

Tennessee Medical Laboratory Board
January 18, 2018
Minutes

Meeting Date: January 18, 2018

Time: 9:00 AM CST

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

Members Present:

Patti J. Walton, MT-Hospital/Lab Manager/Adm. Dir.,
Chair
Mark A. Calarco, DO, Independent Lab
Manager/Administrator
Tereyo M. Cox, MT-Medical-Technologist, General
Carla M. Davis, MD-Pathologist
Jason S. Nolan, MD-Pathologist, Non-Educator
Jon Parham, DO Non-Pathologist Physician
Michael Johnson, MT-Medical Technologist Generalist
Gaye G. Jolly, MT-Hospital Administrator

Members Absent:

Keisha Burnett, S.A.-Cytotechnologist
Stephanie Dolsen, MT Supervisor Vice-Chair
Kathleen Kenwright, MT- Medical Technologist, Educator
Royce Joyner, MD-Pathologist Educator
Michael J. Wright-Citizen Representative

Vacant Position: All board positions filled.

Staff Absent: All staff present for the meeting.

CLIA Manager/Representative: Absent: Sandra Bogard, MT CLIA Manager

Presiding Officer: Patti Walton, MT, Chair

Call To Order: The meeting was called to order at 9:02 am CST by
Board Chair Patti J. Walton.

Introduction of Board Members/
Staff: Board members and staff made their introductions to
the record.

Quorum: Eight board members were present which constitutes a quorum.

Approve Minutes

P & E Committee Meeting

A motion to approve the October 18, 2017 Personnel & Education Committee minutes was made by Dr. Calarco.
Second: Ms. Cox.
Committee Minutes: Approved

Full Board Meeting

A motion to approve the October 19, 2017 board minutes was made by Ms. Jolly.
Second: Dr. Calarco.
Board Minutes: Approved

Board Reports:

Ratification of Initial Determinations

P&E Committee Meeting:

Ms. Walton* reported the actions of the Personnel & Education Committee meeting, January 17, 2018

Motion to ratify Committee actions: Mr. Johnson.
Second: Dr. Calarco.
Report: Accepted as presented by Ms. Walton.

*Ms. Kenwright was unable to be present for the committee meeting because of weather related circumstances, however she did participate in the meeting via conference call.

Ms. Walton chaired the committee meeting and also gave the meeting follow-up report.

Consent, Agreed
Compliance Orders
Letters of Reprimand

Consent Orders

No consent orders presented.

Agreed Orders

No Agreed Orders presented.

Compliance Orders

No Compliance Orders presented.

Letters of Reprimand

No Letters of Reprimand presented.

Presentations to the Board:

Tennessee Professional Peer Assistance
(TnPAP):

Mr. Mike Harkreader, MS,RN,CARN
TnPAP Director

The statistical report for July 1, 2017-December 27, 2017 was presented with two (2) individuals monitored during this time period.

One individual was referred for a substance abuse disorder while the other individual was referred from a treatment facility.
This individual declined services; no practice act violations here.

One of the referrals declined treatment.

Motion to accept the TnPAP report: Dr. Calarco.
Second: Dr. Davis
Report accepted as given.

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 session. Internet site: www.TNPAP.org

Financial Report
Noranda M. French
Presentation/Discussion

Ms. French gave the Mid-Year financial report during the October meeting to include expenditures for the year-end FY17 year.

No updates are and will not be prepared for board review until the mid-year financial statement is released later this year.

No board action taken on this matter

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

Investigations Report
Lori L. Leonard
Disciplinary Coordinator
October 2017-December 2017

Personnel: Four suspensions, one probation, two currently under board order, one TSAC suspension, current monitoring status. Four complaints closed on to OBG for CE violations.

Laboratories: Six new complaints, one complaint currently monitored. Four complaints closed-two with a letter of warning. Currently monitoring one complaint.

Training Programs: No complaints for this period.

Motion To Accept Report: Dr. Calarco.
Second: Dr. Parham.

The investigations report was accepted as given by Ms. Leonard.

