

**Tennessee Medical Laboratory Board**  
**July 19, 2023**  
**Full Board Meeting**  
**Minutes**

**Meeting Date:** July 19, 2023

**Time:** 8:15 a.m. 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:**

Jennifer Gidcomb, MT-Med. Technologist, Gen.-Chairman  
Penny Asbell, MD- Non-Pathologist Physician  
Jerry Barker, MT-Hospital Lab Mgr/Admin. Dir.  
Danielle Gibson, MD-Pathologist  
Marilyn (Buffy) Key, MT-Hospital Administrator  
Chris Litle, MT-Medical Laboratory Supervisor  
James A. Vaughan, MD-Pathologist Educator

**Vacant Positions:** Citizen Representative  
Pathologist

**Members Absent:** LeeAnne Briggs, MT- Med. Technologist, Educator  
Matthew Hardison, Ph.D., Independent Lab Mgr/Adm.  
Michael Johnson, MT-Medical Technologist-General  
Andrew Stanton, CT-Cytotechnologist

**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  
Lori Reynolds, MT Consultant/Surveyor ETRO

**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 8:15 a.m. CDT by Jennifer Gidcomb, the Board Chairman.

**Presiding Officer:**

Ms. Gidcomb conducted the meeting.

**Approve Minutes:**

**P & E Committee Meeting**

A motion to approve the April 27, 2023, Personnel & Education Committee minutes was made by Mr. Barker.  
Second: Mr. Litle

The minutes were approved with the chairman voting.

**Full Board Meeting**

A motion to approve the April 28, 2023, 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:**

Ms. Gidcomb reported the actions of the Personnel & Education Committee meeting, July 18, 2023.

Motion to ratify Committee actions: Dr. Vaughan.  
Second: Mr. Barker

The report was accepted as presented by Ms. Gidcomb, with the chairman voting.

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

1. Lab Plus, LLC  
Nashville, TN  
Consent Order

Lab Plus, LLC, Medical Laboratory, facility license was put on probation for one year under a consent order. Lab Plus, LLC was directed to:

- Self-report all Cytology laboratory practice-related complaints associated with the deficiencies outlined herein, within fifteen (15) days during the probationary period.
- Self-report all Cytology lab supervisory issues, specifically violations of Tenn. Comp. R & Regs. 1200-06-03-.21(2)(a)(2), within fifteen (15) days during the probationary period.

- Ensure that all laboratory personnel are appropriately licensed.
- Comply with all applicable statutes, rules, and regulations of the Medical Laboratory Board.
- Appear before the Board at its next scheduled meeting to give a report demonstrating compliance with all applicable statutes, rules, and regulations of the Board.
- Comply with all applicable statutes, rules, and regulations of CLIA.

Failure to comply with any of the terms of this Order shall constitute a violation of a Board order and may subject the laboratory to additional disciplinary and/or legal action.

Motion: Dr. Vaughan  
Second: Mr. Litle

The motion was approved with the chairman voting.

2. Pamela Joiner  
Knoxville, TN  
Medical Laboratory Supervisor-General  
Consent Order

Ms. Pamela Joiner's Medical Laboratory Supervisor-General license was suspended under a consent order. Ms. Joiner was directed to undergo an evaluation by the Tennessee Professional Assistance Program (TNPAP). Based on the recommendation of TNPAP, she may receive a TNPAP monitoring agreement. In conjunction with the monitoring agreement, her license will stay on probation for no less than three years. If TNPAP does not recommend a monitoring agreement, Ms. Joiner's license will remain on probation for a period of three years. At the completion of the probation, her license will be returned to an unencumbered status.

Motion: Mr. Litle  
Second: Mr. Baker

The motion was approved with the chairman voting.

#### **Presentations to the Board:**

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

The statistical report for July 1, 2022-June 30, 2023, was presented by Ms. Teresa Phillips, Executive Director.

Zero (0) individuals were monitored during this period, with two (2) referrals for substance abuse.

Motion to accept the TNPAP report: Dr. Gibson.  
Second: Mr. Litle

**Investigations Report**

Barbara Granum  
Disciplinary Intake Coordinator

The report was accepted as given with the chairman voting.

Ms. Granum's investigative report included the following:

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

Investigative Licensed Laboratory Personnel: (2023)

Zero (0) new complaints

Zero (0) complaints closed

Zero (0) currently open complaints

Investigative Licensed Laboratory Facilities: (2023)

Zero (0) new complaints

One (1) closed complaints

Six (6) currently open complaints

Investigative Licensed Laboratory Schools: (2023)

Zero (0) new complaints

Zero (0) complaints closed

Zero (0) currently open complaints

Motion to accept the report: Dr. Vaughan.

Second: Mr. Barker

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

**Financial Report**

Keeyona Love, MPS  
Fiscal Manager

No report was given.

**Legislative Update**

Grayson Carter  
Legislative Liaison

Grayson Carter, the Legislative Liaison, presented the following legislative update:

**Noteworthy Health-Related Legislation**

- The Department of Health's administration bill successfully extended current opioid prescription protections that were put into place in 2018 under the Tennessee Together Act.
- The Department of Health was extended to June 30, 2027, following an audit and subsequent sunset hearings.
- Multiple boards administratively attached to the

Department of Health were extended by the legislature following audits and subsequent sunset hearings.

