

**Tennessee Medical Laboratory Board
October 22, 2020
Full Board Meeting-Teleconference
Minutes**

Meeting Date: October 22, 2020

Time: 9:00 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:

Patti J. Walton, MT-Hospital/Lab Mgr./Adm. Dir., Chair
LeeAnne Briggs, MT- Med. Technologist,
Educator, Board Vice-chair
Keisha Burnett, S.A.-Cytotechnologist
Mark A. Calarco, DO, Independent Lab Manager/Adm.
Tereyo M. Cox, MT-Medical-Technologist, General
Carla M. Davis, MD-Pathologist
Paul Fleming, MT Supervisor
Danielle Gibson, MD-Pathologist, Non-Educator
Michael Johnson, MT-Medical Technologist Generalist
James A. Vaughn, MD-Pathologist Educator

Vacant Position: None

Staff Present:

Sandra S. Bogard, MT Consultant, Director
Nina V. Smith, MT Consultant Administrative Office
Kyonzte Hughes-Toombs, Deputy General OGC
Fowlen Anders, MT Consultant/Surveyor ETRO
Taylor Carpenter, MT Consultant/Surveyor ETRO
Debbie Haggard, MT Consultant/Surveyor WTRO
Susan Wilson, MT Consultant/Surveyor MTRO

CLIA Manager/Representative: Richard Carroll, CLIA Manager

Introduction of Board Members: Board members made their introductions by roll call.

Patti J. Walton, MT	Yes
LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Not Present
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes

Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

Quorum:

Ten (10) board members were present which constitute a quorum.

Members Absent:

Gaye G. Jolly, MT-Hospital Administrator
Jon Parham, DO Non-Pathologist Physician
Lynn Stewart, Citizen Representative

Electronic Meeting Process:

To Ensure Everyone Could Hear Each Other:

Board members responded by roll call.

Patti J. Walton, MT	Yes
LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Not Present
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The Board Members Identified If Anyone Is Present With Them:

Board members responded by roll call.

Patti J. Walton, MT	Individual
LeeAnne Briggs, MT	Individual
Tereyo M. Cox, MT	Individual
Gaye G. Jolly, MT	Not Present
Lynn Stewart	Not Present
Paul Fleming, MT	Individual
Michael Johnson, MT	Individual
Keisha Burnett, SA	Individual
Mark A. Calarco, DO	Individual
Carla M. Davis, MD	Individual
Danielle Gibson, MD	Individual
Jon Parham, DO	Not Present
James A. Vaughn, MD	Individual

The Board Members Proceed With Electronic Meeting:

A motion to proceed with the electronic meeting was made by Mr. Johnson.

Second: Ms. Briggs

Roll call vote:

Patti J. Walton, MT	Yes
LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Not Present
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The motion to proceed with the electronic meeting was approved.

The Board Members Determine If
Matters Are Proper For A Teleconference:

A motion that the topics to be discussed are proper for a teleconference was made by Dr. Calarco.

Second: Mr. Fleming

Roll call vote:

Patti J. Walton, MT	Yes
LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Not Present
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The motion that a teleconference meeting is appropriate for the topics to be discussed was approved.

The Board Members Receipt Of Meeting
Material:

Board members responded by roll call.

Patti J. Walton, MT	Yes
LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes

Gaye G. Jolly, MT	Not Present
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

Approve Minutes:

P & E Committee Meeting

A motion to approve the July 22, 2020 Personnel & Education Committee minutes was made by Dr. Burnett.

Second: Mr. Johnson

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Not Present
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The minutes were approved.

Full Board Meeting

A motion to approve the July 22-23, 2020 Board minutes was made by Dr. Gibson.

Second: Dr. Calarco

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Not Present
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes

Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The Board minutes were approved.

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

Ms. Briggs reported the actions of the Personnel & Education Committee meeting, October 21, 2020.

Motion to ratify Committee actions: Mr. Johnson
Second: Dr. Vaughn

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Not Present
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

Report: Accepted as presented by Ms. Briggs.

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

Consent Order

Tennessee Valley Regional Laboratory dba Springs
Medical Lab Lic. # 4260
Owner, Rajen Shah

The facility failed to submit an acceptable plan of correction from the last survey that took place on October 22-23, 2019.

