

Tennessee Medical Laboratory Board
April 28, 2022
Full Board Meeting
Minutes

Meeting Date: April 28, 2022

Time: 9:03 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:

Danielle Gibson, MD-Pathologist, Non-Educator/Chair
Jerry Barker, MT-Hospital Laboratory Mger/Admin. Dir.
LeeAnne Briggs, MT- Med. Technologist, Educator
Jennifer Gidcomb, MT-Medical Technologist, General
Matthew Hardison, Ph.D., Independent Lab Mger/Adm.
Chris Litle, MT-Medical Laboratory Supervisor
Andrew Stanton, CT-Cytotechnologist
James A. Vaughan, MD-Pathologist Educator

Vacant Positions: Non-Pathologist Physician

Members Absent:

Carla M. Davis, MD-Pathologist
Michael Johnson, MT-Med. Technologist Generalist
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

Staff Absent:

Debbie Haggard, MT Consultant/Supervisor WTRO
Richie Scruggs, MT Consultant/Surveyor WTRO
Fowlen Anders, MT Consultant/Supervisor ETRO
Lori Reynolds, MT Consultant/Surveyor ETRO

CLIA Manager/Representative: Erika Haire, CLIA Manager-Absent

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 9:03 am CDT by Dr. Danielle Gibson, the Board Vice-Chairman.

Presiding Officer:

Dr. Danielle Gibson conducted the meeting.

National Medical Laboratory Professionals Week

Dr. Gibson recognized National Medical Laboratory Professionals Week and thanked all laboratory professionals for their hard work.

Recognized New Board Members

Mr. Chris Litle, a new board member, Mr. Mina Girgis, the new Medical Laboratory Board Administrator, and Ms. Sarah Harvey, the new Director of Health Care Facilities, were recognized at this meeting.

Approve Minutes:

P & E Committee Meeting

A motion to approve October 27, 2021, Personnel & Education Committee minutes was made by Dr. Vaughan.

Second: Ms. Briggs

The minutes were approved.

A motion to approve January 20, 2022, Personnel & Education Committee minutes was made by Mr. Barker.

Second: Mr. Stanton

The minutes were approved.

Full Board Meeting

A motion to approve October 28, 2021, Full Board meeting minutes was made by Ms. Gidcomb.

Second: Ms. Briggs

The Board minutes were approved.

Ratification Of Initial Determinations
P & E Committee Meeting:

Ms. Briggs reported the actions of the Personnel & Education Committee meeting, April 27, 2022.

Motion to ratify Committee actions: Dr. Vaughan.

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-December 31, 2021, was presented by Ms. Teresa Phillips, Executive Director.

Zero (0) individuals were monitored during this period.

Motion to accept the TNPAP report: Ms. Briggs.
Second: Dr. Hardison

The report was accepted as given.

The statistical report for January 1, 2022-March 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: Mr. Litle

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

Investigations Report
Roger Knowlton
Disciplinary Intake Coordinator

Mr. Knowlton's investigative report included the following:

Monitored Practitioners (Personnel and Facilities):
(January-December 2021)

Investigative Licensed Laboratory Personnel: (2021)

Four (4) new complaints:

- Three (3) substance abuse
- One (1) unlicensed practice

Five (5) complaints closed:

- Two (2) closed-insufficient
- One (1) referred to OGC
- One (1) closed-no action
- One (1) closed-letter of concern

Investigative Licensed Laboratory Facilities: (2021)

Twelve (12) new complaints:

- One (1) proficiency testing
- One (1) unqualified personnel
- Two (2) diagnostic discrepancies/errors
- One (1) transfusion fatality
- Four (4) unlicensed practice
- Three (3) unprofessional conduct

Seven (7) closed complaints

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

Investigative Licensed Laboratory Personnel: (2022)

Zero (0) new complaints
Zero (0) complaints closed
One (1) currently open

Investigative Licensed Laboratory Facilities: (2022)

Four (4) new complaints:

- One (1) malpractice/negligence
- Two (2) COVID
- One (1) unprofessional conduct

Three (3) closed complaints:

- Two (2) referred to OGC
- One (1) closed-warning letter

Eight (8) currently open complaints

Motion to accept the report: Ms. Gidcomb.

Second: Mr. Barker

The investigations report was accepted as given.

