

Tennessee Medical Laboratory Board Meeting
August 2016
Minutes

Date: August 18, 2016

Time 09:00 AM CDT

Location: Tennessee Department of Health
Division of Health Licensure and Regulation
Metro Center Complex, Iris Room, Ground Floor
665 Mainstream Drive
Nashville, TN 37243

Members Present: Cheryl Arnott, S.A.-Cytotechnologist, Board Chair
Mark A. Calarco, DO, Independent Lab Manager/Administrator
Carla M. Davis, MD-Pathologist
Jason S. Nolan, MD-Pathologist, Non-Educator
Tereyo M. Cox, MT-Medical-Technologist, General
Stephanie Dolsen, MT- Medical Technologist Supervisor
Michael Johnson, MT-Medical Technologist Generalist
Gaye G. Jolly, MT-Hospital Administrator Representative
Kathleen Kenwright, MT- Medical Technologist, Educator

Members Absent: Royce Joyner, MD-Pathologist Educator
Patti J. Walton, MT-Hospital/Lab Manager/Adm. Dir, Vice-Chair
Michael J. Wright-Citizen Representative

Vacant Position: Non-Pathologist Physician

Staff Present: Lynda S. England, Medical Technologist Consultant, Director
Nina V. Smith, Medical Technologist Consultant
Kyonzte Hughes-Toombs, ESQ, MBA, CHC, Deputy General, Office of General Counsel
Julia Daniels, Medical Technologist Consultant/ Surveyor, East Tennessee Regional Office
Taylor Carpenter, Medical Technologist Consultant/Surveyor, East Tennessee Regional Office
Richard Carroll, Medical Technologist Consultant/Surveyor, Middle Tennessee Regional Office
Greer Hinson, Medical Technologist Consultant/Surveyor, Middle Tennessee Regional Office
Karon Hathcoat, Medical Technologist Consultant/ Surveyor, West Tennessee Regional Office
Debbie Haggard, Medical Technologist Consultant/Surveyor, West Tennessee Regional Office

Staff Absent: All staff present.

CLIA Manager/Representative: Sandra Bogard, MT CLIA Manager

Presiding Officer: Cheryl Arnott, S.A.-Cytotechnologist, Chairman

Call To Order: The meeting was called to order at 9:02 am CDT by Board Chair Cheryl Arnott.

Introductions of Board Members: Board members and staff made their introductions to the record.
New Advisory Attorney: Kyonzte Hughes-Toombs

Introductions of Staff:

Quorum: Nine members of the Board were present which constituted a quorum.

Approve Minutes:

P & E Committee Meeting A **motion** to approve the April 20, 2016 Personnel & Education Committee minutes was made by: Mr. Johnson
Second: Ms. Kenwright
Committee Minutes: Approved.

Full Board Meeting A **motion** to approve the April 21, 2016 Board meeting minutes was made by: Ms. Kenwright
Second: Dr. Calarco
Board Minutes: Approved.

Board Reports:

Ratification of Initial Determinations of the P&E Committee Meeting: Ms. Kenwright reported the actions of the Board's Personnel & Education Committee meeting, August 17, 2016.
Motion to ratify Committee actions: Mr. Johnson
Second: Ms. Dolsen
Report ratified as presented.

Contested Cases

No contested cases were presented during this meeting.

Consent, Agreed, Compliance Orders & Letters of Reprimand

Consent Orders No consent orders were presented.

Agreed Orders No Agreed Orders were presented

Compliance Orders No Compliance Orders were presented

Letters of Reprimand No Letters of Reprimand were presented

Presentations to the Board:

**Tennessee Professional
Peer Assistance Program
(TNPAP):**

Ms. England gave the TNPAP report.

The statistical report for July 2, 2015 March 31, 2016 was presented to board members with no (0) individual monitored at this time. There was one (1) referral from an employer to this agency.

Motion to accept the TN PAP report: Ms. Kenwright
Second: Mr. Johnson
Report accepted as presented.

Note: Review of TNPAP materials via internet counts as clock hours toward continuing education credits. A certificate of completion documenting review Of these materials can be completed at the end of the internet session. Internet site: www.TNPAP.org

Financial Report

There was no change to the financial report from the April meeting; Ms. Vanessa Crutcher, Fiscal Officer, will give an updated report on the 2016 fiscal year during the October meeting.

No action taken on this matter.

(Copy of report on file in administrative office)

**Investigations Report
Nichelle Dorroh
Disciplinary Coordinator
Presentation/Discussion**

The investigations report was accepted as presented by Ms. Dorroh. There are two (2) complaints opened in April and one (1) complaint opened in June of this year. One (1) complaint was closed and two (2) complaints were resolved with letters of warning. The complaints currently on file represent: unqualified personnel working in the laboratory; unprofessional conduct and the use of drugs by an individual.