**Non-Health Related Legislative Activity of Note**

- June 19th is now designated as a state holiday for Juneteenth.
- State employees are authorized to use sick leave from a sick leave bank to care for a sick minor child of the employee.
- State employees must be provided six paid weeks of leave for the birth of the employee's child or because of the employee's adoption of a child.
- "Send Me" is now an additional state motto.
- The legislature passed an extensive transportation modernization act.
- The legislature passed a teacher paycheck protection act that, among other things, raises the minimum teacher salary to \$50,000 by 2026.
- Law enforcement officers and the district attorney general's office may extend criminal immunity to persons who are experiencing a drug overdose and who are seeking medical assistance.

**Pertinent Public Chapters:**

**Public Chapter No. 1—SB1/HB1—Johnson/Lamberth**

This law prohibits a healthcare provider from knowingly performing or offering to perform on a minor, or administer or offer to administer to a minor, a medical procedure if the performance or administration of the procedure is for the purpose of enabling a minor to identify with or live as an identity inconsistent with the minor's sex. This bill does not prohibit such medical procedure if the performance or administration is to treat a minor's congenital defect, precocious puberty, disease, or physical injury or the medical procedure began prior to the effective date of this act and concludes on or before March 31, 2024. This law also prohibits a person from knowingly providing a hormone or puberty blocker by any means to a minor if the provision of the hormone or puberty blocker is not in compliance with this bill. This bill is effective on July 1, 2023.

**Public Chapter No. 2—SB3/HB9—Johnson/Todd**

This law creates a Class A misdemeanor offense for a person to perform adult cabaret entertainment on public property or in a location where the adult cabaret

entertainment could be viewed by a person who is not an adult. Subsequent offenses are Class E felonies. This bill was effective on April 1, 2023.

**Public Chapter No. 24—SB248/HB66—  
Johnson/Lamberth**

This law authorized the Department of Intellectual and Development Disabilities to provide home health services to outpatients through its administration of the Tennessee Early Intervention System and the home and community-based services provided through such system. This bill was effective on March 10, 2023.

**Public Chapter No. 36—SB23/HB17—Massey/Faison**

This law designates the month of May as “Silver Alert Awareness Month.” This bill was effective on March 14, 2023.

**Public Chapter No. 41—SB256/HB75—  
Johnson/Lamberth**

This law allows law enforcement or the district attorney general’s office to extend criminal immunity from being arrested, charged, or prosecuted to persons who are experiencing a subsequent drug overdose. This bill takes effect on July 1, 2023.

**Public Chapter No.114—SB255/HB74—  
Johnson/Lamberth**

This law changes the terms "general education development credential," "high school equivalency test," and variations of the terms to "high school equivalency credential" as referenced throughout the code. This law also replaces any references in code from GED(R) or HiSET(R) classes, coursework, testing, or services with the phrase “adult education programming to include preparation and testing toward obtaining a high school equivalency credential” throughout the code. This law is effective on July 1, 2023.

**Public Chapter No.156—SB40/HB206—Roberts/Ragan**

This law extends the Department of Health to June 30, 2027. This law was effective on April 17, 2023.

**Public Chapter No.157—SB86HB734—Walley/Rudd**

This law clarifies that a person requesting public records is not entitled to special or expedited access to those records based on their occupation or association with a profession. This law was effective on April 17, 2023.

**Public Chapter No. 168—SB600/HB90—  
Hensley/Moody**

This law prohibits counties, municipalities, and metropolitan governments from expending funds for the purpose of assisting a person in obtaining a criminal abortion. This prohibition includes using funds as part of a health benefit plan or for travel to another state for the purpose of obtaining an abortion. This law was effective on April 17, 2023.

**Public Chapter No. 188—SB277/HB325—  
Johnson/Lamberth**

This law extends legislation enacted in 2018 to preserve opioid prescription limitations for acute care. In addition, this law exempts individuals who had recent cancer treatment from this prescription limitation. “Recent cancer treatment” is defined as six months following the end of an active cancer treatment. This law creates an exception for informed consent where a healthcare practitioner who issued the initial prescription does not have to obtain and document informed consent, if the subsequent prescription is for the same opioid and for the same episode of treatment. Outside of this exception, informed consent must be updated periodically. This law also requires the Commissioner of the Department of Health to provide a letter, in consultation with the health-related boards, no to certain elected officials that includes information on the impact and the effects of this legislation in each even-numbered year. This law was effective on April 24, 2023.

**Public Chapter 190—SB350/HB294—  
Campbell/Freeman**

This law creates the “Save Tennessee Students Act” and requires public institutions of higher education to include, among other thing, the telephone number of the suicide and crisis lifeline on student identification cards for students enrolled in the institution. This law takes effect July 1, 2023.

**Public Chapter No. 203—SB799/HB859—  
Yarbro/Jernigan**

This law authorizes the Department of Health to disclose de-identified data that is collected from EMS run reports for the purpose of providing opioid overdose response and resources throughout this state. This law was effective on April 24, 2023.

**Public Chapter No. 216—SB276/HB324—  
Johnson/Lamberth**

This law makes various changes to current law pertaining to leave for state employees. Among other things, this law allows an eligible employee to be granted absence from work with pay for a period of time equal to six workweeks because of the birth of the employee's child or because of the placement of a child with the employee for adoption. This law is effective on July 1, 2023, and applies to eligible employees who qualify for leave on or after July 1, 2023.