Financial Report
Matthew McSpadden
Fiscal Manager

Mr. McSpadden gave the Mid-Year FY2022 Fiscal Report, which compared the actual revenue and expenditures for the past three (3) years (FY2020, FY2021, FY2022). The values were comparative with little change from year to year. He also presented the direct expenditures from July 1 to December 31 for FY2020, FY2021, and FY2022. The results indicated minor variations between fiscal years. The direct expenditures were presented for July 1 to December 31 for FY2020, FY2021, and FY2022. The FY2020 and FY2022 were very comparable with little change. FY2021 had an additional \$25,000 of expenditures compared to the other two fiscal years.

Motion to accept the report: Dr. Hardison.

Second: Ms. Briggs

The report was accepted as given.

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

No legislative update was presented at this meeting.

Legislative Update
Elizabeth E. Foy, Esq.
Legislative Liaison

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

1. Saint Francis Hospital

5959 Park Avenue
Memphis TN 38119
Kathy Crews, BS, MT(ASCP)-Lab Manager

The first request is to permit Registered Nurses to perform pH, pCO₂, pO₂, TCO₂, HCO₃, BE, Na, K, Glu, iCa, Hct, and Hgb in the GI Lab utilizing the i-STAT instrument and methodology with the CG8+ cartridge.

Motion: Ms. Briggs
Second: Mr. Stanton

The exemption request was approved.

The second request was to permit Registered Nurses, Cardiovascular Techs, and Perfusionists to perform pH, pCO₂, pO₂, TCO₂, HCO₃, BE, Na, K, Glu, iCa, Hct, and Hgb in the Cath Lab utilizing the i-STAT instrument and methodology with the CG8+ cartridge.

Motion: Dr. Vaughan
Second: Mr. Barker

The exemption request was approved.

2. Parkridge Medical Center

2333 McCallie Avenue
Chattanooga, TN 37404
Helen Richardson, MT-Point of Care
Coordinator

The request was to permit Registered Nurses to perform and report whole blood oximetry (T%HbO₂ & tHb) in the Cardiac Cath Lab utilizing the Avox 1000E instrument and methodology.

Motion: Dr. Vaughan
Second: Dr. Hardison
Abstain: Mr. Litle

The exemption request was approved with the Chairman voting.

3. Parkridge Medical Center Blood Gas Lab

2333 McCallie Avenue
Chattanooga, TN 37404

The request was to permit Respiratory Therapists to perform and report whole blood oximetry (COHB, MetHgb, O₂Hb, and tHb) facility-wide utilizing the Avox 4000 instrument and methodology.

Lisa Caldwell, MSHA, RRT-Director
Cardiopulmonary Services

Motion: Ms. Briggs
Second: Mr. Stanton
Abstain: Mr. Litle

The exemption request was approved with the Chairman voting.

- 4. Fort Sanders Regional Medical Center**
1901 Clinch Avenue
Knoxville, TN 37916
Jane Duncan, MT-Point of Care Technical
Specialist

The request was to permit Registered Nurses to perform and report lactate in the Emergency Department utilizing the Nova Biomedical Lactate Meter instrument and methodology.

Motion: Mr. Barker
Second: Ms. Briggs

The exemption request was approved.

- 5. 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 Registered Nurses to perform and report pH, pCO₂, pO₂, BE, HCO₃, Sodium, Potassium, Ionized Calcium, Glucose, and Hematocrit in the Post Anesthesia Care Unit (PACU) and BAC PACU utilizing the Abbott i-STAT instrument and methodology.

Motion: Dr. Hardison
Second: Mr. Stanton

The exemption request was approved.

- 6. Parkwest Medical Center Laboratory**
9352 Park West Boulevard
Knoxville, TN 37923
Trudy Whitson, MT(ASCP) – Point of Care
Coordinator

The request was to permit Registered Nurses to perform and report lactate in the Emergency Department utilizing the NOVA StatStrip Meter instrument and methodology.

Motion: Ms. Briggs
Second: Mr. Litle

The exemption request was approved.

- 7. Roane Medical Center**
8045 Roane Medical Center Drive
Harriman, TN 37748
Karen Coaker, MT(ASCP)-Laboratory Manager

The request was to permit Registered Nurses to perform and report lactate in the Emergency Department utilizing the NOVA StatStrip Meter instrument and methodology.

Motion: Dr. Vaughan
Second: Ms. Briggs

The exemption request was approved.

