Tennessee Medical Laboratory Board July 28, 2021 Full Board Meeting Minutes

Meeting Date:	July 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, PhD, Independent Lab Mger/Adm. Gaye G. Jolly, MT-Hospital Administrator Andrew Stanton, CT-Cytotechnologist James A. Vaughn, MD-Pathologist Educator
Vacant Positions:	Non-Pathologist Physician Medical Technologist Supervisor
Members Absent:	Lynn Stewart, Citizen Representative
Staff Present:	Sandra S. Bogard, MT Consultant, Director Nina V. Smith, MT Consultant Administrative Office Kyonzte Hughes-Toombs, Deputy General OGC Mark Cole, Senior Associate Counsel Fowlen Anders, MT Consultant/Supervisor ETRO Lori Reynolds, MT Consultant/Surveyor ETRO Debbie Haggard, MT Consultant/Supervisor WTRO Richie Scruggs, MT Consultant/Surveyor WTRO Susan Wilson, MT Consultant/Supervisor MTRO Susan Massey, MT Consultant/Surveyor MTRO
Staff Absent:	All were present.
CLIA Manager/Representative:	Richard Carroll, CLIA Manager was absent.
Introduction of Board Members:	Board members and staff made their introductions to

the audience.

Quorum: Ten (10) board members were present which constitute a quorum. **Call To Order:** The meeting was called to order at 9:05 am CST by Mr. Michael Johnson the Board Chairman. **Presiding Officer:** The meeting was conducted by Mr. Johnson. **Recognized New Board Members** The Board Chairman recognized the following new Board members: Jerry Barker, MT-Hospital Laboratory Mger/Admin. Dir. Jennifer Gidcomb, MT-Medical Technologist, General Matthew Hardison, PhD, Independent Lab Mger/Adm. Andrew Stanton, CT-Cytotechnologist **Approve Minutes:** P & E Committee Meeting A motion to approve the April 28, 2021 Personnel & Education Committee minutes was made by Dr. Gibson. Second: Ms. Briggs The minutes were approved. Full Board Meeting A motion to approve the April 29, 2021 Board minutes was made by Ms. Jolly. Second: Dr. Davis The Board minutes were approved. Ratification Of Initial Determinations Ms. Briggs reported the actions of the P & E Committee Meeting: Personnel & Education Committee meeting, July 27, 2021. Motion to ratify Committee actions: Dr. Vaughn Second: Dr. Gibson 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 No consent, agreed, or compliance orders were Reprimand: presented during this meeting. No letters of reprimand were presented.

Tennessee Professional Peer

Assistance Program (TNPAP) Teresa Phillips, Executive Director

Disciplinary Coordinator

The statistical report for July 1, 2020-June 30, 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. Gibson

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 ReportMs. Leonard's investigative report included the following:

Monitored Practitioners (Personnel and Facilities): (2021)

Investigative Licensed Laboratory Personnel: (2021) Zero new complaints.

One (1) complaint closed.

Two (2) currently open complaints.

Seven (7) currently monitored practitioners:

two under board order. four suspended licenses. one expired license.

Investigative Licensed Laboratory Facilities: (2021)

Five (5) new complaints:

one for unqualified personnel. two for unprofessional conduct. one for diagnostic discrepancy. one for unlicensed practice.

Two (2) complaints closed.

Motion to Accept Report: Dr. Gibson Second: Dr. Vaughn

The investigations report was accepted as given.

Financial Report

Matthew McSpadden Fiscal Manager

Legislative Update

Elizabeth E. Foy, Esq. Legislative Liaison A financial report was not presented at this meeting.

Elizabeth E. Foy, Esq. Legislative Liaison presented the following legislative update:

Public Chapter 37

This act prohibits agencies subject to sunset review from promulgating rules or adopting policies to exempt members solely by virtue of their status as members. This act took effect March 23, 2021.

Public Chapter 242

This act authorizes records custodians to petition a court for injunctive relief from individuals making frequent public records requests with the intent of disrupting government operations, following a fifth (5th) public records request. A records custodian can only petition a court if they notify the person in writing stating the specific conduct may constitute intent to disrupt government operations, and that the person continues to do so. The individual upon a court enjoinment would not be able to make public requests at the agency for up to one (1) year.

This chapter took effect April 28th, 2021 and will sunset July 1, 2025.