The lab was cited for:

- Having inadequate and/or nonexistent quality control procedures
- Failure to follow quality control procedures
- Not having a lab supervisor
- Changing the address of the lab without notice
- Changing a lab director without notice

- Failure of the lab director to fulfill the duties of a director

The plan of correction that was submitted by the laboratory was deemed unacceptable by the surveyor.

The laboratory is not currently performing testing.

Mr. Shah indicated that the lab license has expired and he will voluntarily relinquish the lab license. He will not be opening the lab and all operations have ceased.

Clarification was given that Springs Medical Lab must still submit the civil monetary penalties and court costs. Also, the lab is still responsible to notify the patients and/or ordering physicians regarding the testing discrepancies.

In the future, if the laboratory decides to re-open it would be required to correct all deficiencies and comply with the consent order.

Presentations To The Board:

Tennessee Professional Peer Assistance Program (TNPAP)
Mike Harkreader, MS,RN,CARN
TNPAP Director

The statistical report for July 1, 2020-September 30, 2020 was presented by Mr. Mike Harkreader, Program Director.

Zero (0) individuals were monitored during this period.

Motion to accept the TNPAP report: Ms. Briggs
Second: Mr. Fleming

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Not Present
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The report was accepted as given.

Note: Review of TNPAP materials via 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

Financial Report

Alicia Grice

Presentation/Discussion

Ms. Grice gave the 2020 Fiscal Year Report to include expenditures and projections for the fiscal year.

Those expenditures include those environments associated with board expenditures for that year.

Those values are comparable with those of the 2019 year-end data with little change from year to year.

Motion: Dr. Calarco

Second: Dr. Burnett

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Not Present
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The report was accepted as given.

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

Investigations Report

Lori L. Leonard

Disciplinary Coordinator

Ms. Leonard's investigative report included the following:

Monitored Practitioners (Personnel and Facilities):
(2020)

Four suspensions and two currently under Board order.

Investigative Licensed Laboratory Personnel: (2020)

One new complaint:

one for unprofessional conduct.

Four complaints closed:

one sent on to OGC.

one closed with no action.

two with a letter of concern.

Motion To Accept Report: Mr. Johnson

Second: Dr. Gibson

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Not Present
Lynn Stewart	Not present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The investigations report was accepted as given.

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

1. Big South Fork Medical Center
18797 Alberta Street
Oneida, TN 37841
Gualberto Ruano, MD
Hal Leftwich, DBA, FACHE-CEO
Susan Massey, MT-Lab Manager
Brittany Copeland
Michael Alexander
Judy Carter, BS, MLS(ASCP)^{cm}-Lab Supervisor
Cherylyn Helmstead-CNO

The first request was to permit Registered Nurses, Licensed Practical Nurses, Registered Respiratory Therapists, and Certified Respiratory Therapists in the Emergency Department, Med. Surg. Unit, and Respiratory Department to perform and report Arterial Blood Gases (pH, pO₂, pCO₂, HCO₃, TO₂, BE & sO₂) and Lactate testing utilizing the i-STAT instrument and methodology (CG4+ cartridge).

Motion: Dr. Vaughn

Second: Ms. Briggs

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes

Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The exemption request was approved.

The second request was to permit Registered Nurses, Licensed Practical Nurses, Registered Respiratory Therapists, and Certified Respiratory Therapists in the Emergency Department, Med. Surg. Unit, and Respiratory Department to perform and report Troponin utilizing the i-STAT instrument and methodology (cTnl cartridge).

Motion: Mr. Fleming
Second: Mr. Johnson

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The exemption request was approved.

The third request was to permit Registered Nurses, Licensed Practical Nurses, Registered Respiratory Therapists, Certified Respiratory Therapists, and Radiology Techs in the Emergency Department, Med. Surg. Unit, Respiratory Department, and Radiology Department to perform and report Sodium, Potassium, Chloride, TCO₂, Glucose, BUN, Creatinine, Lactate, and Hematocrit testing utilizing the i-STAT instrument and

methodology (CHEM8+ cartridge).

Motion: Mr. Johnson
Second: Dr. Davis

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The exemption request was approved.

