motion to approve the July 27, 2021 Personnel & Education Committee minutes was made by Dr. Vaughn.

Second: Mr. Barker

The minutes were approved.

Full Board Meeting

A motion to approve the July 28, 2021 Board minutes was made by Ms. Briggs.

Second: Dr. Gibson

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 27, 2021.

Motion to ratify Committee actions: Dr. Gibson.

Second: Mr. Barker

The report was accepted as presented by Ms. Briggs.

**Contested Cases:**

No contested cases were presented during this meeting.

**Consent, Agreed, Compliance Orders, And Letters of Reprimand:**

No consent, agreed, or compliance orders were presented during this meeting. No letters of reprimand were presented.

**Presentations To The Board:**

**Tennessee Professional Peer Assistance Program (TNPAP)**  
Teresa Phillips, Executive Director

The statistical report for July 1, 2021-September 30, 2021, was presented by Ms. Teresa Phillips, Executive Director.

Zero (0) individuals were monitored during this period.

Motion to accept the TNPAP report: Dr. Vaughn.

Second: Ms. Briggs

The report was accepted as given.

Note: Review of TNPAP materials via the internet counts as clock hours toward continuing education credits.

A certificate of completion documenting the review of these materials can be completed at the end of the session. Internet site: [www.TNPAP.org](http://www.TNPAP.org)

**Investigations Report**  
Elizabeth Danler  
Disciplinary Coordinator

Ms. Danler's investigative report included the following:

Monitored Practitioners (Personnel and Facilities): (July 2021-September 2021)

Investigative Licensed Laboratory Personnel: (2021)

Zero (0) new complaints.

One (1) complaint closed.

One (1) currently open complaint.

Six (6) currently monitored practitioners.

Investigative Licensed Laboratory Facilities: (2021)

Two (2) new complaints:

one for unprofessional conduct.

one for unlicensed practice.

Four (4) complaints closed.

Motion to Accept Report: Ms. Briggs

Second: Mr. Barker

The investigations report was accepted as given.

**Financial Report**  
Matthew McSpadden  
Fiscal Manager

Mr. McSpadden gave the Annual Fiscal Report, which compared the actual revenue and expenditures for the past three (3) years (FY2019, FY2020, FY2021). The values were comparative with little change from year to year. He also presented information regarding the revenue sources for FY2021 that included the following fees: renewal, civil penalty, case cost assessment, unassigned cash, penalty-late renewal, reinstatement, return check fee, state regulatory fee, application, licensure, and undefined ASC feed codes.

Motion: Dr. Vaughn

Second: Ms. Gidcomb

The report was accepted as given.

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

**Legislative Update**  
Elizabeth E. Foy, Esq.  
Legislative Liaison

No legislative update was presented at this meeting.

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

- 1. Johnson City Medical Center**  
400 North State of Franklin Road  
Johnson City, TN 37604  
Catherine Greear, MT-Point-of-Care  
Coordinator

The request is to permit Registered Nurses, Perfusionists, and Registered Respiratory Therapists to perform pH, pCO<sub>2</sub>, pO<sub>2</sub>, sodium, ionized calcium, glucose, hematocrit, and hemoglobin in the ICU stations (2700, 2800, & 2900) utilizing the Abbott i-STAT instrument with the CG8+ cartridge.

Motion: Ms. Gidcomb  
Second: Dr. Davis

The exemption request was approved.

The second request was to permit Registered Nurses, Perfusionists, and Registered Respiratory Therapists to perform sodium, potassium, chloride, TCO<sub>2</sub>, glucose, ionized magnesium, ionized calcium, lactate, hematocrit, hemoglobin, pH, pCO<sub>2</sub>, pO<sub>2</sub>, and O<sub>2</sub>Hg testing in the ICU stations (2700, 2800, & 2900) utilizing the Nova Stat Prime Plus instrument and methodology.

Motion: Ms. Briggs  
Second: Mr. Stanton

The exemption request was approved.

The third request was to permit Registered Nurses, Perfusionists, and Registered Respiratory Therapists to perform ACT testing in the ICU stations (2700, 2800, & 2900) utilizing the Abbott i-STAT instrument and methodology.

Motion: Dr. Vaughn  
Second: Dr. Hardison

The exemption request was approved.