Public Chapter 291

This act requires the attorney general and reporter to not approve an emergency rule if the emergency rule does not meet the statutory criteria for adoption of the rule.

This act took effect July 1, 2021.

Public Chapter 328

This act requires that starting December 1, 2023, state agencies submit a report of their effective rules to the chairs of the government operations committee every eight (8) years. The report is required to include a brief description of the department's operations that each chapter affects, as well as each rule and its administrative history, which would include the original promulgated date and the dates the rule was last amended, if applicable. Additionally, the report would include a determination of each rule on whether it is adheres to current state or federal law or court rulings, should be amended or repealed, reviewed further, or continue in effect without amendment. Lastly, if there

are any intentionally false statements in the report, the government operations committee would have the ability to vote to request the general assembly to remove a rule or suspend the department's rulemaking authority for any reasonable period of time.

This act took effect July 1, 2021.

Public Chapter 348

This act requires fetal remains from a surgical abortion to be disposed of solely by burial or cremation. Under this act, an abortion facility is defined as any ASTC, private office, or other facility as defined by TCA 68-11-201 in which abortions are induced or performed. The act does not include hospitals licensed under Title 68 as long as the hospital policies and regulations concerning disposal of fetal remains substantially complies with the requirements of this act. A pregnant woman who has a surgical abortion has the right to choose burial or cremation of the fetal remains as well as the location for the final disposition. The woman is to be provided with forms created by the Department of Health informing her of that right and selecting the means and location. If the woman does not wish the exercise this right, the abortion facility shall determine whether disposition is by cremation or interment. The act also establishes a variety of record keeping requirements on the facility. This act took effect on May 6, 2021 for rulemaking purposes. The rest of the public chapter takes effect July 1, 2021.

Public Chapter 453

This act requires public or private entities or businesses that operate a building open to the general public to post signage regarding public restroom access in certain situations. Specifically, this applies to entities or businesses that have restroom policies allowing either biological sex to use any public restroom within their building. The act includes requirements for language, size, location, and even color for the signage. The act excludes unisex, single occupant restrooms or family restrooms intended for use by either sex.

This act took effect July 1, 2021.

Public Chapter 495

This act authorizes additional exemptions to the original list of licensure requirements from the Tennessee Medical Laboratory Act. They include Tennessee licensed pharmacies that possess an active CLIA Waiver, as well as medical personnel who are employed and

perform testing at a licensed private medical laboratory – including hospital-based laboratories – notwithstanding existing laws on examining and reporting of human specimens, or the soliciting of their practice. The act also authorizes directors of medical laboratories to monitor their personnel remotely. This act took effect May 25, 2021.

Public Chapter 513

This act prohibits the Governor from issuing an executive order and a state agency, department or political subdivision from promulgating, adopting, or enforcing an ordinance or resolution that requires a person to receive an immunization, vaccination, or injection for the SARS-CoV-2 virus or any variant of the SARS-CoV-2 virus. It also deletes the previous override during an epidemic or immediate threat of an epidemic of an objection against vaccination that was made on the basis of religious tenets. The law prohibits requiring the COVID-19 vaccine to attend k-12 schools. The prohibition against requiring vaccines does not apply to governmental entities subject to federal or state statute or rule that prohibits the entity from requiring medical treatment for those who object on religious grounds or right of conscience. The law also does not apply to students of a public institution of higher education delivering healthcare services when the student is participating in/fulfilling requirements of a program in medicine, dentistry, pharmacy, or another healthcare profession.

This act took effect May 25, 2021.

Public Chapter 531

This act limits an agency's authority to promulgate rules without a public hearing. There are exceptions to the public hearing requirement. These exceptions include emergency rules, rules that are nonsubstantive modifications to existing rules (like clerical updates), rules that repeal existing rule, or rules that eliminate or reduce a fee described by an existing rule. This act took effect July 1, 2021.

Public Chapter 532

This act authorizes the joint government operations committee to stay an agency's rule from going into effect for a period of time not to exceed ninety (90) days. If the government operations committee determines that subsequent stays are necessary, then

the joint committee may issue consecutive stays, each for an additional ninety (90) day period, so long as such stays do not extend beyond the fifth legislative day of the year following the year in which the rule is filed with the secretary of state. The initial stay may be done by either the house or senate government operations committee, but subsequent stays must be by agreement by the committees of both chambers. A stay is effective when the respective committee files written notice with the secretary of state, and the respective committee shall specify the length of effectiveness of the stay. This act took effect May 25, 2021.