Legislative Report
DOH Commissioner's Office
Legislative Liaison
Legislative Affairs

No report was given during the meeting because legislative actions effecting the practice of laboratory medicine were not promulgated during the past quarter.

Discuss, review, take action,
if needed:

Ratifications:

Board review per staff, surveyor,
facility request

Autoverification of Laboratory Results*

At the request of regional surveyor, Richard Carroll, board members revisited the autoverification of laboratory test results for any possible revisions.

On July 17, 2003 a memorandum was sent to all laboratories licensed under the Tennessee Medical Laboratory Act-Tennessee Code Annotated §68-29-101 concerning the definition, and operations pertaining to autoverification pertaining to anatomic and clinical laboratory testing in this state.

Post discussion, board members decided to make no change in this 2003 autoverification memorandum and therefore not to promulgate additional rules.

Motion: Mr. Johnson

Second: Ms. Cox
Motion Approved.

- See Attachment 1

Necessity of Licensure

NeoGenomics Laboratories, Inc.
Nashville, TN

Dr. Christopher Mixon appeared before board members to have them determine the necessity of licensure to perform and report reading of pathology information in his home environment. Electronic methodology (format) is utilized in this process with no actual microscope, no slide prep utilized in the reading process, only computer transmissions via internet cloud and his reporting of laboratory results.

Dr. Mixon wants to have the main laboratory's name on the report and not his home address, because he is working as a clinical/technical consultant in the performance of his duties. Results are released after his primary review (report) with the finalization of the report by Dr. Mixon.

Two separate CLIA licenses are required (one for the business) and one for his home testing environment.

After discussion it was determined the definition of a laboratory is set by the Tennessee Code Annotated § 68-29-103 (9) and would have to be changed in some manner, however based on the current statute: a state license is required under these operational circumstances.

After discussion board members decided to table this application on necessity of state licensure until further research is performed concerning certification, then revisit at that time.

Motion: Dr. Calarco.
Second: Dr. Parham.

Abstain: Dr. Davis.

Surveyor Clarification:

Mary Hamblen, regional surveyor, asked for clarification on the following:

Facilities licensed by the state as collection stations are performing urine drug screening testing procedures on children via parental request then giving the screening results to the parent.

The parent then has the ability to take the results of these urine screens to a physician to seek treatment for the minor.

1200-06-03-.18(1) states: "Facilities deemed as collection stations shall perform no clinical testing procedures on site."

After discussion board members determined this urine drug test screening procedure constitutes a diagnostic test and does not comply with the intent of the state's definition of any operational performance in these licensed facilities.

These testing procedures must not be performed in collection stations, if the urine drug testing screens other than for employment purposes are continued, an application for a state license is in order and compliance with Rules and Regulations Governing Medical Laboratories 1200-06-03.

Motion: Mr. Johnson.

Second: Dr. Calarco.

Motion Approved.

Ratifications:

Point of Care Exemptions

1200-06-03-.16(1)

1. TriStar Hendersonville
Medical Center
355 New Shackle Island Road
Hendersonville, TN 37075
Kim Wilburn, Director
Laboratory Services

This exemption request was for Respiratory Therapists (ABG-endorsed) to perform and report blood gas analyses to include: pH, pCO₂, pO₂, HCO₃, BE, O₂ Saturation and Carboxyhemoglobin throughout the facility. The instrument and methodology utilized is the Siemens Rapid Point 500.

Note: Board members requested modified manufacturer SOP with the omission of analysis of pH on body fluid utilizing this Instrument. That documentation can be sent to the

administrative office to be placed in facility file.

Motion: Dr. Nolan.
Second: Dr. Calarco.
Exemption granted.

2. Erlanger Medical Center
975 East Third Street
Chattanooga, TN 37043
Rita Stewart
Lab Support Services

Point of care exemption requests from this facility:

1-permits contractual personnel (licensed nurse practitioners, and licensed midwives) to perform and report sodium, potassium, chloride, CO₂, Ca⁺, glucose, BUN, creatinine, lactate, hematocrit, blood gases with calculated parameters, and troponin analyses in the Obstetric Emergency Department utilizing the i-STAT.