**Public Chapter 246—SB1294/HB1309—Kumar/Bailey**

This law prohibits a life insurance provider from canceling a life insurance policy based on genetic information, from requesting or requiring genetic testing as a condition of insurability, and from accessing the genetic data of an individual without consent. This law is ultimately effective on January 1, 2024.

**Public Chapter No. 252—SB221/HB273—Roberts/Terry**

This law requires the division of health-related boards to consult with the Board of Medical Examiners in the hiring of a medical consultant. This law also gives the medical consultant authority to consult on various issues and to work with the board's attorney on certain portions of the complaint and settlement process. Additionally, the division must provide biannual surveys to the Board for its feedback and review of the consultant. This law authorizes the Board to promulgate rules to effectuate this process. This law was effective on April 28, 2023.

**Public Chapter No. 265—SB669/HB0981—  
Reeves/Faison**

This law vacates and reconstitutes the Tennessee Emergency Medical Services Board, as of July 1, 2023. This law staggers the initial terms of appointment so that a portion of new members must be appointed in each year for the next four years. Members serving on the Board as of June 30, 2023, may be reappointed to the new Board. After the initial round of appointments, the terms of appointment expand to four years. Additionally, this law also makes various changes to the qualifications for candidates being considered as an appointment for the Board. For purposes of promulgating rules and carrying out administrative duties, this law was effective on April 28, 2023. For all other purposes, this law takes effect on June 30, 2023.



**Public Chapter No. 300—SB551/HB448—Lowe/Davis**

This law requires governmental entities to provide a period of public comment for public meetings but authorizes the governmental entities to place reasonable restrictions on the period for public comment. This does not apply to a meeting of a governing body, or a portion thereof, where the governing body is conducting a disciplinary hearing or a meeting for which there are no actionable items on the agenda. This takes effect July 1, 2023.

**Public Chapter 313—SB745/HB883—Helton-Haynes/Briggs**

This law specifies that terminating an ectopic or molar pregnancy does not constitute a criminal abortion. This law removes the current affirmative defense in law and instead provides that it is not an offense of criminal abortion if the abortion is performed or attempted by a licensed physician in a licensed hospital or ambulatory surgical treatment center and certain conditions are met. This law also requires the Department of Health to collect reports submitted under this law and report quarterly the number of abortions performed in this state to certain individuals in the executive and legislative branches no later than January 1, April 1, July 1, and October 1 of each year. This law is effective April 28, 2023.

**Public Chapter No. 316—SB1426/HB1004—Roberts/Darby**

This law requires an appointed member of a governing body for a state entity to serve in such capacity until the member's successor is duly appointed and qualified. Under this, an appointed member of a board, commission, or other governing body for a state governmental entity may be removed by the member's appointing authority with or without cause. A vacancy created by the removal of a member must be filled by the appointing authority in the same manner as the original appointment. This law also creates an advisory council on state procurement. This law was effective on April 28, 2023.

**Public Chapter No. 325—SB1191/HB1388—Bailey/Ragan**

This law terminates the Radiologic Imaging and Radiation Therapy Board of Examiners with no wind down period. This law authorizes the Board of Medical

Examiners to establish and issue limited and full X-ray certifications. This law was effective on April 28, 2023.

**Public Chapter No. 337—SB269/HB317—  
Johnson/Lamberth**

This law designates June 19th as a new official state holiday for Juneteenth. This law was effective on May 5, 2023, and applies to June 19, 2023.

**Public Chapter No. 379—SB0365/HB0355—  
Massey/Alexander**

This law requires that a health benefit plan that provides coverage for a screening mammogram must provide coverage for diagnostic imaging and supplemental breast screening without imposing a cost-sharing requirement on the patient. This law is effective 90 days after May 11, 2023.

**Public Chapter 386—SB193/HB702—Lundberg/Doggett**

This law adds fentanyl, carfentanil, remifentanil, alfentanil, and thiafentanil to what constitutes a qualifying controlled substance for purposes of certain felony offenses. This law is on July 1, 2023, and applies to offenses after that date.

**Public Chapter No. 412—SB1398/HB1242—  
Reeves/Powers**

This law makes it a Class A misdemeanor to knowingly possess xylazine and makes it a Class C felony to knowingly manufacture, deliver, or sell xylazine, or to knowingly possess xylazine with intent to manufacture, deliver, or sell xylazine. This law exempts veterinarians. This law is effective July 1, 2023.

**Public Chapter No. 423—SB0378/HB0403—  
Briggs/Lamberth**

This law creates the regulation of the production and sale of hemp-derived cannabinoids, including products known as delta-8 and delta-10 under the Department of Agriculture and the Department of Revenue. The sections of this law have varying effective dates, but this law is ultimately effective July 1, 2024.

**Public Chapter No. 426—SB0458/HB0496—  
Watson/Martin**

This law requires certain health related boards to either render a decision on the application or inform the applicant of the need to appear before such board within 60 days from the date the respective board

receives a completed application for licensure from either an initial applicant or an applicant who is licensed in another state or territory of the United States or in the District of Columbia. This law was effective on May 11, 2023, and applies to applications submitted on or after that date.

**Public Chapter No. 431—SB698/HB1358—  
Crowe/Farmer**

This law directs the Department of Health to officially request the United States Department of Health and Human Services to add newborn screening for metachromatic leukodystrophy to the recommended uniform screening panel. This law took effect on May 11, 2023.