- 8. Morristown-Hamblen Healthcare System**
908 West 4th North Street
Morristown, TN 37814
Beth Powers, MLS(ASCP) – Laboratory
Manager

The first request was to permit Registered Nurses to perform and report lactate in the Emergency Department utilizing the NOVA Biomedical Lactate Meter instrument and methodology.

Motion: Ms. Briggs
Second: Dr. Hardison

The exemption request was approved.

The second request was to permit Registered Nurses, Registered Cardiovascular Invasive Specialists (RCIS), and Cardiovascular Technologists (CVT) to perform and report O2 Saturation in the Cardiac Catheterization Lab utilizing the ITC AVOXimeter 1000E instrument and methodology.

Motion: Dr. Hardison
Second: Ms. Gidcomb

The exemption request was approved.

- 9. Lab Plus LLC – Saint Thomas Midtown**
2000 Church Street
Nashville, TN 37236
Russell Ashley, MLS(ASCP)cm – Point of Care
Coordinator

The request was to permit Respiratory Therapists to perform and report lactate facility-wide utilizing the Abbott i-STAT instrument and methodology.

Motion: Dr. Hardison
Second: Ms. Briggs

The exemption request was approved.

- 10. Claiborne Medical Center**
1850 Old Knoxville Road
Tazewell, TN 37879
Dewayne Graves – Laboratory Manager

The request was to permit Registered Nurses to perform and report lactate in the Emergency Department utilizing the Nova Biomedical Lactate Meter instrument and methodology.

Motion: Ms. Briggs
Second: Mr. Litle

The exemption request was approved.

- 11. Fort Loudoun Medical Center**
550 Fort Loudon Medical Center Drive
Lenoir City, TN 37772
Melissa Wright, MT(ASCP) – interim Lab
Manager

The request was to permit Registered Nurses to perform and report lactate in the Emergency Department utilizing the Nova Biomedical Lactate Meter instrument and methodology.

Motion: Mr. Stanton
Second: Ms. Briggs

12. LeConte Medical Center

742 Middle Creek Road
Sevierville, TN 37862
Amanda Sutton, MLS(ASCP) – Laboratory
Manager

The exemption request was approved.

The request was to permit Registered Nurses to perform and report lactate in the Emergency Department utilizing the Nova Biomedical Lactate Meter instrument and methodology.

Motion: Ms. Briggs
Second: Ms. Gidcomb

The exemption request was approved.

13. Vanderbilt Tullahoma-Harton Hospital

1801 N. Jackson Street
Tullahoma, TN 37388
Chun Luong, MLS(ASCP)cm – Administrative
Laboratory Director

The request was to permit Registered Respiratory Therapists and Certified Respiratory Therapists (ABG endorsed) to perform pH, pCO₂, pO₂, sO₂, BE, HCO₃, Carboxyhemoglobin, Methemoglobin, Total Hgb, Lactate, Sodium, Potassium, Chloride, Glucose, and ionized Calcium in the Respiratory Department and Intensive Care Unit utilizing the Gem 5000 Premier instrument and methodology.

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

The exemption request was approved with the Chairman voting.

14. TriStar Hendersonville Medical Center

355 New Shackle Island Road
Hendersonville, TN 37075
Daniel Peavey, MSHA, MSHQS, MLS(ASCP)^{cm} -
Admin. Lab Director

The request was to permit Registered Nurses and Certified Registered Nurse Anesthetists (CRNA) to perform and report ACT testing in the Cath Lab utilizing the Abbott i-STAT instrument and methodology.

Motion: Dr. Vaughan
Second: Mr. Barker
Abstain: Mr. Litle

The exemption request was approved with the Chairman voting.

15. Memorial Hospital-A Division of SCNHC

2525 DeSales Avenue
Chattanooga, TN 37404
Tina Smith-Zitzow, MT – Supervisor Point of
Care

The request was to permit Registered Nurses and Radiological Technologists to perform and report ACT testing in the Interventional Neurology Department utilizing the Abbott i-STAT instrument and methodology.

Motion: Dr. Vaughan
Second: Mr. Barker

The exemption request was approved.

16. Marshall Medical Center

1080 N. Ellington Parkway
Lewisburg, TN 37091
Michelle Hargrove – ER Nurse Manager

The request was to permit Registered Respiratory Therapists and Registered Nurses to perform pH, pCO₂, pO₂, sO₂, BE, HCO₃, TCO₂, and Lactate in the Emergency Department and Medical Surgical Nursing Unit utilizing the Abbott i-STAT (cartridge CG4+) instrument and methodology.