2. Jellico Medical Center
188 Hospital Drive
Jellico, TN 37762
Gualberto Ruano, MD
Hal Leftwich, DBA, FACHE-CEO
Susan Massey, MT-Lab Manager
Brittany Copeland
Michael Alexander
Judy Carter, BS, MLS(ASCP)cm-Lab Supervisor
Cherylyn Helmstead-CNO

The first request was to permit Registered Nurses, Licensed Practical Nurses, Registered Respiratory Therapists, and Certified Respiratory Therapists in the Emergency Department, Med. Surg. Unit, and Respiratory Department to perform and report Arterial Blood Gases (pH, pO₂, pCO₂, HCO₃, TO₂, BE & sO₂) and Lactate testing utilizing the i-STAT instrument and methodology (CG4+ cartridge).

Motion: Ms. Briggs
Second: Mr. Fleming

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The exemption request was approved.

The second request was to permit Registered Nurses, Licensed Practical Nurses, Registered Respiratory Therapists, and Certified Respiratory Therapists in the Emergency Department, Med. Surg. Unit, and Respiratory Department to perform and report Troponin utilizing the i-STAT instrument and methodology (cTnl cartridge).

Motion: Mr. Fleming

Second: Dr. Gibson

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The exemption request was approved with the requirement that the laboratory follows patients only using one analytic method.

The third request was to permit Registered Nurses, Licensed Practical Nurses, Registered Respiratory Therapists, Certified Respiratory Therapists, and Radiology Techs in the Emergency Department, Med. Surg. Unit, Respiratory Department, and Radiology Department to perform and report Sodium, Potassium, Chloride, TCO₂, Glucose, BUN, Creatinine, Lactate, and Hematocrit testing utilizing the i-STAT instrument and methodology (CHEM8+ cartridge).

Motion: Mr. Johnson

Second: Ms. Jolly

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The exemption request was approved.

3. TriStar Hendersonville Medical Center
355 New Shackle Island Road
Hendersonville, TN 37075
Nikki Stewart, MT(ASCP)
Administrative Director

The request was to permit Licensed Respiratory Therapists and Technicians to perform and report Arterial Blood Gases (pH, pO₂, pCO₂, HCO₃, BE, & sO₂) and Hematocrit facility-wide utilizing the Siemens EPOC instruments and methodologies.

Motion: Mr. Johnson

Second: Ms. Cox

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Abstain
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The exemption request was approved.

4. TriStar Southern Hills Medical Center
391 Wallace Road
Nashville, TN 37211
Brandy Whitehouse
Point of Care Coordinator

The request was to permit Licensed Respiratory Therapists to perform and report Arterial Blood Gases (pH, pO₂, pCO₂, HCO₃, BE, & sO₂) facility-wide utilizing the Siemens EPOC instruments and methodologies.

Motion: Mr. Johnson

Second: Dr. Gibson

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Abstain
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The exemption request was approved.

5. Tenna Healthcare-Clarksville
651 Dunlop Lane
Clarksville, TN 37040
Christopher Baggett, MLS(ASCP)^{cm}
Administrative Director

The request was to permit the following staff to perform and report Arterial Blood Gases (pH, pO₂, pCO₂, TCO₃), Electrolytes (Sodium, Potassium, Chloride) along with BUN, Creatinine, Glucose, ionized Calcium, Lactate, and Hematocrit utilizing the Siemens EPOC instruments and methodologies:

1. Registered Nurses, Licensed Practical Nurses, and Registered Respiratory Therapists – facility-wide
2. Certified CV Perfusionists – Cardiac OR
3. Registered Cardiovascular Invasive Specialists – Cath Lab
4. Anesthesiologists, Certified Nurse Anesthetists (CRNA's) – Surgery
5. Registered Radiological Techs, Certified Nuclear Med Techs, & Registered MRI Techs – Diagnostic Imaging

Motion: Mr. Fleming
Second: Dr. Gibson

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes

Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The exemption request was approved.

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

1. Melissa C. Chiles, MD
Columbia, TN

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

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

- Octapharma Plasma, Inc-3810 Chapman Hwy, Knoxville, TN 37920
- Westbrook Medical Center-931 Adell Ree Park Lane, Suite A, Knoxville, TN 37909
- Starr Regional Medical Center Etowah-886 Highway 411 North, Etowah, TN 37331(Pending)
- Starr Regional Medical Center – Athens-1114 W Madison Ave, Athens, TN 37303(Pending)
- Edmunds Gastroenterology – 4713 Papermill Drive, NW, Knoxville, TN 37909 (Physician Office Lab)

Motion: Mr. Johnson
Second: Mr. Fleming

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Abstain
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

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

Discuss, Review, And Take Action, if Needed:

Governor’s Executive Orders

Governor Lee’s Executive Order 63 was reviewed by the Board.