- 2. Lab Plus, LLC - Saint Thomas Rutherford**  
1700 Medical Center Parkway  
Murfreesboro, TN 37129

The request was to permit Paramedics to perform pH, pO<sub>2</sub>, pCO<sub>2</sub>, O<sub>2</sub>sat., lactate testing facility-wide utilizing

Teri Reed, MT – Lab Manager

the Abbott i-STAT (CG4+ cartridge) instrument and methodology.

Motion: Ms. Briggs

Second: Dr. Hardison

The exemption request was approved.

The second request was to permit Registered Nurses, Licensed Practical Nurses, and Paramedics to perform Troponin testing in the Emergency Department utilizing the Abbott i-STAT instrument and methodology.

Motion: Dr. Vaughn

Second: Ms. Briggs

The exemption request was approved.

**3. Baptist Memorial Hospital-Memphis**

6019 Walnut Grove Road

Memphis, TN 38120

Karen Clark, BS, MT(ASCP)SH-Point of Care Supervisor

The request was to permit Certified Registered Nurse Anesthetists to perform ACT testing in Surgery utilizing the Hemochron Elite instrument and methodology.

Motion: Ms. Briggs

Second: Mr. Barker

The exemption request was approved.

The second request was to permit Certified Registered Nurse Anesthetists to perform sodium, potassium, glucose, ionized calcium, hematocrit, pH, pCO<sub>2</sub>, pO<sub>2</sub>, BE, and HCO<sub>3</sub> in Surgery utilizing the Abbott i-STAT instrument and methodology.

Motion: Dr. Gibson

Second: Mr. Stanton

The exemption request was approved.

**4. TriStar Summit Medical Center**

5655 Frist Boulevard

Hermitage, TN 37076

Christi King, BSC, MT-Admin. Director  
Laboratory Services

The request was to permit Registered Nurses, Certified Perfusionists, and Registered Cardiovascular Invasive Specialists to perform Hct, pH, pO<sub>2</sub>, pCO<sub>2</sub>, HCO<sub>3</sub>, BE, and O<sub>2</sub>sat in the Operating Rooms, Intensive Care Units, Post Catheterization Lab, Cath Lab, and Non-Invasive Cardiology Department utilizing the Siemens Epoc instrument and methodology.

Motion: Ms. Briggs

Second: Dr. Gibson

The exemption request was approved.

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

Nothing to present.

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

Discuss Off-Label Use of SARS-CoV-2 Testing Kits with Asymptomatic Individuals

After discussion, the Board indicated that the clinical laboratory often does not know if a patient is asymptomatic because they only receive the specimen. The lab needs to educate the providers about the proper use of the test kits. The Board recommended that laboratories follow the SARS-CoV-2 test kit manufacturer's instructions for use. If the manufacturer requires two tests to be performed during a specific time interval, the lab needs to request the patient return for a repeat test or follow up with a PCR test. The Board also recommended that the lab put a footnote on the test results indicating what the manufacturer requires regarding repeat testing and the use of PCR testing for asymptomatic patients.

It will be difficult for the survey staff to determine if tests were performed on asymptomatic patients during the survey process. Therefore, this would not be an area for them to write deficiencies.

No motion was needed.

Discuss Task Force Recommendations Regarding Digital Imaging and Remote Work

The Board Members that participated in the Task Force voted if they wanted the Full Board to discuss the recommendations.

The Board Members responded by roll call vote:

Michael Johnson, MT	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes

Based on the vote, the Board discussed the recommendations of the Task Force. The Board requested that the second objective be revised in the minutes to reflect that remote work includes many different areas and is not limited to only cytogenetics, pathology, flow cytometry, FISH, or toxicology.

The Board clarified that remote work includes digital work.

They also indicated that pathologists that read slides at their home are not required to obtain a state lab license

for the home location. That testing would be under the purview of the central laboratory. The Board regulates the person performing the test, not the location.

The Board accepted the following recommendations of the Task Force:

**Objective:** What are the responsibilities of a medical laboratory director while working remotely?

**Response:** The medical laboratory director is responsible for all the duties in the regulations located at 1200-06-01-.20(5) which include, competency assessment, proficiency testing enrollment, monthly visits, etc. Director oversight must be documented. There is no change in the responsibilities of the medical laboratory director regardless if he or she is working physically in the lab or remotely.