Motion: Ms. Jolly.
Second: Dr. Parham.
Exemption: Approved

2-permits contractual personnel (licensed nurse practitioners and licensed midwives) to perform and report KOH/saline wet mounts in the Obstetric Emergency Department.

Motion: Dr. Calarco.
Second: Dr. Davis.
Exemption: Approved

3-permits contractual personnel (licensed nurse practitioners and licensed midwives) to perform Fern Testing procedures on amniotic fluid in the Obstetric Emergency Department.

Motion: Dr. Calarco.
Second: Mr. Johnson.
Exemption: Approved.

3. Baptist Memorial Hospital
6019 Walnut Grove Road
Memphis, TN 38120
Karen S. Clark, BS
Point of Care Supervisor

This point of care exemption request permits Registered

Nurses and Radiology Technologists to perform and report creatinine analyses in the outpatient and inpatient Radiology Department utilizing a non-CLIA waived test procedure on the i-STAT instrument.

Note: Request tabled until the April 19, 2018 board meeting.

No action taken by board members.

4. Johnson City Med. Center
400 N. St. of Franklin Rd
Johnson City, TN 37604
Catherine Greer, MT
Point of Care Coordinator

This facility requested the following point of care exemptions from the laboratory board:

1-permit Licensed Registered Nurses, Perfusionists, Licensed Practical Nurses, CRNA's, Cardiovascular Technologists, and Radiologic Technologists (Diagnostic Imaging Techs) to perform ACT-C utilizing the i-STAT instrument.

The locations: Perioperative Areas (Operating Rooms, Open Heart Operating Room, Operating Holding Areas, Staging and Special Procedure Areas, Cath Laboratory, and Interventional Holding Areas.

Note: i-STAT procedures were not included with the request but later submitted to the administrative office and included with the original request. This request added personnel not previously exempted for these point of care testing procedures.

Motion: Mr. Johnson.
Second: Dr. Calarco.
Exemption granted.

2-permits Licensed Registered Nurses, Perfusionists, Licensed Practical Nurses, CRNA's, Cardiovascular Technologists, and Radiologic Technologists (Diagnostic Imaging Techs) to perform and report PT/INR analyses on the Hemochron-Elite in the Perioperative Areas to include: Operating Rooms, Open Heart Operating Room, Operating Holding Areas, Staging Special Procedure Areas, Cath Laboratory, and Interventional Holding Areas.

Motion: Mr. Johnson.
Second: Dr. Calarco.
Exemption approved.

3-permits Licensed Perfusionists to perform and report PT/INR on the Hemochron-Elite in the Perioperative

Services Open Heart Arena. (change from Hemochron Response ACT-C)

Motion: Dr. Calarco.
Second: Mr. Johnson.
Exemption approved.

4-permits Licensed Registered Nurses to perform and report PT/INR results in the Emergency Department on the Hemochron-Elite. (Change from the i-STAT)

Motion: Mr. Johnson.
Second: Dr. Calarco.
Exemption approved.

5-Regional One Health
877 Jefferson Avenue
Memphis, TN 38103
Elaine Pickens
Point of Care Coordinator

The facility presented these two requests for point of care exemptions:

1-permits Registered Nurses, Licensed Practical Nurses, CRNA's, and MCTII's(EMT's) to perform and report PT/INR and APTT testing procedures on the Hemochron Signature Elite in the CCA/Shock Trauma and the Trauma Unit utilizing citrated blood.

Motion: Dr. Davis.
Second: Dr. Parham.
Exemption Approved.

2-permits Registered Nurses and Nurse Practitioners to perform and report urine drug screens in the Plastic Surgery Center and the Laser Center utilizing the Blue Rapid Screening Cup.

Motion: Dr. Calarco.
Second: Dr. Parham.
Exemption granted.

Direct 3+ Labs
1200-06-03-.13(5)

1-Henry D. Edwards, M.D.
Department of Pathology
St. Thomas Midtown Hospital
Nashville, TN 37336

Dr. Edwards currently is the medical laboratory director of the following hospital laboratories:

1-LabPlus St. Thomas River Park -McMinnville, TN 37110.