There were no questions or requests concerning the information as presented.

Motion To Accept Report: Ms. Kenwright
Second: Dr. Calarco
Report accepted as given.

Compliance Orders

There was no compliance orders from the Bureau of Investigations submitted for discussion during the meeting.

**Discuss, review, take action, if
needed, regarding but not limited to:**

Ratifications: The following items were presented to board members for ratification per staff, state surveyor or facility request:

Consider Rule Making for 1200-06-01-.1(22) and 1200-06-03-.08(d) (5) relative to pathologists reading slides/location of diagnosis.

This topic will be addressed during a task force meeting held August 25, 2016 with a report to be presented by the board chair during the during the October 20, 2016 quarterly board meeting.

No action taken on this matter.

Discuss QC Measures 1200-06-03-.09 in regards to CLIA IQCP January 01, 2016 implementation

Per previous board discussion the review of CLIA/IQCP was tabled until the appropriate information can be compiled for board review.

No board action taken on this matter.

Discuss Review of Fecal Microbiota Transplant (FMT) Process to include: Screenings, Donor Guidelines, Categories, etc.

Board members discussed and clarified the position of clinical laboratory operation in the performance of Fecal Microbiota Transplant (FMT) procedures within a hospital. After discussion, board members determined it would be more in order for this procedure to be performed in the pharmacy or the endoscopy suites as FMT is classified as a medical procedure and should not be performed within the laboratory arena. No action was taken other than clarification.

Discuss bedside testing procedures in long term facilities; mobile testing personnel and ultimately sending referral samples to a laboratory in North Carolina.

There was no representative from SKYY laboratory present during this meeting. No additional information was presented for discussion.

No discussion; no action taken on this matter.

**Representative: Daniel Turklay
In-House Counsel
Sky Laboratory
North Carolina**

Ratifications: The following items were presented to board members for ratification per staff, state surveyor or facility request:

1:

**CHI Memorial Hospital
2525 DeSales Avenue
Chattanooga, TN 37404-1102**

Exemptions for point of care testing procedures (POCT) in a licensed Facility

On January 28, 1997, and June 1, 2007 facility was granted an exemption by the board with only change to exemption request to quantify Charge Nurses to perform the tests. Charge nurses are RN's therefore no additional presentation is necessary for the performance to use the i-STAT instrument.

Request withdrawn: No action taken.

2:

**Jackson Madison County
General Hospital
620 Skyline Drive
Jackson, TN 38301**

Two (2) Requests:

1-To permit licensed Registered Nurse Anesthetists to perform and report acid/base, electrolytes, and hematocrit, hospital-wide. The instrument utilized in the performance of these tests is the Abbott i-STAT EG7+ cartridge.

Motion: Ms. Kenwright

Second: Mr. Johnson

Exemption Approved:

2-To permit licensed Registered Nurse Anesthetists to perform acid/base, electrolytes, glucose and hemoglobin utilizing the Simens Rapidpoint analyzer hospital-wide.

Motion: Ms. Dolsen

Second: Dr. Calarco

Exemption Approved.

3.

**TriStar Horizon Medical
Center
111 Highway 70 East
Dickson, TN 37055**

First exemption request was to permit Registered Nurses, Licensed Practical Nurses, and Paramedics to perform and report lactic acid analyses in the Full Service Emergency Department (FSED) utilizing the i-STAT instrument.

Motion: Ms. Dolsen

Second: Dr. Nolen

Exemption Approved.

Second Request: To permit Licensed Registered Nurses, Licensed Practical Nurses and Paramedics to perform and report Troponin in the Full Service Emergency Department (FESD) utilizing the i-STAT instrument and methodologies.

Motion: Dr. Davis

Second: Dr. Calarco

Request: Exemption Approved.

4. **Baptist Memorial Hospital for Women**
6625 Humphreys Blvd.
Memphis, TN 38120

This exemption request was for Respiratory Therapists (ABG-endorsed) to perform and report: pH, pCO₂, pO₂, sodium, potassium, chloride, Ca⁺, glucose, lactate, hematocrit, total hemoglobin, oxyhemoglobin, carboxyhemoglobin, methemoglobin, and oxygen saturation hospital wide.

Motion: Ms. Kenwright
Second: Dr. Calarco
Request: **Approved.**

**Direct more than three (3)
Laboratories**

No requests were made during the past quarter.