Motion: Mr. Stanton
Second: Mr. Litle
Abstain: Ms. Gidcomb

The exemption request was approved with the Chairman voting.

17. VUMC dba Vanderbilt Wilson County Hospital

1411 W. Baddour Parkway
Lebanon, TN 37087
Joseph S. Tobia, MT(ASCP) DLM – Admin.
Director of Laboratory

The request was to permit Registered Respiratory Therapist, Certified Respiratory Therapist (ABG endorsed) to perform pH, pCO₂, pO₂, sO₂, Carboxyhemoglobin, Methemoglobin, Total Hgb, Oxyhemoglobin, Lactate, Sodium, Potassium, Chloride, Glucose, and ionized Calcium in the Respiratory Department, Emergency Department, Intensive Care Unit, and Cardiac Catheterization Lab utilizing the Gem 5000 Premier instrument and methodology.

Motion: Mr. Barker
Second: Mr. Litle
Abstain: Mr. Stanton

The exemption request was approved with the Chairman voting.

18. Cumberland Medical Center

421 South Main Street
Crossville, TN 38555
George Rohweder- MS, MT/SC(ASCP),
CC(NRCC)-Chief Technologist

The request was to permit Registered Nurses to perform and report lactate in the Emergency Department utilizing the Nova StatStrip Lactate Meter instrument and methodology.

Motion: Mr. Barker
Second: Mr. Litle

The exemption request was approved.

19. Vanderbilt Bedford Hospital

2835 Highway 231 North
Shelbyville, TN 37160
Deanna Bell, MBA, MLS(ASCP)cm – Admin.
Director of Lab Services

The request was to permit Registered Respiratory Therapists and Certified Respiratory Therapists (ABG endorsed) to perform and report Lactate, Sodium, Potassium, Chloride, Glucose, and ionized Calcium in the Blood Gas Laboratory utilizing the Gem Premier 5000 instrument and methodology.

Motion: Ms. Briggs
Second: Ms. Gidcomb
Abstain: Mr. Stanton

The exemption request was approved with the Chairman voting.

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

1. Theodore Kieffer, MD
Nashville, TN 37210

Dr. Kieffer appeared before the Board to request approval to direct a total of four (4) laboratories.

Dr. Kieffer currently serves as a medical laboratory director for the following Tennessee licensed laboratory facilities:

- Blood Assurance, Inc.-60 Parris Avenue, Nashville, TN 37403 (lic. # 4432)-high complex testing
- Blood Assurance, Inc.-600A Frazier Drive, Suite 110, Franklin, TN 37067 (lic. # 4454)-waived testing
- Blood Assurance, Inc.-4686 Lebanon Pike, Hermitage TN 37076 (lic. # 4463)-waived testing
- Blood Assurance, Inc.-7112 Hwy 70 S, Suite D1, Nashville, TN 37221 (lic. # 4465)-waived testing

Motion: Ms. Briggs
Second: Mr. Stanton

The request for Dr. Kieffer to direct four (4) laboratories was approved.

2. John R. Olson, MD
Columbia, TN 38401

Dr. Olson appeared before the Board to request approval to direct a total of five (5) laboratories.

Dr. Olson currently serves as a medical laboratory director for the following Tennessee licensed laboratory facilities:

- Wayne Medical Center-103 JV Mangubat Drive, Waynesboro, TN 38485
- Marshall Medical Center-1080 North Ellington Parkway, Lewisburg, TN 37091
- Northcrest Medical Center-Anatomic-100 Northcrest Drive, Springfield, TN 37172
- Perry Community Hospital-2718 Squirrel Hollow Drive, Linden, TN 37096-Closed

- Northcrest Medical Center-Clinical-100
Northcrest Drive, Springfield, TN 37172-NE

Motion: Dr. Hardison
Second: Mr. Stanton
Abstain: Dr. Gibson
Abstain: Ms. Gidcomb

Dr. Olson's request had to be tabled until the July Board meeting due to the lack of a quorum because of abstentions.

3. Lori M. Proctor, MD
Chattanooga, TN 37421

Dr. Proctor appeared before the Board to request approval to direct a total of five (5) laboratories.