These are general summaries of legislation. For more detailed information and all specifics/requirements, please review the links to each public chapter

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

Bristol Regional Medical Center Point-of-Care
 Medical Park Boulevard, Suite G50
 Bristol, TN 37620
 Christina Hurt, MLT(ASCP)-Point-of-Care
 Coordinator

The request was to permit Certified Registered Nurse Anesthetists, Registered Nurses, Perfusionists, and Registered Cardiovascular Invasive Specialists to perform hematocrit, sodium, potassium, chloride, hemoglobin, pH, pO2, pCO2, ionized magnesium, ionized calcium, glucose, lactate, and O2Hg testing in the Cardiovascular Operating Rooms/CVOR, and Cath Lab utilizing the Nova Stat Prime Plus instrument and methodology.

Motion: Dr. Vaughn Second: Ms. Briggs

The exemption request was approved.

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

The request to permit Certified Registered Nurse Anesthetists, Perfusionists, Certified Cath Lab Techs, Registered Nurses, Certified Licensed Practical Nurses, and Anesthesiologists to perform sodium, potassium, chloride, TCO2, glucose, ionized magnesium, ionized calcium, lactate, hematocrit, hemoglobin, pH, pCO2, pO2, and O2Hg testing in the Cath Lab, Cardiac Intensive Care (2600), and perioperative Services (SS/Holding, Main Operating Room, & Coronary Operating Room) utilizing the Nova Stat Prime Plus instrument and methodology.

Motion: Dr. Gibson Second: Dr. Davis 3. Holston Valley Medical Center Point-of-Care

130 West Ravine Road Kingsport, TN 37660 LaDonna Compton, MT(ASCP) – Lead Point-of-Care Coordinator The exemption request was approved.

The request was to permit Certified Registered Nurse Anesthetists, Perfusionists, Radiology Technologists, Registered Cardiovascular Invasive Specialists, and Registered Nurses, to perform sodium, potassium, chloride, TCO2, glucose, ionized magnesium, ionized calcium, lactate, hematocrit, hemoglobin, pH, pCO2, pO2, sO2, and O2Hg testing in the Cardiovascular Operating Room, Cardiovascular Intensive Care Unit, Cardiovascular Catheterization Lab, and Cardiovascular Post Anesthesia Care Unit utilizing the Nova Stat Prime Plus instrument and methodology.

Motion: Ms. Briggs Second: Mr. Barker

The exemption request was approved.

4. West Tennessee Healthcare-North Hospital

367 Hospital Boulevard Jackson, TN 38305 Shelia Boswell, MT - Point of Care Coordinator The request was to permit Certified Registered Nurse Anesthetists to perform blood gases, sodium, potassium, ionized calcium, and hematocrit testing facility-wide utilizing the Abbott i-STAT (EG7+ cartridge) instrument and methodology.

Motion: Dr. Vaughn Second: Dr. Gibson Abstain: Mr. Barker

The exemption request was approved.

5. TriStar Horizon Medical Center

111 Highway 70 East Dickson, TN 37055 Sheri Sutton-Administrative Director The request was to permit Registered Nurses and Respiratory Therapists to perform pH, pCO2, pO2, HCO3, TCO2, SO2, and BE testing facility-wide utilizing the Siemens EPOC instrument and methodology.

Motion: Ms. Briggs Second: Dr. Davis Abstain: Dr. Gibson

The exemption request was approved.

6. LabPlus, LLC - Saint Thomas Midtown

2000 Church Street Nashville, TN 37203 G. Russell Ashley, MLS(ASCP)^{cm} – Point-of-Care The request was to permit Registered Nurses to perform ionized calcium testing facility-wide utilizing the Abbott i-STAT instrument and methodology.

Motion: Ms. Briggs Second: Ms. Gidcomb

7. LabPlus, LLC - Saint Thomas West

4220 Harding Pike Nashville, TN 37205

G. Russell Ashley, MLS(ASCP)cm-Point-of-Care

The exemption request was approved.

The request was to permit Registered Nurses, Cardiovascular Technologists, Registered Cardiovascular Invasive Specialists, and Radiologic Technologists to perform hematocrit, hemoglobin, oxyhemoglobin, and carboxyhemoglobin testing in the Cardiac Cath Lab utilizing the Nova Stat Prime Plus instrument and methodology.