2-LabPlus St. Thomas Highlands -Sparta, TN 38583.
3-LabPlus St, Thomas Dekalb -Smithville, TN 37166

Dr. Edwards appeared before the board and requested an exemption to Rules Governing Medical Laboratories 1200-06-03-.13(5) to direct a fourth laboratory:

LabPlus St. Thomas Stones River-Woodbury, TN 37190.

After discussion members agreed to grant the exemption to direct a 4th laboratory following a motion by Mr. Johnson.

Second to the motion: Ms. Jolly.

Abstain: Dr. Davis

2-James W. Denham, M.D., MBA, FCAP
Sullivan and Partners Laboratory
Kingsport, TN 37660

Dr. Denham currently serves as the medical laboratory director for the following licensed facilities:

1-Sullivan and Partners-Kingsport, TN 37660.
2-Integralabs MDG Incorporated-Piney Flatts, TN 37686.
3-Resolve Diagnostics-Franklin, TN 37064

Dr. Denham requested the addition of a fourth laboratory under his direction:

Integralabs MDG Incorporated-Piney Flatts, TN 37686.
Esoteric Laboratory: Esoteric Toxicology

After discussion board members granted this exemption request to direct a 4th laboratory.

Motion: Dr. Nolan.

Second: Dr. Davis.

Reports/Requests
Board Director's Report
Lynda S. England BS MT(ASCP)

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

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

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

Board Attorney Report
Kyonzté Hughes-Toombs
Deputy General Counsel

Counsel Hughes-Toombs gave her report for the past quarter:
No cases were reviewed in investigations. The re-write of the Rules Governing Medical Laboratory Personnel 1200-06-01 are still under internal review.
Motion: Ms. Jolly.
Second: Ms. Cox.

Report approved as given.

Reinstatement of License

No licenses were presented for reinstatement this quarter.

Additions/Deletions Board's Waived Test List

Chattanooga CARES
Dr. Jay Sizemore
Chattanooga, TN 37403

Dr. Sizemore, representing Chattanooga CARES, presented a request for the addition of the Trinity Biotech Syphilis Health Check Kit. This test kit represents a rapid qualitative screening test utilized in the detection of the *Treponema palladium* (spirochaete-bacteria) (syphilis) utilizing whole blood samples, making the process CLIA waived.

This test serves as an initial screening test utilized in conjunction with other laboratory tests and clinical findings to assist with the diagnosis of a syphilis infection.

Test screens are performed by the prevention/education trained staff from Chattanooga CARES and the also East Tennessee State University Center of Excellence.

These screenings provides greater access to those individuals in rural areas and/or hard-to-reach high risk populations that may or may not can utilize clinical settings.

This operation works in tandem with the Department of Health's HIV/STD/AIDS division to coordinate agencies and public screens for Departmental health fair events. After discussion board members agreed to add this test

to their approved test list for health fairs and health screens on a motion by Mr. Johnson.

Second: Ms. Jolly.

Addition: Approved.

Licensure of Medical
Laboratory Director

1-Vishwananthan Huchtagowder, Ph.D.
Maryville, TN 37804

Dr. Huchtagowder received his BS degree from Bharathiar University, India and his MS degrees from Bharathidasan University, India with both degrees in Zoology.

His Ph.D. was obtained from Bharathiar University, India in Environmental Sciences-Human Genetics.

Dr. Huchtagowder was a Fellow associated with the University of Hawaii in Human Genetics and the Washington University School of Medicine, in St. Louis MO, Department of Pathology and Immunology in Clinical Genomics.

The applicant is currently certified by the American Board of Medical Genetics and Genomics in Cytogenetics and Genomics as of September 2017.

Dr. Huchtagowder appeared before board members to respond to questions and after discussion, he was granted a license as a Director of Cytogenetics.

Motion: Ms. Jolly.

Second: Dr. Davis.

Approved: Director Cytogenetics.