**Public Chapter No. 443—SB296/HB779—  
Gardenhire/Helton-Haynes**

This law requires the Board of Medical Examiners, the Board of Osteopathic Examination, the Board of Nursing, the Board of Physician Assistants, and the Alcohol and Drug Abuse Counselors Board to, upon the receipt of a completed application for licensure from an applicant who is licensed in another state or territory of the United States or in the District of Columbia, render a decision on the application or inform the applicant of the need to appear before the board within 45 days from the date the board receives the application. This law requires the Board of Athletic Trainers to, upon the receipt of a completed application for licensure from an applicant who is licensed in another state or territory of the United States or in the District of Columbia, render a decision on the application or inform the applicant of the need to appear before the board within 60 days from the date the board receives the application. "Completed application" means an application that satisfies all statutory and board rule requirements. This law takes effect May 17, 2023.

**Public Chapter No. 446—SB361/HB942—  
Massey/Alexander**

This law creates the dentist and dental hygienist compact. The compact details licensure requirements and other provisions related to the practice of dentists and dental hygienists who participate in the compact. While this law has been enacted in Tennessee, it will not take effect until the date the seventh compact state enacts the same legislation. This legislation has been enacted in three states as of the date of this publication:

Tennessee, Washington, and Iowa. Four states have this legislation: Texas, Kansas, Minnesota, and Ohio. Public Chapter No. 457—SB753/HB1317—Haile/Kumar This law changes the composition and number of members of the Board of Pharmacy by adding two members to the Board and adding a residency requirement of no less than five years for pharmacist members of the board. This law authorizes the Board of Pharmacy to issue advisory opinions. This law also specifies that the current board members must serve on July 1, 2023, through the end of the members' existing terms. This law was effective May 17, 2023.

**Public Chapter No. 469—SB469/HB1484—  
Lundberg/Hulseay**

This law authorizes county jails to utilize federal or state funds, if available, for the payment of medication for HIV positive patients. Additionally, this law authorizes the Department of Health to pay for HIV medication for inmates subject to availability of federal or state funds. This law was effective on May 17, 2020.

**Public Chapter No. 477—SB1111/HB1380—  
Bowling/Ragan**

This law creates the "Mature Minor Doctrine Clarification Act." This act prohibits a healthcare provider from providing a vaccination to a minor unless the healthcare provider first receives informed consent from a parent or legal guardian of the minor. The healthcare provider must document receipt of and include in the minor's medical record proof of prior parental or guardian informed consent. This law also requires written consent from a parent or legal guardian before providing a minor with a COVID-19 vaccine. Additionally, this law prohibits an employee or agent of the state to provide, request, or facilitate the vaccination of a minor child in state custody except when certain situations apply. This law was effective May 17, 2023.

**Public Chapter No. 484—SB1275/HB874—  
Briggs/Lafferty**

The law prohibits a health insurance issuer or a managed health insurance issuer from (1) denying a licensed medical laboratory the right to participate as a participating provider in a policy, contract, or plan on the same terms and conditions as offered to another medical laboratory under the same circumstances and (2) preventing a person who is a party to or beneficiary

of a policy, contract, or plan from selecting a licensed medical laboratory of a person's choice to furnish services under the contract, policy, or plan. This law becomes effective July 1, 2023.

**Public Chapter No. 486—SB1440/HB239—  
Roberts/Bulso**

This law defines "sex" in code to mean a person's immutable biological sex as determined by anatomy and genetics existing at the time of birth and evidence of a person's biological sex. "Evidence of a person's biological sex" includes, but is not limited to, a government-issued identification document that accurately reflects a person's sex listed on the person's original birth certificate. This law takes effect on July 1, 2023.

Motion: Dr. Vaughan

Second: Dr. Gibson

The report was approved with the chairman voting.

Mr. McLemore presented a verbal report to the Board regarding the surveyor workload. One surveyor resigned, and he has started the interview process.

No motion was needed.

Surveyor Update  
Tracy McLemore, MT  
CLIA Director

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

- 1. Baroness Erlanger Hospital Laboratory**  
Chattanooga, TN  
Rita Stewart  
Laboratory Support Services Coordinator

The request was to permit Licensed Perfusionists to perform and report Hemostasis Monitoring in Cardiovascular Surgery utilizing the TEG 6s Analyzer.

Motion: Dr. Vaughan

Second: Dr. Gibson

The exemption request was approved with the chairman voting.

- 2. Saint Francis Hospital-Bartlett, Inc.**  
Bartlett, TN  
Veda Duncan, MSCLM, MT(ASCP)  
Administrative Laboratory Director

The first request was to permit Registered Nurses and Licensed Practical Nurses to perform and report Sodium, Potassium, Chloride, TCO<sub>2</sub>, ionized Calcium, Glucose, BUN, Creatinine, and Hematocrit hospital-wide utilizing the Abbott i-STAT instrument and methodology (Chem 8 cartridge).

Motion: Dr. Gibson

Second: Dr. Asbell

The exemption request was approved with the chairman voting.

The second request was to permit Registered Respiratory Therapists and Certified Respiratory Therapists to perform and report pH, pCO<sub>2</sub>, pO<sub>2</sub>, BE, HCO<sub>3</sub>, THB, O<sub>2</sub>HB, COHB, METHB, and Lactic Acid hospital-wide utilizing the Siemens RapidPoint 500e Blood Gas Analyzer.