**RECEIVE REPORTS AND /OR
REQUESTS:**

Board Director's Report

Ms. England gave the board director's report for the quarter April 1, 2016 thru July 31, 2016.

The report included a statistical report of activities of licensure for personnel and laboratory facilities.

Motion to accept Director's report: Ms. Kenwright
Second: Dr. Davis
Report accepted.
(Copy of report is on file in the Administrative Office)

REINSTATEMENT OF LICENSES

No licenses to reinstate this quarter.

**ADDITIONS/DELETIONS TO THE
BOARD'S WAIVED TEST LIST**

LEGISLATIVE UPDATE

Public notice information from the 2016 legislative session was included in the report by Kyonzte Hughes-Toombs, Board Council.

**Office of General Counsel's
Report:**

**Kyonzte Hughes-Toombs
Deputy General Counsel**

There are no open cases in the Office of General Counsel.

The update of the Rules and Regulations Governing Medical Laboratory Personnel 1200-06-01 rewrite are still in internal review in the Office of General Counsel.

Motion: Ms. Kenwright
Second: Dr. Calarco
Report: Accepted As Presented.

**Review/Discuss Approval
Licensure of Medical Laboratory
Director**

Ayman Ibrahim, Ph.D.
Woodridge, IL 60517 Nashville, TN 37211
Director: Chemistry

Dr. Ibrahim was unable to make an appearance before the board because of a family emergency however board members did review his application seeking licensure as a laboratory director in clinical chemistry.

His qualifications include a B.S. and M.S. in biochemistry from Ain Shams University, Egypt. (1990; 1996)

Ph.D. in Biochemistry from Cairo University, Egypt. (2001)
M.S. Rush University, Chicago, IL in Biotechnology. (2011)

He has been a Fellow: Fulbright Fellowship, Wisconsin University, Lacrosse, WI (2007); International Cancer Technology Transfer Fellowship, Roswell Park Cancer Institute, Buffalo, NY. (2008)

Dr. Ibrahim is boarded by the National Registry of Certified Chemists in Clinical Chemistry. (December 31, 2016)

Motion: Ms. Johnson
Second: Ms. Dolsen
Directorship Approved

Ikhlas D. Darkhalil, Ph.D.
Erie, PA 16506
Director: Clinical Chemistry

Dr. Darkhalil holds a BA degree from the University of Missouri in Chemistry. (2008) and BLA in Liberal Arts from the University of Missouri (2008) with a Ph.D. in Analytical/Physical Chemistry from the University of Missouri obtained in 2014.

She trained at the University of Missouri, Kansas City Department of Chemistry from 2011-2014 with graduate research and as a Teaching Assistant.

Dr. Darkhalil is boarded by the National Registry of Certified Chemists (NRCC) with an expiration date of December 31, 2016.

Dr. Darkhalil was not present for the review and staff did not have the completion of the criminal background check which would have completed the file.

This application was tabled until the October 2016 meeting.

Samantha Bouldin, Ph.D.
Murfreesboro, TN 37128
Director: Clinical Chemistry

Dr. Bouldin, obtained a BS Degree from TN Technological University, Cookeville, TN in 2005 and a Ph.D. in Chemistry from the University of South Carolina at Columbia, in 2010.

Her postdoctoral fellowship was in the Department of Pathology, Microbiology and Immunology at Vanderbilt University Medical Center, Nashville, TN from 2010-2014.

Her training was obtained at Cairn Diagnostics Brentwood, TN in Gastric Emptying Breath Analysis 2014-2016.

Dr. Bouldin is boarded by the National Registry of Certified Chemists (NRCC) Clinical Chemistry Technologist with an expiration date of December 31, 2016.

After board review, this application was denied based on the completion of an NRCC examination at the Clinical Chemist level because the clinical chemistry technologist level does not qualify her for directorship in clinical chemistry.

Motion: Ms. Kenwright

Second: Ms. Dolsen

Application: Denied

Regional Surveyors Reports

Complaint Investigations and proficiency testing (East, West and Middle TN)

ETRO Report
Julia Daniels

East TN Regional Office: Taylor Carpenter for the second quarter of 2016, (April-July ,2016).

Unsatisfactory/ Unsuccessful Proficiency Testing: One (1)

Analyte: CKMB Plan of Correction: Acceptable.

Complaint Investigations: Zero (0)

MTRO Report
Richard Carroll

Middle TN Regional Office: First quarter of 2016, (April-July 2016).

Unsatisfactory/Unsuccessful Proficiency Testing:

Two (2)-Both with acceptable Plan of Correction.