Motion: Dr. Vaughn Second: Dr. Gibson

The exemption request was approved.

The second request was to permit Pharmacists to perform PT/INR testing in the Anticoagulation Monitoring Clinic utilizing the Abbott i-STAT instrument and methodology.

Motion: Ms. Briggs Second: Dr. Vaughn

The exemption request was approved.

 LabPlus, LLC – Saint Thomas Rutherford 1700 Medical Center Parkway Murfreesboro, TN 37118 Teri Reed, MT – Lab Manager The request was to permit Certified Registered Nurse Anesthetist, Registered Nurses, and Respiratory Therapists (ABG endorsed) to perform lactate facility-wide utilizing the Abbott i-STAT (CG4+ cartridge) instrument and methodology.

Motion: Dr. Gibson Second: Ms. Briggs

The exemption request was approved.

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

After the Board discussion, it was decided to table this exemption request until the October Board meeting.

The following additional information needs to be submitted by the facility:

- Correlation studies
- Troponin panic values
- BNP procedure

 Procedure on how patients are handled through the emergency room (workflow).

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

Elizabeth E. Culler, MD Chattanooga, TN

Dr. Culler appeared before the Board to request approval to director more than three (3) laboratories.

The labs that she requested the exemption for include:

- Blood Assurance, Inc.-705 E. 4th Street, Chattanooga, TN 37403 (lic. # 2274) high complex testing
- Blood Assurance, Inc.-2855 Keith Street, NW, Cleveland, TN 37312 (lic. # 2159)
 waived testing
- Blood Assurance, Inc.-5425 Highway 153, Hixson, TN 37343 (lic. # 3342)
 waived testing
- Blood Assurance, Inc.-1740 Gunbarrel Road, Chattanooga, TN 37421 (lic. # 4017)
 waived testing
- Blood Assurance, Inc.-155 W. Broad Street, Cookeville, TN 38501 (lic. # 4070)
 waived testing
- Blood Assurance, Inc.-604 N. Jackson Street, Tullahoma, TN 37388 (lic. # 4093)
 waived testing
- Blood Assurance, Inc.-1412 Trotman Ave., Suite 69, Columbia, TN 38401 (lic. # 4339) waived testing
- Blood Assurance, Inc.-1767 Wilma Rudolph Blvd., Clarksville, TN 37040 (lic. # pending) waived testing

The Board recommended that the documentation of monthly visits must continue, at all locations, regardless if the oversight is in person or remote.

The Board also indicated that the Administrative Office can approve interim plans for director oversight of greater than three (3) labs for the short term between board meetings.

Motion: Dr. Gibson Second: Dr. Hardison

The request was approved.

Discuss, Review, And Take Action, if Needed:

Discuss Toxicology Validity Testing

During the October 17, 2002 Board meeting, it was determined that the specific gravity of urine for the purposes of determining specimen validity is not a medical laboratory test.

During the October 18, 2018 meeting, the Board suggested a disclaimer be placed on the final lab report stating the creatinine analysis is provided solely for urine specimen validation purposes. They also determined that with the disclaimer, on an esoteric laboratory final report, it is not necessary for them to obtain an additional clinical lab license.

After discussion, the Board agreed with the previous determinations. They expanded the tests used for specimen validity testing to include creatinine, pH, and specific gravity.

No motion was needed.

Task Force Recommendations Regarding Digital Imaging and Remote Work

The Task Force meeting occurred on July 27, 2021. The recommendations are currently being reviewed by the Task Force members. The Board discussion was postponed until the October Board meeting.

No motion was needed.

Discuss Supervisor Qualifications for Arterial Blood Gas Lab

The Board discussed their current regulations regarding the requirements for arterial blood gas lab supervision. They requested input from the Respiratory Care Board concerning their regulatory requirements regarding the appropriate personnel to supervise an arterial blood gas laboratory.

Further discussion will take place at the October meeting.

Motion: Dr. Davis Second: Ms. Briggs

The motion was approved.

Discuss Use of Expired COVID-19 Test Kits, Reagents, and Collection Swabs

After discussion, the Board adopted the CMS (Centers for Medicare and Medicaid Services) and CAP (College of

American Pathologists) policy regarding the use of expired COVID-19 test kits, reagents, and collection swabs.