Note: This candidate also sought licensure as a director of molecular diagnostics but did not successfully challenge the national board examination.

Rules and Regulations 1200-06-01-.13(3) states the "Individuals who possess a state laboratory personnel license in one category will not be eligible for a temporary license in a different category." Therefore Dr. Huchtagowder is not eligible for another temporary

license for the molecular diagnostics national examination.

His practice is currently limited to those tests (molecular included) that fall under the category of Clinical Cytogenetics.

2- Charbel Abou-Diwan, Ph.D.
Scottsdale, AZ

Dr. Abou-Diwan appeared before the board to respond questions from members. He obtained his BS degree at the American University of Beirut in Medical Laboratory Technology and Ph.D. in Clinical-Bio analytical Chemistry from Cleveland State University, Cleveland, OH. Fellowship studies were completed at Emory University School of Medicine in Clinical Chemistry.

Dr. Abou-Diwan is certified by the America Board of Clinical Chemistry (2012) and currently is in active status until December 31, 2018.

After discussion, board members granted a license as Director of Chemistry on a motion made by Dr. Nolan.
Second: Dr. Calarco.
Approved.

3- Yan Zou, Ph.D.
Smyrna, GA 30080

Dr. Zou receiver her BS from the University of Science and Technology of China (Chemistry), her MS from Miami University Oxford, OH(Chemistry) and her Ph.D. from North Carolina State University in Raleigh NC (Chemistry).

Her clinical experience was obtained at Castle Medical, LLC, Smyrna, GA from 2013 to the present date.

Dr. Zou is currently boarded by the National Registry of Certified Chemists (NRCC) as a toxicological chemist until December 2020.

Note: Dr. Zou was unable to appear before the board because of bad weather, however the file was in order with no additional questions presented by members.

After discussion board members agreed to license Dr. Zou as a Director of Toxicology on a motion by Dr. Calarco.
Second: Mr. Johnson
Approved:

Regional Surveyors Reports:
Complaint Investigations
Proficiency Testing Events

Regional Offices:
East, Middle, West Tennessee

ETRO Report
Taylor Carpenter, MT
Consultant/Surveyor

East TN Regional Office: October 01-December 31, 2017

Complaint Investigations: Zero

Unsuccessful Proficiency Testing:
One first unsuccessful PT event for pCO2 with an acceptable plan of correction provided to the surveyor.

2nd Unsuccessful PT Event: Zero

MTRO Report
Richard Carroll, MT
Consultant/Surveyor

Middle TN Regional Office: October 01-December 31, 2017

Complaint Investigations: Zero
Unsuccessful Proficiency Testing:
Two facilities were reported with a first unsuccessful PT.

2nd Unsuccessful PT Event: Zero

WTRO Report
Debbie Haggard, MT
Consultant/Surveyor

West TN Regional Office: October 01-December 31, 2017

Complaint Investigations: Zero

First Unsuccessful Proficiency Testing : Zero
Second Unsuccessful Proficiency Testing: One

Motion to accept regional surveyor reports: Mr. Johnson.
Second: Dr. Calarco.

All surveyor reports accepted as presented.

Board Ratifications
Initial Facility Applications

IVF Laboratories of Nashville
d.b.a. Ovation Fertility
1725 Medical Center Parkway #200
Murfreesboro, TN 37219

Specialties: Hematology, Endocrinology, Andrology

Laboratory Director: Melanie R. Freeman, M.D.
American Board of Bioanalysis
HCLD-Clinical Chemistry

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

Integral Labs MDG Incorporated
136-A Industrial Park Road
Piney Flatts, TN 37686

Specialties: Esoteric Toxicology

Laboratory Director: James W. Denham, M.D.
Anatomic/Clinical Pathology

Motion: Dr. Calarco.
Second: Ms. Cox.
License Approved.*

*To be revisited during the April 19, 2018 meeting.

IQuity, Inc.
111 10th Avenue South
Suite 100
Nashville, TN 37203

Specialties: Molecular Diagnostics

Laboratory Director: Mary Mayo, Ph.D., BCLD, ABB
Director-General

Motion: Mr. Johnson.
Second: Ms. Davis.
Licensed Approved.