Dr. Proctor currently serves as a medical laboratory director for the following Tennessee licensed laboratory facilities:

- Parkridge East Hospital Laboratory, 941 Spring Creek Road, Chattanooga, TN 37412 (lic. #2141)
- Parkridge East Respiratory Care Department Laboratory, 941 Spring Creek Road, Chattanooga, TN 37412 (lic. #4068)
- Parkridge North ER Laboratory, 7402 Lee Highway, Chattanooga, TN 37421 (lic. #4437)
- Park Ridge Medical Center, 2333 McCallie Avenue, Chattanooga, TN 37404 (lic. #2186)
- Associated Pathologists, LLC dba PathGroup (McCallie), 2333 McCallie Avenue, Chattanooga, TN 37404 (lic. #3345)

Motion: Dr. Hardison
Second: Ms. Briggs

The request for Dr. Proctor to direct five (5) laboratories was approved.

Discuss, Review, And Take Action, if Needed:

Discuss lab surveyor workload.

Ms. Sarah Harvey, Director of Health Care Facilities, presented information to the Board regarding the upcoming merger between Health Care Facilities (HCF) and Health Services and Development Agency (HSDA) to form the Health Facilities Commission (HFC). An interagency agreement will be in place at the next Board meeting regarding the use of lab surveyors. HCF will present a proposal to the Board regarding their suggestions for addressing the survey backlog. After

discussion, the Board indicated they wanted a report each Board meeting from the CLIA Manager regarding the lab surveyor workload and backlog. The Board also requested a crosswalk from the CLIA Manager that listed the laboratories that did not have any surveyor visit from both CLIA and State licensure.

The option of performing remote self-audit state licensure surveys was discussed. The Board decided to table the final decision on remote surveys pending a legal interpretation.

Motion: Ms. Gidcomb
Second: Ms. Briggs

The motion was approved.

Discuss tests that can be performed by Blood Donor Center per 1200-06-03-.15.

Lifeline Blood Services

Nikki Watlington, MT(ASCP), Director of Quality and Regulatory Services with Lifeline Blood Services, requested clarification from the Board if donor white blood cell counts and donor platelet counts could be performed as donor suitability testing by blood donor centers per the regulations. The facility is using the waived Sysmex XW-100 instrument. After discussion, the Board decided the facility only needed to submit a Waived Testing Notification form for the waived tests.

No motion was needed.

Discuss the types of degrees required for licensure under 1200-06-01-.22.

After discussion, the Board provided clarification that the bachelor's degree referred to in regulation 1200-06-01-.22 can be in any subject area and was not limited to chemical, physical, or biological science degrees.

No motion was needed.

Discuss the use of the state-issued laboratory personnel license as a primary source verification document.

CMS asked if the Medical Laboratory Board would consider adding additional educational information to the personnel license so it could serve as a primary source verification (PSV) document for CMS.

After discussion, the Board requested that Sandra Bogard, the Board Director contact CMS and verify if the highest level of degree awarded and the subject area of that degree on the state license would that be sufficient to serve as a PSV document for them.

No motion was needed.

Discuss Individualized Quality Control Plan (IQCP) process in state-licensed labs.

The Board discussed the use of Individualized Quality Control Plans (IQCP) and decided it was an acceptable process and would be recognized in state-licensed laboratories.

Motion: Dr. Hardison

Second: Mr. Barker

The motion was approved.

Discuss Stem Cell Labs and when they require state licensure.

Dr. Vincent LaRussa with the University of Tennessee Medical Center in Knoxville requested clarification from the Board if their Cell Therapy Laboratory would need to obtain a state license. After discussion, the Board decided that even though the lab is using the results to produce a product, the results are also being used for patient healthcare decisions because they are included in the patient's lab report. Based on this information, the lab does need to be state-licensed.

University of Tennessee Medical Center- Knoxville

Motion: Ms. Gidcomb

Second: Mr. Stanton

Abstain: Dr. Vaughan

The motion was approved with the chairman voting.

Discuss the health screening notification process and oversight for the HIV/STI/Viral Hepatitis Section and their Partners.

Dr. Pamela Talley, Medical Director HIV/STI/Viral Hepatitis, Mr. Eric Leue, VP of Prevention and Clinical Services-Friends for Life Corporation, Mr. Cory Howard, COO-Cempa Community Care, and Shamia Roberts, BSN, RN-Viral Hepatitis Prevention and Clinical Coordinator presented to the Board a request for clarification regarding the health screening notification process and oversight. After discussion, the Board decided to grant the Section of HIV/STI/Viral Hepatitis and their partners an exemption to report waived health screening tests performed in the community setting by the Section or its designees quarterly to the Board's Administrative Office.