**Objective:** How to regulate remote lab work that includes many different areas, including but not limited to cytogenetics, pathology, flow cytometry, FISH, and toxicology.

**Response:** Oversight for testing performed remotely will occur at the main state-licensed laboratory. The interpretive process rendered by medical professionals, which includes the review of slides, histograms, and FISH, is limited to the analysis of electronic data can be performed remotely and fall under the oversight of the main lab.

**Objective:** Identify any issues with pathologists using digital imaging to read clinical slides.

**Response:** The reading of digital images can occur at multiple locations. HIPAA policies are in effect at the central lab, along with training requirements for staff.

**Objective:** Where is the diagnosis rendered?

**Response:** The diagnosis is rendered at the main state-licensed laboratory. All other testing sites fall under that location's license. They are an extension of the main lab. This guidance is not limited to any specific lab specialty or department.

**Objective:** If testing is performed in a home, is it subject to inspection?

Response: Home inspections for pathology do not add any value and are unnecessary. All records can be reviewed at the main state-licensed lab. There is no need for individual facility licensure at a pathologist's home. The surveyors can review all remote testing documents at the main lab.

Objective: What is the impact on pathologists that read in multiple locations?

Response: Pathologists that read digital slides remotely have an improved turn-around time. The focus does not need to be on the location where the pathologist resides but instead on the credentials of the pathologist performing the slide interpretation.

Objective: How will remote work be regulated, and how will oversight occur?

Response: Lab surveyors will review all the remote documents at the main laboratory during an inspection. The lab director will perform his or her oversight either in person or remotely.

A motion to approve the revised July 27, 2021, Task Force meeting minutes was made by Ms. Gidcomb.  
Second: Mr. Barker

The minutes were approved.

#### Discuss Supervisor Qualifications for Arterial Blood Gas Lab

The Board discussed their current regulations regarding arterial blood gas lab supervision requirements. After consulting with the Respiratory Care Board, the Medical Laboratory Board decided that individuals that want to perform the duties of a laboratory supervisor of an arterial blood gas (ABG) lab must possess the Registered Respiratory Therapist (RRT) credentials along with ABG endorsement.

If the Registered Respiratory Therapist does not possess a bachelor's degree, the lab director will be responsible for signing all personnel competencies.

Motion: Dr. Hardison.  
Second: Ms. Briggs

The motion was approved.



### Discuss Mobile Collection Stations

The Board discussed mobile COVID-19 collection sites.

Mr. Ahsan Sheikh presented the North Shore Medical Labs Mobile Collection Station model. The collection station will periodically move to a different location but will be a fixed site at the new location.

The Board determined that a mobile collection station must notify the Board's Administrative Office when it moves to a different address and must pay \$100 each time it relocates per the regulations at 1200-06-03-.02(3)(h).

The Board recommended that mobile collection stations consider having a permanent home base location.

Motion: Ms. Gidcomb.

Second: Dr. Hardison

The motion was approved.

### Discuss Acceptable Options to Verify Accuracy of Waived Tests.

The Board discussed the different options labs have to verify the accuracy of waived test systems.

The following options to verify the accuracy of waived testing will be added to the Board's Waived Testing Policy:

Proficiency testing samples

Split samples

Test blind/unknown samples

Note: Normal quality control material with known values run regularly is not acceptable to verify accuracy.

No motion was needed. Board will vote on the new policy.

### Discuss the Delegation of the Verification of Performance Specifications Under Rule 1200-06-01-.21.

After Board discussion, the following clarification was provided regarding the duties that can be delegated during the verification process:

Lab directors need to sign off on all validation studies of new procedures.

The lab supervisor can sign off the twice-a-year verification study.

The lab director can delegate validation study approval to the lab supervisor for replacement, or additional instrumentation provided the same instrument or model is used.

Motion: Ms. Briggs  
Second: Dr. Hardison

The motion was approved.

### **Review And Discuss The Licensure Of Medical Laboratory Directors:**

1. Bonita Taffe, PhD  
Jacksonville, FL 32225  
Director: Toxicology

Dr. Taffe received her B.S. degree in Biology at the University of Connecticut in Storrs, CT, in 1976.

She received her Ph.D. in Environmental Science/Toxicology from John Hopkins School of Public Health at Baltimore, MD, in 1988.