Specialties: Spun Hematocrit & Total Serum Protein

Laboratory Director: Suzanne Baker, M.D.
Family Practice

Motion: Ms. Jolly.

Second: Mr. Johnson.
License Approved.

CQuentia NGS, LLC
3740 Business Drive Ste.100
Memphis, TN 38125

Specialties: Molecular Diagnostics

Laboratory Director: Ryan Brock Neil, Ph.D., BCLD, ABB
Director-General

Motion: Mr. Johnson.
Second: Ms. Jolly.
License Approved.

Biolife Service, LP
540 Pleasant Grove Road
Mount Juliet, TN 37122

Specialties: Plasma Donor Center
Total Protein, Hematocrit

Laboratory Director: Alberto Cadena, M.D.
OB/GYN

Motion: Dr. Calarco.
Second: Dr. Parham.
License Approved.

Laboratory Corp. of America
205 Hospital Drive Suite Q
McKenzie, TN 38201

Specialties: Hematology, Clinical Chemistry, Urinalysis,
Endocrinology, Toxicology, Infectious Mono
Screen, KOH, Wet Prep, RSV, UCG

Laboratory Director: Cynthia Carruth, M.D.
Anatomic/Clinical Pathology

Motion: Ms. Jolly.
Second: Mr. Johnson.
License Approved.

Discussion:

Two items were presented for board
clarification/discussion during this meeting:

1-Board members were asked to clarify the regulation of collagen as tissue product as related to compliance with the Tennessee Medical Laboratory Act §68-29-101.

Tissue regulatory agencies define this collagen-type item as “tissue” while other agencies do not classify as such. The inquirer wanted to obtain directive as to state rules for compliance with Joint Commission’s regulations (TJC).

Research of other boards rules and regulations by advisory council, and staff could not determine other regulations existed concerning this collagen-type product usage and disposal other than those of TJC.

After open discussion, board members and advisory council suggested the questioning entity retain and consult their legal department for whatever rules may or may not be applicable to the tissue-process under these circumstances.

No further action was taken on this matter.

2-A licensed hospital in Tennessee requested guidance concerning regulation oversight of a community mobile van per operation/compliance with the Rules and Regulations Governing Medical Laboratories 1200-06—03.

This board does not license mobile entities but does license fixed locations where the mobile units are home-based.

After discussion, board members determined the licensed clinical laboratory located within the hospital that is associated with the van’s operations must assume the responsibility for operations.

Regulations promulgated for Board Approved Waived Testing procedures 1200-06-03-.17 would apply to these clinical health screens/health testing events. The medical director for the hospital’s clinical laboratory would assume responsibility for these mobile clinical testing operations.

No further board action was taken.

Board officers were elected for the 2018 calendar year:

Board Chair: Patti Walton, MT

Nominated by Dr. Davis.

Second: Ms. Jolly

No other nominations for board chair.

Unanimous vote for approval.

Board

Vice-Chair: Stephanie Dolsen, MT*

Nominated by: Ms. Jolly.

Second: Dr. Calarco.

No other nominations for board chair.

Unanimous vote for approval.

*Ms. Dolsen declined acceptance of vice-chair because of other commitments.

Nominations for board vice-chair will be held during the April 19, 2018 meeting.

Personnel & Education Committee Chair:

Kathy Kenwright, MT

Nominated by: Dr. Calarco.

Second: Ms. Jolly.

Unanimous vote for approval.

Ms. Kenwright did not attend the meeting because of weather related issues but accepted the chair duties via email after later in the next week.

Statement of Next Meeting:

The next meeting will be April 19, 2018, and is scheduled to begin at 9 AM CDT in the Iris Conference Room, Ground Floor, MetroCenter Complex 665 Mainstream Drive Nashville, TN 37243.

With no further business to discuss, the meeting adjourned at 1:08 pm CST.

Motion to adjourn: Dr. Parham.

Second: Mr. Johnson.

Meeting Adjourned.