Discuss Proposed Policy Statement Regarding
68-29-135 Medical laboratory directors-
Restricted licenses-Qualifications

The Board reviewed the following proposed policy statement:

Qualifications for a Medical Laboratory Supervisor of a
30 bed or less Hospital

Applicants licensed as a medical laboratory director or supervisor pursuant to T.C.A. 68-29-135 shall have a modifier placed on the license to indicate that the license is a restricted medical laboratory director license or a restricted medical laboratory supervisor license.

Other than the qualifications listed in T.C.A. 68-29-135(b), an individual with a restricted supervisor license must, pursuant to Rule 1200-06-01-.21(1)(d), complete forty-five (45) contact hours in management continuing education within the first two (2) years after obtaining the license.

If an individual, with a restricted supervisor license, wants to obtain an unrestricted license, he or she will need to submit an application, complete forty-five (45) contact hours in management continuing education, and provide proof of three (3) years of lab supervisory work experience.

After Board discussion, it was decided to revise the last paragraph of the policy statement by replacing the word “complete” with the phrase, “previously documented proof of.”

Motion: Mr. Fleming

Second: Ms. Briggs

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes

Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The motion was approved.

Discuss Determination of
Physician Office Lab Status
Lewis Health Center
Hohenwald, TN
Hugh Bennett, Operations Director

The Board discussed the organizational structure and laboratory testing that was offered through the Lewis Health Center Laboratory, Imaging Center, and MRI Mobile Unit. The Board decided that the organizational structure of Lewis Health Center was considered a physician office laboratory and not subject to state licensure. The creatinine testing offered in the Imaging Center and MRI Mobile Unit was considered a state waived test and the facility needed to submit a Waived Testing Notification Form to the Board's Administrative Office.

No motion was needed.

Discuss Point of Care Testing Models
HCA HealthCare
Free Standing Emergency Department
Kelli Riggins, AVP-Laboratory Services HCA
Laura Medley-Director of Laboratory Services

HCA Healthcare proposed a Free Standing Emergency Department (FSED) model in which nursing staff performs the tests on the following menu:

- CBC with Diff - Sysmex XP-300
- Basic Metabolic Panel - EPOC
- Liver Profile - Piccolo
- Magnesium
- Phosphorus
- Amylase
- Pregnancy - Clinitek Status
- Troponin - Quidel Triage Meter
- Lactic Acid - EPOC
- Blood Gases
- BNP - Quidel Triage Meter
- Urine Drug Screen - iCUP or Quidel Triage Meter
- PT - Hemocron Signature Elite
- PTT
- D-Dimer - Quidel Triage Meter
- UA - Clinitek Status
- Flu A&B - Sophia
- RSV
- Strep A
- Occult Blood - Hemocult
- Gastric Occult Blood - Gastrocult

They are proposing not to have a medical technologist

or laboratory supervisor present when testing is being performed.

The Board was concerned about testing staff competencies, training, staff time away from nursing duties, and patient care.

The model is currently being piloted in the State of Florida.

Office of General Counsel clarified that State-licensed laboratories need to have appropriated licensed personnel which includes technologists, technicians, supervisors, and lab directors. The current Executive Order does allow for laboratory supervisors and testing staff to work remotely. Once the Executive Order expires lab supervisors must be onsite during regular testing hours and accessible after hours.

HCA Healthcare presented two models:

Proposed Model:

1. Obtain POC license from State
2. Acquire exemption for the tests included in the test menu below but not waived by the State of Tennessee
3. Point of Care Coordinator (POCC) would oversee 5-6 FSEDs

Response-

This scenario would limit the FSEDs to only performing tests approved as waived by the Medical Laboratory Board. The lab would also be required to have a state-licensed lab supervisor onsite during regular working hours.

Alternate Model:

1. Obtain or maintain current Laboratory License with a Licensed Supervisor on-site
2. Acquire exemption for the tests included in the test menu below but not waived by the State of Tennessee
3. Testing is performed at the POC with oversight by Supervisor (Supervisor could assist with lab testing during normal business hours)

HCA Healthcare requested to return to the January 2021 Board meeting.

Task Force Update

No motion was needed.

The Board's Administrative Office is in the process of assembling members for a task force to discuss digital imaging and remote work.