Motion: Dr. Hardison

Second: Dr. Vaughan

The motion was approved.

Discuss continuous glucose monitoring and regulatory oversight.

The Board discussed continuous glucose monitoring devices and decided they did not fall under the Board's preview. The use of these devices is a hospital policy issue.

Discuss the reading of microbiology plates remotely.

No motion was needed.

The Board was asked for guidance regarding the following question:
If a laboratory uses a microbiology system that images its microbiology plates, can the plates be read from a remote location?

After discussion, the Board decided that the remote reading location does not need a state license provided the central laboratory location is licensed. This is based on the decision from the Board's Remote Work Task Force.

No motion was needed.

Discuss Inpatient Rehab Hospital Testing and Licensure Requirements.

Baptist Memorial Rehabilitation Hospital-Germantown

Latina Hoy, BS, RRT, Director of Quality Management, and Chris Bareolus, CEO of Baptist Memorial Rehabilitation Hospital in Germantown, requested clarification from the Board regarding if their facility needed to be a state-licensed laboratory. After discussion, the Board decided that based on the non-waived Troponin testing being performed at the facility, it would need to obtain a state laboratory license.

Motion: Ms. Gidcomb
Second: Mr. Stanton

The motion was approved.

Review And Discuss The Licensure Of Medical Laboratory Directors:

1. Binu Porath, Ph.D.
Nashville, TN 37211
Director of Cytogenetics & Molecular Diagnostics

Dr. Porath received her B.S. degree in Zoology at the Union Christian College in Kerala, India, in 2000.

She received her M.S. degree in Biological Sciences at the University of Houston Clear Lake in Houston, TX, in 2006.

Dr. Porath received her Ph.D. in Cell Biology and Anatomy from the University of Kansas Medical Center in Kansas City, KS, in 2011.

She is certified by the American Board of Medical Genetics and Genomics (ABMGG) in Laboratory Genetics and Genomics through Dec. 31, 2022.

She received her ABMGG fellowship training at the Children's Mercy Hospital in Kansas City, KS, from 2017-2020.

Dr. Porath is seeking licensure as a Director in Cytogenetics and Molecular Diagnostics.

Motion: Dr. Hardison
Second: Ms. Briggs

The license was approved.

2. Patrick Blackburn, Ph.D.
Hernando, MS 38632
Director of Cytogenetics & Molecular Diagnostics

Dr. Blackburn received his B.S. degree in Biochemistry and Molecular Biology from the University of Florida in Gainesville, FL, in 2002.

He received his Ph.D. in Clinical and Translational Science from Mayo Clinic Graduate School in Rochester, MN, in 2015.

Dr. Blackburn is certified by the American Board of Medical Genetics and Genomics (ABMGG) in Laboratory Genetics and Genomics through Dec. 31, 2022.

He received his ABMGG fellowship training at the Mayo Clinic School of Graduate Medical Education in Rochester, MN, in 2017-2020.

Dr. Blackburn is seeking licensure as a Director of Cytogenetics and Molecular Diagnostics.

Motion: Mr. Stanton
Second: Mr. Barker

The license was approved.

3. Rebecca Smith, Ph.D.
Hendersonville, TN 37075
Director of Cytogenetics & Molecular Diagnostics

Dr. Smith received her B.S. degree in Biology at the University of Chattanooga, Chattanooga, TN, in 2001.

She received her Ph.D. in Genetics from the University of Alabama Birmingham in Birmingham, AL, in 2009.

Dr. Smith is certified by the American Board of Medical Genetics and Genomics (ABMGG) in Laboratory Genetics and Genomics through Dec. 31, 2022.

She received her ABMGG fellowship training at Vanderbilt University Medical Center in Nashville, TN, from 2018-2020.

Dr. Smith is seeking licensure as a Director of Cytogenetics and Molecular Diagnostics.

Motion: Ms. Briggs.
Second: Ms. Gidcomb
Abstain: Dr. Hardison

The license was approved with the Chairman voting.

4. Aletta Esterhuizen, Ph.D.
Jackson, MS 30211
Director of Andrology

Dr. Esterhuizen received her B.S. degree in Plant Physiology at the University of Pretoria in Pretoria, South Africa, in 1983.