Motion: Mr. Barker  
Second: Dr. Vaughan

The exemption request was approved with the chairman voting.

- 3. Fort Sanders Regional Medical Center**  
Knoxville, TN  
Kristi Parker, MT-Laboratory Manager  
Pattie Polakow-Manager Respiratory Therapy

The request was to permit Registered Respiratory Therapists (ABG endorsed) and Certified Respiratory Therapists (ABG endorsed) to perform and report Sodium, Potassium, Chloride, Lactic Acid, pH, pCO<sub>2</sub>, pO<sub>2</sub>, COHb%, MetHb%, sO<sub>2</sub>%, O<sub>2</sub>Hb%, Hemoglobin, ionized Calcium, and Glucose hospital-wide utilizing the Radiometer ABL90 Flex Blood Gas Analyzer.

Motion: Dr. Gibson  
Second: Ms. Key

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 was unable to act on this request because one Board member had to recuse herself, 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 October Board meeting.

**Theodore Tsaltas, MD**  
Chattanooga, TN

Theodore Tsaltas, MD requested to direct four (4) laboratories.

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

- CSL Plasma, Inc.-1501 Riverside Drive, Suite 110, Chattanooga, TN 37406 (L2161)-Mod. Complexity
- CSL Plasma, Inc.-2809 E. 50th Street, Chattanooga, TN 37407 (L21914)-Mod. Complexity
- CSL Plasma, Knoxville Center-1616 Grand Avenue, Knoxville, TN 37916 (L2190)-Mod. Complexity
- CSL Plasma, Inc. Murfreesboro-1628 S. Middle Tennessee Boulevard, Murfreesboro, TN 37130 (L4290)-NEW

Motion: Dr. Vaughan

Second: Mr. Litle

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

**Charles Bramlett, MD**  
Columbia, TN

Charles Bramlett, MD requested to direct six (6) laboratories.

The Board was unable to act on this request because one Board member had to recuse herself, 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 October Board meeting.

**Henning Gertz, MD**  
Nashville, TN

Henning Gertz, MD requested to direct five (5) laboratories.

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

- Associated Pathologists, LLC dba PathGroup (TriStar Hendersonville)-355 New Shackle Island Road, Hendersonville, TN 37075 (L4415)
- TriStar Hendersonville Medical Center-355 New Shackle Island Road, Hendersonville, TN 37075 (L2143)
- TriStar Portland ER Laboratory-105 Redbud Drive, Portland, TN 37148 (L4272)

- TriStar Skyline Medical Center-3441 Dickerson Pike, Nashville, TN 37207 (L2094)-NEW
- TriStar Skyline Medica Center Arterial Blood Gas Lab-3441 Dickerson Pike, Nashville, TN 37207 (L3332)-NEW

Motion: Dr. Gibson

Second: Dr. Asbell

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

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

Discuss if pulmonary departments need to request point-of-care exemptions when performing testing only inside the pulmonary department.

The Board discussed Respiratory Departments that perform arterial blood gas (ABG) testing and the need for an exemption request. After discussion, the Board determined that all respiratory departments that perform ABG testing, regardless of whether the testing is performed in the respiratory department or at the patient's bedside, must apply for a Point-of-Care testing (POCT) exemption under 1200-06-03-.16.

If the Respiratory Department already has an approved exemption for ABG testing or is state-licensed as an ABG Lab, no action is needed.

If not, they must submit a POCT exemption request for Board Director review and interim approval, followed by review and ratification by the Board.

The Board's Administrative Office will send a letter to all Respiratory Departments that perform ABG testing by the end of 2023, notifying them they must have a POCT exemption request on file for all ABG testing. The labs will be given until the end of 2024 to comply with this request. The lab surveyors will not cite this deficiency during this timeframe, only educate the labs.

Motion: Mr. Litle

Second: Dr. Gibson

The request was approved with the chairman voting.

Discuss CLIA Post-Public Health Emergency Guidelines regarding remote work.

The Centers for Medicare and Medicaid Services (CMS) Post-Public Health Emergency Guidelines were reviewed by the Board.



The Board determined that the CMS policy differs from the Board's Remote Work Policy in the following two areas:

1. CMS limits remote work to the review of digital slides only, not physical slides.
2. CMS requires the physical location of where the slides are read to be printed on the final patient report so it is traceable.

No motion was taken, only discussion.

Discuss the Board Policy Statement on Remote Work and possible revisions to 1200-06-03 Rules Governing Medical Laboratories.

After discussing the Centers for Medicare and Medicare Services (CMS) Post-Public Health Emergency Guidelines, the board decided to revise its Remote work Policy to indicate, "The specific location where the digital slides are read must be traceable."

If a laboratory does not meet the Remote Work Policy, it must obtain a laboratory license.

Motion: Mr. Litle  
Second: Dr. Gibson

The motion was approved with the chairman voting.

Discuss if mobile PET/CT Imaging glucose testing needs a state mobile lab license.

The Board discussed the PET/CT Imaging Units and the glucose testing they perform. Based on that discussion, the Board had some additional questions that included:

Alliance Healthcare Services

1. Are the glucose results recorded in a patient's chart?
2. What type of CLIA certificate do they have?
3. Do the mobile imaging units have a home base location?
4. What are the decision-making criteria the glucose test results are used for?