The policy states, "The CMS and the CAP allows laboratories to use expired COVID-19 test kits, reagents, and swabs during the public health emergency. If this use deviates from the manufacturer's instructions, the use would not be authorized under the EUA (Emergency Use Authorization). The laboratory or testing site may use expired supplies until in-date supplies become available provided:

- There is a written policy in place to ensure the reagents are performing as expected and
- The kits and reagents pass quality control tests for **each** assay run.

This exception applies to reagents, kits, and swabs used in COVID-19 testing **only**. Laboratories may not adopt policies that would allow for regular use of expired reagents."

Also, the Board discussed that labs need to document the lack of supplies. It was also determined that multiplex test kits can only report the expired COVID-19 result and not the other analytes.

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

The motion was approved.

Discuss Sodium Citrate Tube Shortage

The Board discussed the shortage of sodium citrate tubes. The CDC (The Centers for Disease Control and Prevention) guidance was also reviewed.

CDC recommends the following conservation strategies:

- Do not use sodium citrate tubes unless medically necessary.
- Do not include sodium citrate tubes in routine collections of a variety of specimens at the time of other blood sampling or IV insertion.
- Do not use sodium citrate tubes as discard tubes; consider clear top or red stopper tubes as an alternative.

 Limit allocation of 1.8 mL sodium citrate tubes for difficult blood collections.

No motion was needed.

Proficiency Testing, Validation, and Correlation Guidance for Waived Testing

After Board discussion the following guidelines were adopted for waived testing:

Proficiency Testing (PT)-

- The lab must verify the accuracy of waived testing twice a year.
 OR
- Enroll with a PT provider.

The performance of PT can be rotated among the different waived test systems/instruments every six (6) months.

Verification Studies-

- Each analyte must perform acceptably during verification studies/validation prior to being put into use for patient testing.
- Verification study requirements are the same for all testing regardless of complexity level.

Correlation Studies-

These studies are burdensome for waived testing and not necessary.

A policy statement, regarding waived testing, will be issued by the Board at the October meeting.

Motion: Dr. Gibson Second: Dr. Davis

The motion was approved.

Review And Discuss The Licensure Of Medical Laboratory Directors:

Deborah Payne, PhD
 Nashville, TN 37211
 Director: Molecular Diagnostics &
 Microbiology

Dr. Payne received her B.A. degree in Microbiology and Immunology at the University of Texas in Austin in 1985.

She received her Ph.D. in Microbiology from the University of Texas Medical Branch at Galveston in 1993.

Dr. Payne is certified by the American Board of Clinical Chemistry (ABCC) in Molecular Diagnostics through Dec.

31, 2021. She is also certified by the American Board of Medical Microbiology (ABMM) through Dec. 31, 2022.

She received her postdoctoral fellowship training at the University of Texas Medical Branch at Galveston from 1993-1997.

Dr. Payne is seeking licensure as a Director of Molecular Diagnostics & Microbiology.

Motion: Ms. Jolly Second: Dr. Vaughn

The license was approved.

Dr. Robbins received his B.A. degree in Chemistry at John Hopkins University in Baltimore, MD in 1978.

He received his Ph.D. in Biochemistry from the University of Texas in Austin, TX in 1983.

Dr. Robbins is certified by the American Board of Clinical Chemistry (ABCC) in Molecular Diagnostics through Dec. 31, 2021.

He received his postdoctoral fellowship training at the University of Kentucky in Lexington, KY from 1983-1988.

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

Motion: Dr. Gibson Second: Ms. Gidcomb

The license was approved.

The gavel was handed over to Ms. Jolly to preside over the Board meeting when the chairman, Mr. Johnson, left the meeting.

Dr. Bove received her B.A. degree in Biological Sciences at the University of Delaware in Newark, DE in 1978.

She received her Ph.D. in Genetics & Molecular Biology from the University of Delaware in Newark, DE in 1996.

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

David Robbins, PhD
 New Orleans, LA 70119
 Director: Molecular Diagnostics

Presiding Officer

Betsy Bove, PhD
 Wilmington, DE 149804
 Director: Molecular Diagnostics

She received her postdoctoral fellowship training at Fox Chase Cancer Center in Philadelphia, PA from 1996-2002.

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

Motion: Dr. Vaughn Second: Dr. Hardison

The license was approved.

4. Natalie Whitfield, PhD Dr. Whitfield received her B.A. degree in Biological Oceanside, CA 92056 Sciences at the University of Texas in El Paso in 2001.

She received her Ph.D. in Cellular and Molecular Biology from the University of Michigan in Ann Arbor, MI in 2009.