She received her M.S. degree in Plant Physiology at the University of Pretoria in Pretoria, South Africa, in 1987.

Dr. Esterhuizen received her Ph.D. in Obstetrics and Gynecology from the University of Stellenbosch in Stellenbosch, South Africa, in 2000.

She is certified by the American Board of Bioanalysis (ABB) as an HCLD in Andrology and Embryology through Dec. 31, 2022.

She received her training in Reproductive Services at Drs. Buisson and Partners, Ampath in Pretoria, South Africa from 1996-2000.

Dr. Esterhuizen is seeking licensure as a Director of Andrology.

Motion: Dr. Vaughan
Second: Ms. Briggs

The license was approved.

5. Stephanie Carnes, Ph.D.
Lakeland, TN 38002
Director-Microbiology

Dr. Carnes received her B.S. degree in Biology from Indiana University in Bloomington, IN, in 2013.

She received her Ph.D. in Microbiology and Immunology from Vanderbilt University Medical Center in Nashville, TN, in 2019.

Dr. Carnes is certified by the American Board of Medical Microbiology (ABMM) through Dec. 31, 2024.

She received her American Society for Microbiology fellowship training in Medical and Public Health Laboratory Microbiology at the University of Washington in Seattle, WA, in 2019-2021.

Dr. Carnes is seeking licensure as a Director of Microbiology.

Motion: Mr. Barker
Second: Mr. Stanton

The license was approved.

6. Theresa Brown, Ph.D.
New Orleans, LA 70131
Director-Clinical Cytogenetics &
Molecular Genetics

Dr. Brown received her B.S. degree in Genetic Biology from Purdue University in West Lafayette, IN, in 1990.

She received her Ph.D. in Medical Genetics from the University of Alabama Birmingham in Birmingham, AL, in 1997.

Dr. Brown is certified by the American Board of Medical Genetics and Genomics (ABMGG) through Dec. 31, 2025.

She received her post-doctoral fellowship training in Clinical Cytogenetics at NIH/Georgetown University in Metro Washington, DC, in 1998-2000.

Dr. Brown is seeking licensure as a Director of Cytogenetics and Molecular Genetics.

Motion: Ms. Briggs
Second: Ms. Gidcomb

The license was approved.

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 2021 and the First Quarter of 2022.

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

Staffing updates:

- Newly hired Regulatory Board Administrative Assistant 2 – Mr. Mina Girgis.

- Middle Tennessee surveyor positions remain vacant.

Board meeting dates for 2022 and 2023 were presented.

One (1) New Board Member:

- Mr. Chris Litle-Laboratory Supervisor position.

One (1) Vacancy on the Board:

- Non-Pathologist Physician

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: Mr. Barker.

Second: Ms. Briggs

The report was accepted as given.

Board Attorney Report

Mark Cole

Senior Associate General Counsel

Counsel Mark Cole gave his report for the Fourth Quarter of 2021:

- 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 were filed with the Secretary of State's Office.

Counsel Mark Cole gave his report for the First Quarter of 2022:

- The Conflict-of-Interest Policy was reviewed with the Board members.
- Two (2) open cases and one (1) respondent are currently in the Office of General Counsel.
- New personnel and training program rules became effective on April 13, 2022.

Motion to accept the Office of General Counsel Reports as given: Mr. Barker.

Second: Mr. Litle

The reports were accepted as given.

Waived Testing Policy Statement was revised based on Board recommendations at the October 28, 2021, meeting.

Mr. Barker made a motion to accept the revised Waived Testing Policy statement.

Second: Ms. Gidcomb

The policy statement was approved.

Regional Surveyor Reports:

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

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

East Tennessee Regional Office –Fourth Quarter 2021:

Complaint Investigations: Two (2)-pending

Unsuccessful Proficiency Testing: Zero (0)

ETRO Report: 1st Quarter

East Tennessee Regional Office –First Quarter 2022:

Complaint Investigations: Two (2)-substantiated & closed

Unsuccessful Proficiency Testing: Zero (0)

MTRO Report: 4th Quarter

Middle Tennessee Regional Office–Fourth Quarter 2021:

No report given.

MTRO Report: 1st Quarter
Fowlen Anders, MT
Consultant/Surveyor

Middle Tennessee Regional Office—First Quarter 2022:

Unsuccessful Proficiency Testing: One (1)

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

Reports were accepted as given.