After discussion, the Board decided to table the discussion until the October Board meeting when they receive additional information.

Motion: Mr. Barker  
Second: Dr. Asbell

The motion was approved with the chairman voting.

Discuss if a collection station needs a laboratory license if cytotechnologists read slides onsite.

The Board discussed collection stations that have cytotechnologists reading glass slides on the premises. After the discussion, the Board decided that if a collection station has cytotechnologists onsite reading

Laboratory Corporation of America

glass slides, they are required to obtain a state laboratory license.

Motion: Dr. Gibson  
Second: Mr. Litle

The motion was approved with the chairman voting.

Discuss if collection stations can use one hub location instead of licensing numerous sites.

The Board discussed collection stations that use the hub model where one collection station is state-licensed, and the other draw stations send their samples to that location.

The Board took a roll call vote if they wanted to discuss this issue further.

The vote was:  
Ms. Gidcomb: No  
Dr. Vaughan: Yes  
Mr. Litle: No  
Mr. Barker: Yes  
Ms. Key: Yes  
Dr. Asbell: Yes  
Dr. Gibson: Yes

The majority vote was "Yes".

After further discussion, the Board decided that all collection stations in Tennessee, except those that receive patient-collected specimens, must have an individual license as a collection station. The hub model will not continue.

The Board's Administrative Office will send a letter to all state-licensed collection stations by the end of 2023 notifying them that all draw stations, except those that receive patient-collected specimens, must obtain an individual collection station license. The collection station must also self-report the name and address of all draw stations that submit samples to them. The collection stations will be given until the end of 2024 to comply with this request.

The lab surveyors will not cite this deficiency during this timeframe, only educate the collection stations.

Motion: Dr. Vaughan  
Second: Mr. Litle

Discuss the possibility of licensing out-of-state laboratories.

The motion was approved with the chairman voting.

The Board discussed the possibility of licensing out-of-state laboratories.

After the discussion, the Board took the following roll call vote:

Ms. Gidcomb: No

Dr. Vaughan: No

Mr. Litle: Yes

Mr. Barker: No

Ms. Key: No

Dr. Asbell: No

Dr. Gibson: Yes-optional licensure

The majority vote was “No”.

The decision was not to license out-of-state laboratories with the chairman voting.

Discuss red-line rule revisions of 1200-06-03 Rules Governing Medical Laboratories.

The red-line version of the laboratory facility regulations was discussed by the Board.

The following revisions were requested:

- Under 1200-06-03-02. revise by adding a laboratory facility verification fee of \$25.
- Under 1200-06-03-.08(1)(a)5. revise by adding “tissue for” before “biopsy”.

Motion: Dr. Vaughan

Second: Mr. Barker

The motion was approved with the chairman voting.

Discuss adding ABIM Pulmonology boarding to the Accepted Credentialing Agencies List for lab directors.

The Board discussed the American Board of Internal Medicine (ABIM) Pulmonary boarding.

After the discussion, the board decided that a physician with the ABIM Pulmonology boarding qualifies to direct an arterial blood gas laboratory.

Motion: Dr. Vaughan

Second: Dr. Gibson

The motion was approved with the chairman voting.

Discuss updating the American Board of Medical Genetics and Genomics boarding information on the Accepted Credentialing

After discussion, the Board decided to update the name of the credentialing agency American Board of Medical Genetics to its new name, American Board of Medical

Agencies List for lab directors.

Genetics and Genomics, on their approved director credentialing list.

They also decided to recognize the Laboratory Genetics and Genomics boarding as a route to qualify as a lab director of Clinical Cytogenetics and Molecular Diagnostics.

Motion: Dr. Gibson

Second: Mr. Litle

The motion was approved with the chairman voting.

Discuss if clinical work experience for a MLT(Technician) applicant seeking MT(Technologist) licensure will be recognized only after national certification at the MLT(Technician) level.

This topic was discussed when the red-line version of the Medical Laboratory Personnel was reviewed.

Discuss red-line rule revisions of 1200-06-01 Rules Governing Medical Laboratory Personnel

The red-line version of the laboratory personnel regulations was discussed by the Board.

The following revisions were requested:

- Under 1200-06-01-.20, revise (d) by adding “or Board certification by American Board of Internal Medicine (ABIM) in Pulmonary Disease” after “pulmonary function”.
- Under 1200-06-01-.22(1)(a)2.(ii) revise by adding change full-time clinical laboratory work experience from three (3) to two (2) years...subsequent to national certification at the technician level...”

Motion: Mr. Barker

Second: Dr. Vaughan

The motion was approved with the chairman voting.

Discuss red-line rule revisions of 1200-06-02 Rules Training Programs for Medical Laboratory Personnel

The red-line version of the training programs for medical laboratory personnel regulations was discussed by the Board.

No additional revisions were requested.

Motion: Dr. Vaughan

Second: Dr. Asbell

The motion was approved with the chairman voting.

**Review and Discuss the Licensure of Medical  
Laboratory Directors:**

1. Jeffrey McCormack, Ph.D  
Edmond, OK 73013  
Director- Molecular Diagnostics

Dr. McCormack received his Ph.D. in Microbiology and Immunology from the University of Oklahoma Health Sciences Center, Oklahoma City, OK in 1989.