Dr. Taffe is certified by the National Registry of Certified Chemistry (NRCC) as a Toxicological Chemist through Dec. 31, 2022.

She received her postdoctoral fellowship training at the Michigan Department of Health and Human Services Bureau of Laboratories in Lansing, MI as a Section Manager from 2007-2014.

Dr. Taffe is seeking licensure as a Director in Toxicology.

Motion: Dr. Vaughn  
Second: Dr. Gibson

The license was approved.

2. Saradhi Mallampati, PhD  
Houston, TX 77085  
Director: Molecular Diagnostics

Dr. Mallampati received his D.M.V. degree in Veterinary Medicine at A.N.G. Ranga Agricultural University in Hyderabad, India, in 2000.

He received his M.S. in Veterinary Public Health, Microbiology, & Immunology from G.B. Pant University of Agriculture and Technology in Pantnagar, India, in 2002.

He received his Ph.D. in Molecular Medicine from J. Nehru University in New Delhi, India, in 2008.

Dr. Mallampati is certified by the American Board of Bioanalysis (ABB) HCLD in Molecular Diagnostics through Dec. 31, 2021.

He received his postdoctoral fellowship training at the University of Texas MD Anderson Cancer Center in the Molecular Diagnostic Laboratory, Genomic Test Development Laboratory, and the Division of Pathology and Laboratory Medicine in Houston, TX, from 2018-2021.

Dr. Mallampati is seeking licensure as a Director of Molecular Diagnostics.

Motion: Dr. Gibson  
Second: Ms. Briggs

The license was approved.

3. Sung Choi, Ph.D.  
Woodinville, WA 98077  
Director: Clinical Chemistry

Dr. Choi received her B.S. degree in Food and Nutrition at the Seoul National University in Seoul, South Korea, in 1998.

She received her Ph.D. in Molecular and Biochemical Nutrition from the University of California in Berkley, CA, in 2007.

Dr. Choi is certified by the American Board of Clinical Chemistry (ABCC) as a Clinical Chemist through Dec. 31, 2021.

She received her postdoctoral fellowship training at the Seattle Cancer Care Alliance Pharmacokinetics Laboratory in Seattle, WA, as a Laboratory Director from 2018-2021.

Dr. Choi is seeking licensure as a Director in Clinical Chemistry.

Motion: Ms. Gibson.  
Second: Mr. Stanton

The license was approved.

#### Reports/Requests:

**Board Director's Report**  
Sandra Bogard, MS, MT(ASCP) QLC <sup>cm</sup>

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

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

Staffing updates:

- In the hiring process for the Regulatory Board Administrative Assistant 2 position.

Board meeting dates for 2022 were presented.

Two (2) Vacancies on the Board:

- Non-Pathologist Physician
- Laboratory Supervisor

Board positions that expire on December 31, 2021:

- Carla Davis, MD-Pathologist
- Gaye Jolly-Hospital Administrator
- Lynn Stewart-Citizen Member
- James Vaughn, MD-Pathologist Educator

Continue to work on the collaborative database between CEDEP (Communicable and Environmental Diseases and Emergency Preparedness) and the Medical Laboratory Board. The Board Director is currently working with a Project Manager on the design components of the database.

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

Motion to approve the report as given: Ms. Gidcomb  
Second: Dr. Davis

The report was accepted as given.

**Board Attorney Report**

Mark Cole  
Senior Associate General Counsel

Counsel Mark Cole gave his report for the past quarter:

The Conflict of Interest Policy was reviewed with the Board members.

One (1) open case is currently in the Office of General Counsel.

The personnel rule revisions are under review at the Attorney General's Office.

Motion to accept the Office of General Counsel Report  
as given: Dr. Vaughn  
Second: Ms. Gidcomb  
Absent: Dr. Hardison

The report was accepted as given.

**Regional Surveyor Reports:**

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

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

East Tennessee Regional Office –Third Quarter 2021

Complaint Investigations: Zero (0)

Unsuccessful Proficiency Testing: Two (2)-April 2021  
Two (2)-Sept. 2021

- 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))

**MTRO Report: 3rd Quarter**  
Susan Wilson, MT  
Consultant/Surveyor

Middle Tennessee Regional Office –Third Quarter 2021

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))

**WTRO Report: 3rd Quarter**  
Debbie Haggard, MT  
Consultant/Surveyor

West Tennessee Regional Office –Third Quarter 2021

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))

Motion to accept the reports as given: Ms. Briggs.  
Second: Dr. Gibson  
Absent: Dr. Hardison

Reports were accepted as given.