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

West Tennessee Regional Office –Fourth Quarter 2021:

Complaint Investigations: Two (2)

- One substantiated
- One unsubstantiated

Unsuccessful Proficiency Testing: Two (2)

- 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)

WTRO Report: 1st Quarter

West Tennessee Regional Office –First Quarter 2022:

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: Ms. Gidcomb.
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:

1. **Blood Assurance, Inc. Clarksville
Donor Center**

Specialties: Hemoglobin

1767 Wilma Rudolph Blvd.
Clarksville, TN 37040

Laboratory Director: Elizabeth Culler, MD
Clinical Pathology

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Dr. Vaughan
Second: Mr. Stanton

The license was approved.

- 2. Blood Assurance, Inc.-Franklin Donor Center, LLC**
600-A Frazier Drive, Suite 110
Franklin, TN 37067

Specialties: Hemoglobin

Laboratory Director: Theodore Kieffer, MD
Clinical Pathology
Blood Banking/Transfusion Medicine

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Ms. Briggs
Second: Ms. Gidcomb

The license was approved.

- 3. LabCorp at Walgreens Bartlett**
5950 Stage Road
Bartlett, TN 38143

Specialties: Collection Station

Laboratory Director: Pamela Osborne, MD
Clinical & Anatomic Pathology

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Mr. Barker
Second: Mr. Litle

The license was approved.

- 4. North Shore Medical Laboratories, Inc.**
401 Market Street
Chattanooga, TN 37402

Specialties: Collection Station

Laboratory Director: Marcelo Venegas-Pizarro, MD
Internal Medicine

Surveyor: Fowlen Anders, MT Consultant II/ETRO
Lori Reynolds, MT Consultant I/ETRO

Motion: Mr. Stanton
Second: Dr. Vaughan

The license was approved.

- 5. Tennessee Fertility Laboratory-Downtown**
2201 Murphy Ave., Ste 401
Nashville, TN 37203
Surveyors: Debbie Haggard/Susan Massey

Specialties: Andrology

Laboratory Director: Greg L. Christensen, PhD, ABB
ABB Andrology & Embryology

Surveyor: Debbie Haggard, MT Consultant II/WTRO
Susan Massey, MT Consultant I/MTRO

Motion: Ms. Briggs
Second: Mr. Litle

The license was approved.

- 6. MDx Laboratories**
357 Riverside Dr., Suite 106
Franklin, TN 37064

Specialties: Molecular Diagnostics

Laboratory Director: Pamela Osborne, MD
Clinical & Anatomic Pathology

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Mr. Barker
Second: Mr. Stanton

The license was approved.

- 7. Blood Assurance, Inc. – Hermitage Donor Center**
4686 Lebanon Pike
Hermitage, TN 37076

Specialties: Hemoglobin

Laboratory Director: Theodore Kieffer, MD
Clinical Pathology
Blood Banking/Transfusion Medicine

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Mr. Stanton
Second: Mr. Barker

The license was approved.

- 8. Biomat USA, Inc.**
526 S. Willow Avenue
Cookeville, TN 38501

Specialties: Total Protein
Spun Hematocrit

Laboratory Director: Keith Hill, MD

Surveyor: Fowlen Anders, MT Consultant II/ETRO

Motion: Ms. Briggs.
Second: Ms. Gidcomb

The license was approved.

9. Blood Assurance, Inc. – Bellevue Donor Center

7112 Highway 70 S, Suite D1
Nashville, TN 37221

Specialties: Hemoglobin

Laboratory Director: Theodore Kieffer, MD
Clinical Pathology
Blood Banking/Transfusion Medicine

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Mr. Barker.

Second: Mr. Litle

The license was approved.

10. Pathology Laboratories West, PLLC dba Parkwest Med Ctr Dept Anatomic Pathology

9352 Park West Boulevard
Knoxville, TN 37923

Specialties: Histopathology
Cytopathology (non-GYN)
Cytogenetics
Immunohistochemistry

Laboratory Director: Brandon E. Smithey, MD
Clinical & Anatomic Pathology

Surveyor: Fowlen Anders, MT Consultant II/ETRO

Motion: Ms. Briggs

Second: Mr. Litle

The license was approved.

Other Business/Discussion:

Adjournment:

With no further business to discuss, the meeting was adjourned at 4:02 pm CDT.

Motion to adjourn: Dr. Vaughan.

Second: Mr. Barker

The meeting was adjourned.