He was certified by the American Board of Bioanalysis (ABB) HCLD Microbiology in 2008, expiring on 12/31/2023.

Dr. McCormack is an Affiliate of the American College of Histocompatibility & Immunogenetics (ACHI) 2021 (Diplomate, ABHI 1995).

He received his post-doctoral fellowship training at:

- Diagnostics Laboratory of Oklahoma (DLO) as a Director of the Transplant Immunology Laboratory from 2/2014 to present.
- Provectus Diagnostics Laboratory as a Director from 3/2015-present.
- University of Texas at Arlington (UTA) as a Director of North Texas Genome Center (NTGC) from 10/2019 to present.

Dr. McCormack is requesting an exemption to Rule 1200-06-01-.20(1)(c). He does not have certification in Molecular Diagnostics, but he has extensive work experience in the field. National certification is available through the American Board of Bioanalysis (ABB) and the American Board of Clinical Chemistry (ABCC).

He is seeking licensure as a Director of Molecular Diagnostics.

Motion: Dr. Vaughan  
Second: Dr. Gibson

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

**Reports/Requests:**

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

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

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

Staffing updates:

- Kim Shannon, Middle Tennessee laboratory surveyor, resigned.

Board meeting dates for 2023 and 2024 were presented.

New Board Members that have been appointed to the Board:

Non-Pathologist Physician-Penny Asbell, MD  
Hospital Administrator-Marilyn (Buffy) Key, MT

Vacancies on the Board:

- Pathologist
- 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.

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

West TN – 17 surveys

Middle TN – 12 surveys

East TN – 30 surveys

January-June 2023 (completed all survey types):

West TN – 30 surveys

Middle TN – 22 surveys

East TN – 34 surveys

On July 17, 2023, the Department of Health conducted a virtual board member training for all Health Related Boards.

The Board reviewed a new Laboratory Personnel Report Form to be used during the survey process. After review, the Board requested that a column be added for the MD lab director. Also, it was requested to expand the terms listed in the definition key.

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

Motion to approve the report as given: Dr. Vaughan.  
Second: Mr. Litle

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 Second Quarter of 2023:

- The Conflict-of-Interest Policy was reviewed with the Board members.
- Two (2) consent orders for Board review.
- OCG is assisting the Task Force in completing the review and rewrite of the Medical Laboratory Board Rules.

**Disciplinary Report**

Ronda Webb-Stewart  
Senior Associate General Counsel

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

- Six (6) licensees are being monitored.
- Two (2) with terms of reprimand.
- Four (4) with terms of suspension.

Motion to accept the Office of General Counsel Report and the Disciplinary Report as given: Mr. Barker.  
Second: Dr. Gibson

The reports were accepted as given with the chairman voting.

**Regional Surveyor Reports:**

Complaint Investigations  
Proficiency Testing Events  
Regional Offices:

East, Middle, and West TN

**ETRO Report: 2nd Quarter**  
Fowlen Anders, MT  
Consultant/Surveyor

East Tennessee Regional Office –Second Quarter 2023:

Complaint Investigations: Zero (0)

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)

**MTRO Report: 2nd Quarter**  
Robert Sommer, MT  
Consultant/Surveyor

Middle Tennessee Regional Office–Second Quarter 2023:

Complaint Investigations: One (1)

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)

**WTRO Report: 2nd Quarter**  
Debbie Haggard, MT  
Consultant/Surveyor

West Tennessee Regional Office –Second Quarter 2023:

Complaint Investigations: Zero (0)

Unsuccessful Proficiency Testing: Zero (0)

- First Occurrence (two in a row or two out of three unsatisfactory scores: Zero (0)
- Second Occurrence (three in a row or three out of five unsatisfactory scores: Zero (0)

Motion to accept the reports as given: Dr. Vaughan.  
Second: Mr. Stanton

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. **Laboratory Management Services, LLC** Independent Laboratory



Nashville, TN

Specialties: Microbiology, Bacteriology, Parasitology, Virology, Histopathology, and Molecular Diagnostics.

Medical Laboratory Director: Hugh Tobin, M.D.  
ABP/Anatomic & Clinical Pathology

Surveyor: Robert Sommer, MT Consultant II/MTRO

**2. Ariana Diagnostics, LLC**  
Nashville, TN

Independent Laboratory

Specialties: Bacteriology, Parasitology, Virology, and Molecular Diagnostics

Medical Laboratory Director: Alexander Thurman, MD  
ABP/Anatomic & Clinical Pathology

Surveyor: Robert Sommer, MT Consultant/MTRO

**3. Biomat USA, Inc.**  
Chattanooga, TN

Plasma Donor Center

Specialties: Total Serum Protein and Hematocrit(spun)

Medical Laboratory Director: Kenneth Patric, MD  
Family Medicine

Surveyors: Lori Reynolds, MT Consultant/ETRO

**4. Verici DX, Inc.**  
Franklin, TN

Independent Laboratory

Specialties: Diagnostic Immunology & Molecular Diagnostics

Medical Laboratory Director: Michael J. Donovan, MD  
ABP/Anatomic & Clinical Pathology

Surveyor: Robert Sommer, MT Consultant/MTRO

**5. Kedplasma, LLC**  
LaVergne, TN

Plasma Donor Center

Specialty: Total Serum Protein and Hematocrit(spun)

Medical Laboratory Director: Theodore Tsaltas, MD  
Obstetrics & Gynecology

Surveyor: Robert Sommer, MT Consultant/MTRO

After discussion, the Board decided to ratify the five (5) laboratories listed above since they had no deficiencies cited during their initial inspection.