Review And Discuss The Licensure Of Medical Laboratory Directors:

1. Joe Weincek, PhD
Nashville, TN
Director: Chemistry

Dr. Weincek received his BA degree in Chemistry from Ohio State University, Columbus, OH in 2008. He received his Ph.D. in Clinical Chemistry from Cleveland State University, Cleveland, OH in 2015.

Dr. Weincek is certified by the National Registry of Certified Chemists (NRCC) as a Clinical Chemist through Dec. 31, 2022.

Dr. Weincek received his postdoctoral fellowship training at Vanderbilt University Medical Center in Nashville, TN from July 1, 2015-July 1, 2017.

Dr. Weincek is seeking licensure as a Director of Chemistry.

Motion: Dr. Calarco
Second: Mr. Fleming

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The license was approved.

2. Marc Rumpler, PhD
Addiction Labs of America, LLC
Brentwood, TN

Dr. Rumpler received his BS degree in Toxicology from Northeastern University, Boston, MA in 2001.

He received his MS degree and Ph.D. in Toxicology from

the University of Florida in Gainesville, FL 2008, and 2012 respectively.

Dr. Rumpler is certified by the National Registry of Certified Chemists (NRCC) as a Clinical Chemist and a Toxicological Chemist through 2022.

His post-doctoral fellowship was completed at the College of Medicine at the University of Florida from 2012-2013.

Dr. Rumpler is currently licensed as a TN Medical Laboratory Director of Chemistry and Toxicology.

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

After discussion, the Board decided to add the modifier "Limited Molecular COVID Testing" to Dr. Rumpler's Laboratory Director license.

Motion: Mr. Fleming

Second: Ms. Jolly

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Abstain
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The addition of the license modifier "Molecular Diagnostics Limited to COVID Testing" to Dr. Rumpler's license was approved.

Reports/Requests:

Board Director's Report

Sandra Bogard, MS, MT(ASCP) QLC^{cm}

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.

Recent updates include:

- Laboratory Facility Application
- New Emerging Technology list
- Director Credential list
- Waived testing list

Staffing updates:

- Taylor Carpenter, East TN Survey Supervisor, is retiring in January 2021.
- Middle TN Surveyor position and West TN Surveyor position are in the hiring process with interviews pending.

Board meeting dates for 2021 were presented.

Board terms that expire in December:

- Hospital Laboratory Manager-Ms. Patti Walton
- Independent Laboratory Manager-Dr. Mark Calarco
- Cytotechnologist-Dr. Keisha Burnett
- Medical Technologist-Ms. Tereyo Cox

Collaboration between the Medical Laboratory Board and the Communicable and Environmental Diseases and Emergency Preparedness Division (CEDEP) was discussed which involved the building of a database to facilitate better communication with all laboratories across the State of TN.

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

Motion to approve the report as given: Mr. Johnson
Second: Ms. Cox

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present

Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The report was accepted as given.

Board Attorney Report

Kyonzté Hughes-Toombs
Deputy General Counsel

Counsel Hughes-Toombs gave her report for the past quarter:

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

The personnel rule revisions are in the internal review process. The Board will vote on whether to send the rules through the “proposed rules” process, which does not require a rulemaking hearing.

Motion to accept the report as given: Ms. Briggs
Second: Dr. Calarco

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The report was accepted as given.

Request for Rule 1200-06-01 Rewrite
to be Submitted as Proposed Rules

The Board discussed approving the rewrite of Rule 1200-06-01 to go through as proposed rules without a rulemaking hearing.

Motion: Ms. Jolly
Second: Dr. Gibson

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The motion was approved.

Presentation of Proposed Rule
1200-06-01 Rewrite

The Board discussed the rewrite of regulation 1200-06-01-.21(1)(a)1. Qualifications and Duties of the Medical Laboratory Supervisor.

Motion to remove “subsequent to obtaining a doctoral degree” in paragraph one page 43. Also approved the addition of “ and (2) submit evidence of national certification, at the technologists level, by a national certifying agency that is recognized by the Board” at the end of paragraph one.

Motion: Mr. Johnson

Second: Dr. Gibson

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The motion was approved.