Dr. Whitfield is certified by the American Board of Medical Microbiology (ABMM) through Dec. 31, 2021.

She received her training in Clinical and Molecular Microbiology as a Division Manager at the University of Arizona Medical Center in Tucson, AZ from 2010-2013.

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

Motion: Dr. Gibson Second: Dr. Davis

The license was approved.

Reports/Requests:

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

Director: Microbiology

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:

 New West TN Surveyor, Richie Scruggs, started on June 23, 2021.

Board meeting dates for 2021 were presented.

Four (4) new Board Appointments:

- Hospital Laboratory Manager-Mr. Jerry Barker
- Independent Laboratory Manager-Dr. Matthew Hardison
- Cytotechnologist-Mr. Andrew Stanton
- Medical Technologist-Ms. Jennifer Gidcomb

Two (2) Vacancies on the Board:

- Non-Pathologist Physician
- Laboratory Supervisor

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: Dr. Vaughn Second: Ms. Briggs

The report was accepted as given.

A request was made to purchase two (2) printers/scanners for survey staff to have a backup for the older models in current use.

Motion to approve the request for printers/scanners: Dr. Davis

Second: Ms. Briggs

The request was approved.

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 in an internal review.

Board Attorney Report

Mark Cole

Senior Associate General Counsel

Motion to accept the Office of General Counsel Report

as given: Ms. Briggs Second: Dr. Hardison

The report was accepted as given.

Regional Surveyor Reports:

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

ETRO Report: 2nd Quarter

Fowlen Anders, MT Consultant/Surveyor

East Tennessee Regional Office – Second Quarter 2021

Complaint Investigations: One (1)

Unsuccessful Proficiency Testing: Zero (0)

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

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

MTRO Report: 2nd Quarter

Susan Wilson, MT Consultant/Surveyor Middle Tennessee Regional Office – Second 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)

WTRO Report: 2nd Quarter
Debbie Haggard, MT

Consultant/Surveyor

West Tennessee Regional Office –Second Quarter 2021

Complaint Investigations: One (1)

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: Ms. Gidcomb

Second: Mr. Stanton

Reports were accepted as given.

Board Ratifications Initial Facility Applications:

1. Blood Assurance, Inc. Nashville Reference Laboratory

60 Parris Avenue Nashville, TN 37210 Specialties: Immunohematology

ABO Group Rh Type

Antibody Detection Transfusion
Antibody Detection Non-Transfusion

Antibody Identification

Laboratory Director: Theodore Kieffer, MD

Clinical Pathology

Surveyor: Susan Wilson, MT Consultant II/MTRO

Motion: Dr. Vaughn Second: Ms. Gidcomb

The license was approved.

2. Octapharma Plasma, Inc.-Memphis

> 4212 Elvis Presley Blvd Memphis, TN 38116

Specialties: Spun Hematocrit

Total Serum Protein

Laboratory Director: Matthew Dress, MD

Clinical & Anatomic Pathology

Hematopathology

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Dr. Gibson Second: Ms. Briggs

The license was approved.

3. TriStar Century Farms FSED

2127 Century Farms Parkway Antioch, TN 37013

Specialties: Microbiology

Bacteriology Virology Chemistry Urinalysis Endocrinology Toxicology Hematology

Laboratory Director: Nitin Marwaha, MD

Clinical & Anatomic Pathology

Surveyor: Susan Wilson, MT Consultant II/MTRO

Motion: Dr. Gibson Second: Ms. Gidcomb

The license was approved.

4. TDS Labs, LLC.

342 22nd Avenue North Nashville, TN 37203 Specialties: Virology (Limited)

General Immunology (Limited)

Molecular Diagnostics

Laboratory Director: Jess G. Evans, PhD

Surveyor: Susan Wilson, MT Consultant II/MTRO

Motion: Ms. Briggs Second: Mr. Barker

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 table this decision

until the October Board meeting.

Motion: Ms. Gidcomb Second: Mr. Barker

The motion was approved.

Election of Vice-Chairman

The nomination for Full Board Vice-Chairman was Ms.

Jolly.

Motion: Dr. Davis Second: Mr. Barker

The nomination was approved.

Adjournment:

With no further business to discuss, the meeting was

adjourned at 12:15 pm CDT.

Motion to adjourn: Dr. Gibson

Second: Dr. Davis

The meeting was adjourned.