Motion: Mr. Litle  
Second: Mr. Barker

The licenses were approved with the chairman voting.

**6. PCA Southeast Summit Campus dba  
Opus Pathology**  
Hermitage, TN

Anatomic Laboratory

Specialties: Pathology, Histopathology, & Cytopathology

Medical Laboratory Director: Estelle E. May, MD  
ABP/Anatomic, Cytopathology, & Neuropathology

Surveyor: Robert Sommer, MT Consultant/MTRO

This facility's initial license ratification was tabled until the October meeting of the Board because one board member had to recuse herself from the vote, and there was no longer a quorum.

**7. Baptist Arlington Freestanding  
Emergency Department**  
Arlington, TN

Emergency Department Laboratory

Specialties: Bacteriology-limited, Virology-limited, Hematology, General Immunology, Routine Chemistry, Urinalysis, and Transfusion Services.

Medical Laboratory Director: Andrew Gold, DO  
ABP/Anatomic & Clinical Pathology

Surveyor: Debbie Haggard, MT Consultant/WTRO

Motion: Dr. Vaughan  
Second: Dr. Gibson

The license was approved with the chairman voting.

**8. Ascension St. Thomas Rutherford  
Westlawn**  
Murfreesboro, TN

Hospital Laboratory

Specialties: Hematology, Routine Chemistry, Urinalysis, Toxicology-limited, Transfusion Services, coagulation Studies (PT, PTT), RSV, and Strep A Antigen Screen

Medical Laboratory Director: Evan Alston, MD  
ABP/Anatomic & Clinical Pathology

Surveyor: Robert Sommer, MT Consultant/MTRO

**9. Haywood County Community Hospital, Inc.**  
Brownsville, TN

Motion: Mr. Barker  
Second: Mr. Litle

The license was approved with the chairman voting.

Hospital Laboratory

Specialties: Bacteriology-limited, Virology-limited, Hematology, Routine Chemistry, Urinalysis, Toxicology, Transfusion Services, Arterial Blood Gases & pH, and Wet Preps.

Medical Laboratory Director: Edwin A. Raines, MD  
ABP/Anatomic & Clinical Pathology

Surveyor: Debbie Haggard, MT Consultant/WTRO

Motion: Mr. Litle  
Second: Ms. Key

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 June 20, 2023, Task Force meeting.

No motion was needed.

Policy Statement Regarding Separate Lab Licenses for Point-of-Care Testing Sites on the Campus of a Hospital with a Licensed Medical Laboratory

The Board reviewed the Policy Statement regarding Separate Lab Licenses for Point-of-Care Testing Sites on the Campus of a Hospital with a Licensed Medical Laboratory.

Motion to retire the policy: Dr. Vaughan  
Second: Mr. Litle

The policy was retired with the chairman voting.

Policy Statement Regarding Microscopic Testing for Cytology Screening to be Performed in a Licensed Laboratory

The Board reviewed the Microscopic Testing for Cytology Screening to be Performed in a Licensed Laboratory Policy Statement.

Motion to retire the policy: Mr. Litle  
Second: Dr. Asbell

The policy was retired with the chairman voting.

Policy Statement for Esoteric Labs  
Performing SARS-CoV2 Testing

The Board reviewed the Policy Statement for Esoteric  
Labs Performing SARS-CoV2 Testing.

Motion to retire the policy: Dr. Gibson  
Second: Mr. Litle

The policy was retired with the chairman voting.

Policy Statement for Labs Which  
Conduct Employment-Related Urine  
Drug Screens

The Board reviewed the Labs Which Conduct  
Employment-Related Urine Drug Screens Policy  
Statement.

Motion to retire the policy: Mr. Litle  
Second: Dr. Asbell

The policy was retired with the chairman voting.

Policy Statement for Patient Test  
Management/Laboratory Reports

The Board reviewed the Policy Statement for Patient  
Test Management/Laboratory Reports.

Motion to retire the policy: Mr. Litle  
Second: Mr. Barker

The policy was retired with the chairman voting.

Policy Statement on Mobile  
Laboratories

The Board reviewed the Mobile Laboratories Policy  
Statement.

Motion to retire the policy: Dr. Gibson  
Second: Mr. Litle

The policy was retired with the chairman voting.

Policy Statement Regarding the TN  
Chronic Kidney Disease Screening Act

The Board reviewed the Policy Statement regarding the  
TN Chronic Kidney Disease Screening Act.

Motion to retire the policy: Mr. Litle  
Second: Dr. Gibson

The policy was retired with the chairman voting.

Policy Statement Regarding Blood  
Volume Detection Using Tagged  
Albumin

The Board reviewed the Blood Volume Detection Using  
Tagged Albumin Policy Statement.

Motion to keep the policy: Mr. Litle  
Second: Dr. Vaughan

The policy was not retired with the chairman voting.

**New Business:**

No new business was presented.

**Public Comment:**

No public comments.

**Adjournment:**

With no further business to discuss, the meeting was  
adjourned at 4:58 p.m. CST.

Motion to adjourn: Mr. Litle.  
Second: Mr. Barker

The meeting was adjourned with the chairman voting.