Regional Surveyor Reports:

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

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

East Tennessee Regional Office –Third Quarter 2020

Complaint Investigations: One (1) in process
One (1) unsubstantiated

Unsuccessful Proficiency Testing: Zero (0)

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

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

Middle Tennessee Regional Office –Third Quarter 2020

Complaint Investigations: One (1) unsubstantiated

Unsuccessful Proficiency Testing: Zero (0)

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

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

West Tennessee Regional Office –Third Quarter 2020

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: Dr. Calarco
Second: Mr. Fleming

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes

Carla M. Davis, MD Yes
Danielle Gibson, MD Yes
Jon Parham, DO Not Present
James A. Vaughn, MD Yes

Reports were accepted as given.

Board Ratifications Initial Facility Applications:

1. ADMA Bio Center Georgia, Inc.
5072 Clinton Highway
Knoxville, TN 37912
(Plasma Donor Center)

Specialties: Spun Hematocrit
Total Serum Protein

Laboratory Director: Nancy L. Witherspoon, DO
Geriatric Medicine

Surveyor: Fowlen Anders, MT Consultant I/ETRO

Motion: Mr. Fleming
Second: Ms. Briggs

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Gaye G. Jolly, MT Yes
Lynn Stewart Not Present
Paul Fleming, MT Yes
Michael Johnson, MT Yes
Keisha Burnett, SA Yes
Mark A. Calarco, DO Yes
Carla M. Davis, MD Yes
Danielle Gibson, MD Yes
Jon Parham, DO Not Present
James A. Vaughn, MD Yes

The license was approved.

2. EDP Biotech
6701 Baum Drive, Suite 110
Knoxville, TN 37919

Specialties: General Immunology

Laboratory Director: Gregory S. Ray, MD
ABP/Anatomic-Clinical Pathology

Surveyor: Taylor Carpenter, MT Consultant II/ETRO

Motion: Dr. Calarco
Second: Mr. Johnson

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The license was approved.

3. Harrogate Health Quick Draw
6650 Cumberland Gap Parkway
Harrogate, TN 37752
(Collection Station)

Specialties: Collection Station

Laboratory Director: Tommy Livesay, MD
Family Medicine

Surveyor: Taylor Carpenter, MT Consultant II/ETRO

Motion: Dr. Davis
Second: Dr. Burnett

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The license was approved.

4. Midsouth Wellness Collection
Station
6005 Park Avenue, Suite 704
Memphis, TN 38119
(Collection Station)

Specialties: Collection Station

Laboratory Director: Todd F. Brooks, MD
Obstetrics and Gynecology

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Dr. Calarco
Second: Dr. Davis

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The license was approved.

5. NeoVect Technologies, LLC
5142 Stage Road, Suite 101
Memphis, TN 38134

Specialties: Virology

Laboratory Director: Alex Ryder, MD, PhD
ABP/Clinical Pathology

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Dr. Burnett
Second: Mr. Johnson

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The license was approved.

6. Quest Diagnostics TB-LLC-Esoteric
5846 Distribution Drive

Specialties: Immunology-Esoteric

Memphis, TN 38141
(Esoteric Lab)

Laboratory Director: Charles R. Handorf, MD, PhD
ABP/Anatomic-Clinical Pathology

Surveyor: Debbie Haggard, MT Consultant II/WTRO

Motion: Mr. Fleming
Second: Dr. Gibson

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The license was approved.

Other Business/Discussion:

Election of Officers for 2021

Personnel and Education Committee Chairman-

Motion to nominate Ms. Leanne Briggs: Mr. Johnson
Second: Mr. Fleming

Board members responded by roll call.

Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The nomination was approved.

Full Board Chairman-

Motion to nominate Mr. Michael Johnson: Ms. Walton
Second: Dr. Davis

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Paul Fleming, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The nomination was approved.

Full Board Vice-Chairman-

Motion to nominate Mr. Paul Fleming: Ms. Cox
Second: Dr. Calarco

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Michael Johnson, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The nomination was approved.

Adjournment:

With no further business to discuss, the meeting was adjourned at 2:01 pm CDT.

Motion to adjourn: Mr. Johnson
Second: Mr. Fleming

Board members responded by roll call.

LeeAnne Briggs, MT	Yes
Tereyo M. Cox, MT	Yes
Gaye G. Jolly, MT	Yes
Lynn Stewart	Not Present
Michael Johnson, MT	Yes
Paul Fleming, MT	Yes
Keisha Burnett, SA	Yes
Mark A. Calarco, DO	Yes
Carla M. Davis, MD	Yes
Danielle Gibson, MD	Yes
Jon Parham, DO	Not Present
James A. Vaughn, MD	Yes

The meeting was adjourned.