Zero (0) Complaint Investigations

WTRO Report
Karon Hathcoat

West TN Regional Office: First quarter of 2016, (April-July 2016).

Unsatisfactory/Unsuccessful Proficiency Testing: One (1)

Complaint Investigations: Zero (0)

Move to accept reports : Ms. Dolsen

Second: Mr. Johnson

Regional Reports accepted as presented.

**Board Ratification of Laboratory
Initial License:**

**Marsh Regional Blood Center-
Washington County
2428 Knob Creek Road
Johnson City, TN 37604**

Medical Laboratory Director

Don E. Asberry, M.D.
Anatomic/Clinical Pathology

Specialties:

Blood Donor Center

Surveyor:

Julia Daniels, MT
Consultant 2/Surveyor ETRO

Motion: Mr. Johnson

Second: Ms. Dolsen

License Approved.

**Abcodia Laboratories
3945 Hacks Cross Road #201
Memphis, TN 38125**

Medical Laboratory Director:

Carolina Montes, M.D.
Anatomic/Pathology

Specialties:

Clinical Chemistry

Surveyor:

Karon Hathcoat, MT
Consultant 2/WTRO

Motion: Ms. Kenwright

Second: Mr. Johnson

License Approved

**Reliable Mobile Labs, LLC
1645 Murfreesboro Pike #1
Murfreesboro, TN 37217**

Medical Laboratory Director

Louis B. Brill II, M.D.
Anatomic/Clinical Pathology

Specialties:

Bacteriology, Hematology,
Clinical Chemistry

Surveyor:

Richard Carroll, MT
Consultant II/MTRO

Motion: Ms. Dolsen

Second: Ms. Jolly

License Approved

**Sano Informed Prescribing, Inc.
393 Nichol Mill Lane #34
Franklin, TN 37067**

Medical Laboratory Director: Tara Chang, M.D.
Anatomic/Clinical Pathology

Specialties: Toxicology

Surveyor: Richard Carroll, MT
Consultant II/MTRO
ESOTERIC LABORATORY

Board members reviewed this application for licensure as an esoteric laboratory but after a lengthy discussion members were unable to agree that all results reported by this applicant were esoteric in nature. Reverting to Rule 1200-06-03-.22 (1)(c) and (3)(a) (b) board members decided to table their final decision until additional information could be provided by the applicant and an application re-review could take place.

**Motion To Table: Dr. Calarco
Second: Mr. Johnson
Item tabled until the October
2016 meeting.**

**BioReference Laboratories, Inc. @
Women's Medical Associates
2201 Murphy Avenue # 110
Nashville, TN 37203**

Medical Laboratory Director: Rajendra Persad, M.D.
Anatomic/Clinical Pathology

Specialties: Collection Station

Surveyor: Richard Carroll, MT
Consultant II/Surveyor MTRO

**Motion: Mr. Johnson
Second: Dr. Nolan
License Approved**

**Maury Regional Hospital
Toxicology Laboratory
1224 Trotwood Avenue Bldg. D
Columbia, TN 38401**

Medical Laboratory Director Charles B. Bramlett, Jr., M.D. D.
Anatomic/Clinical Pathology

Specialties: Toxicology

Surveyor: Richard Carroll, MT
Consultant II/Surveyor MTRO

**ESOTERIC LABORATORY
APPLICLATION WITHDRAWN
BEFORE MEETING**

**CirQuest Lab, LLC
955 Madison Avenue
Memphis, TN 38103**

Medical Laboratory Director Frank White, M.D.
Anatomic/Clinical Pathology
Hematology

Specialties: d-Dimer Technology

Surveyor: Karon Hathcoat, MT
Consultant II/Surveyor WTRO

Motion: Ms. Jolly
Second: Ms. Kenwright
Initial License Approved.

OTHER BUSINESS:

Item 1

**Per Surveyor/Director
Request for Board Review**

Board clarification of items relating to operation of administrative office technicalities:

**A. Continuing
Education**

Staff requested clarification on the following:

Applicant: Director of Toxicology

Boarded: Forensic Pathology
Anatomic Pathology

Guidelines needed for qualification: Boarding
Board members addressed the necessity of completion of the requirements for continuing education in that the continuing education events, must be within the two (2) years preceding the renewal event to be acceptable per 1200-06-01-.12 (1) for compliance with the audit process.
Discussion only.

Statement of Next Meeting

The next meeting will be held on October 20, 2016.

Record of Adjournment

With no further business to discuss the meeting was adjourned at 1:30 pm CDT.

Motion: Ms. Kenwright
Second: Dr. Calarco
Meeting Adjourned.

09/13/2016