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

Discuss Adding CareStart Rapid Antigen  
Test to the Approved Health Screening  
Test List

The Board discussed the CareStart COVID-19 Rapid  
Antigen Test system reviewing the EUA (Emergency Use  
Authorization) Letter from FDA and the manufacturer's  
instructions for use.

After discussion, the Board decided to deny the request  
to add the test system to the Board-approved Health  
Screening Test List.

Motion: Dr. Hardison.  
Second: Ms. Briggs

The request was denied.

**Board Ratifications Initial Facility Applications:**

- 1. Accupath Diagnostic Laboratories,  
Inc.**  
1652 Mason Bates Bend Road  
Centerville, TN 37033

Specialties: Hematology  
General Immunology  
Histopathology

Laboratory Director: Ronald Thomason, MD  
Anatomic/Clinical  
Pathology/Hematology

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Dr. Vaughn  
Second: Ms. Gidcomb  
Absent: Dr. Hardison

The license was approved.

- 2. ImmunoTek Bio Centers, LLC**  
6500 Quince Road  
Memphis, TN 38119

Specialties: Spun Hematocrit  
Total Serum Protein

Laboratory Director: Jarad L. Hopper, MD  
Internal Medicine

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Ms. Gidcomb.  
Second: Mr. Stanton  
Absent: Dr. Hardison

The license was approved.

**3. Octapharma Plasma, LLC**  
3329 Austin Peay Highway  
Memphis, TN 38128

Specialties: Spun Hematocrit  
Total Serum Protein

Laboratory Director: Sean Klepper, MD  
Clinical & Anatomic Pathology

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Ms. Briggs.  
Second: Mr. Barker  
Absent: Dr. Hardison

The license was approved.

**Other Business/Discussion:**

Guidance for Administrative Staff  
Regarding the Processing of Urgent  
Point-of-Care Exemption Requests  
Between Board Meetings

After discussion, the Board decided to authorize the Board's administrative staff to approve urgent point-of-care (POCT) exemption requests provided one of the following criteria is met:

- New instrumentation/methodology for the facility but already approved in the State of TN.
- New location for POCT for the facility but already approved in the State of TN.
- New personnel or department(s) for the facility but already approved in the State of TN.

The Board would make a final determination after review at the following meeting.

The Point-of-Care Exemption packet would need to indicate that it is an "urgent request."

Motion: Dr. Davis.  
Second: Mr. Stanton  
Absent: Dr. Hardison

The motion was approved.

Discuss the Reactivation Process and  
Needed Fees After a Temporary Lab  
Facility License has Expired

The Board decided that a lab must pay the initial application fee again if the temporary license has expired.

No motion was needed.

Discuss the Possibility of Waiving the  
Penalty Fee for an Expired Lab Facility

The Board indicated that per Regulation 1200-06-03-.02(3)(c), a late laboratory license renewal penalty fee of

License.

\$500 is to be paid when the lab fails to timely renew the license annually.

Motion: Mr. Barker.  
Second: Mr. Stanton  
Abstain: Dr. Hardison

The motion was approved. The facility's request to have the penalty fee removed was denied.

Governor's Executive Orders

Governor Lee's Executive Orders 83 and 88 were reviewed by the Board.

Election of Chairman - Full Board

The nomination for Full Board Chairman was Mr. Johnson.

Motion: Dr. Gibson.  
Second: Ms. Gidcomb  
Abstain: Mr. Johnson

The nomination was approved.

Election of Vice-Chairman – Full Board

The nomination for Full Board Vice-Chairman was Dr. Gibson.

Motion: Dr. Vaughn.  
Second: Ms. Gidcomb  
Abstain: Dr. Gibson

The nomination was approved.

Election of P & E Committee Chairman

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

Motion: Dr. Vaughn.  
Second: Mr. Barker  
Abstain: Ms. Briggs

The nomination was approved.

**Adjournment:**

With no further business to discuss, the meeting was adjourned at 12:48 pm CST.

Motion to adjourn: Mr. Barker  
Second: Ms. Briggs

The meeting was adjourned.