

**Tennessee Medical Laboratory Board Meeting  
October 2015  
Minutes**

**Date:** October 15, 2015

**Time** 09:02 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, Chairman  
Stephanie Dolsen, Medical Technologist, Supervisor, Vice Chair  
Kathleen Kenwright, Medical Technologist, Educator  
Carla M. Davis, MD, Pathologist  
Tereyo M. Cox, Medical Technologist, General  
Mark A. Calarco, DO Independent Lab Manager/Administrator  
Michael Johnson, Medical Technologist Generalist  
Patti J. Walton, Hospital/Lab Manager/Adm. Dir  
Michael J. Wright-Citizen Representative

**Members Absent:** Royce Joyner, MD, Pathologist Educator  
Jason S. Nolan, MD, Pathologist Non Educator  
VACANT: Non-Pathologist Physician  
VACANT: Hospital Administrator

**Staff Present:** Lynda S. England, Medical Technologist Consultant, Director, TMLB  
Devin Wells, Deputy General Counsel, 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  
Angie Sneed, Medical Technologist Consultant/Surveyor, Middle Tennessee Regional Office  
Mary Hamblen, Medical Technologist Consultant/Surveyor, West Tennessee Regional Office  
Karon Hathcoat, Medical Technologist Consultant/ Surveyor, West Tennessee Regional Office

**Staff Absent:** VACANT: Medical Technologist Consultant-Administrative Office

**CLIA Manager/Representative:** Sandra Bogard, CLIA Manager

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

**Call To Order:** The meeting was called to order at 9:05 am CDT by Chair Cheryl Arnott.

**Introductions of Board Members:** Board members and staff made their introductions to the record.  
New Board Member: Michael J. Wright-Citizen Representative

**Quorum:** At least seven members of the Board were present which constituted a quorum.

**Approve Minutes:**

**P & E Committee Meeting** A **motion** to approve the July 15, 2015 Personnel & Education Committee minutes was made by: Ms. Kenwright  
**Second:** Ms. Dolsen  
**Committee Minutes Approved**

**Full Board Meeting** A **motion** to approve the July 16, 2015, Board meeting minutes was made by: Dr. Davis  
**Second:** Ms. Walton  
**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, October 15, 2015.

**Motion to ratify Committee actions:** Ms. Walton  
**Second:** Mr. Johnson

Report ratified as presented.

**Contested Cases** No Contested Cases were presented.

**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):** Mr. Mike Harkreader, Executive Director of TNPAP presented the TNPAP Report.

Ms. England gave the report in the absence of Mr. Harkreader. The statistical report for July 1, 2014 to September 30, 2015 presented to board members showed zero (0) individuals being monitored. There were zero (0) referrals. No activity of record was noted on this report during the past three months. Board members discussed how to more efficiently utilize this agency for medical laboratory personnel. It was suggested that information about the advocacy agency be placed in each individual and facility renewal to more familiarize medical laboratory professionals and hospital/health care resource (HR's) departments of the availability of this service.

Utilized as discussion only: no report made.

*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](http://www.TNPAP.org)*

## **Financial Report**

The financial report had not changed from the April meeting when Ms. Tittle's verbal presentation was given to board members. Because there were no changes noted within the report the document was accepted as presented during the April 2015 quarterly meeting.

No Action Taken

Report accepted as presented in April 2015.

## **Investigations Report Nichelle Dorroh Presentation/Discussion**

There were seven (7) new complaints in September which were categorized as unprofessional conduct most of which were related to continuing education violations connected with divisional audit of personnel.

There were no questions or requests concerning the information presented.

**Motion:** Ms. Kenwright

**Second:** Ms. Walton

Report accepted.

## **Compliance Orders**

*There were no compliance orders discussed during the meeting.*

## **Q8 Necessity of Licensure for American Esoteric Laboratory Memphis, TN 38134**

### **Two Sites/ One License**

Board members reviewed a request with and by Dr. David Smalley, Company President, relative to the following circumstances:

American Esoteric Laboratory (AEL) licensed and certified laboratory located on ground floor at 80 Humphreys Avenue, Memphis TN.

Boston Baskin Oncology Clinic is located on the 3<sup>rd</sup> floor of the same building.

AEL acquired space within the clinic to receive specimens and utilize a cell counter to analyze Complete Blood Counts (CBC's) on patients scheduled for chemotherapy.

Dr. Smalley requested board review and determination as to the applicability of this adjacent site falling under the umbrella of the currently licensed AEL laboratory on the ground floor with the same CLIA number and state license number.

Discussion revealed the previous laboratory at the 3<sup>rd</sup> floor site had its own CLIA number and was licensed by the state. When operations ceased, these files were closed via notification to state and federal licensure/certification agencies.

An on-site survey performed in April 2015, determined the necessity of licensure because of location in the Oncology Clinic, physician's office arena. Discussion also revealed the laboratory performed tests not only for the single physician's office but for other physician offices located throughout the building, and at time overflow testing from the main laboratory on the ground floor.

The 3<sup>rd</sup> floor laboratory currently is operating without a CLIA number and state license because clarification of previously submitted documentation to the CLIA office appears to be confusing to all participants associated with certification and licensure.

Discussion between CLIA representatives and state counsel determined additional information must be submitted to Atlanta with subsequent determination as to the necessity of a separate CLIA number for the laboratory on the 3<sup>rd</sup> floor.

State counsel suggested the board table this request until further documentation could be presented for board interpretation of their regulations concerning state licensure.

**Motion: To Table On Recommendation of Counsel  
No further action taken at this time.**

**Discuss Quality Control  
Measures CLIA/IQCP  
State Regulations QC  
1200-06-03-09**

Board members, staff, surveyors and recognized members of the audience discussed the implementation of IQCP to be implemented by CLIA (Clinical Laboratory Improvements Act) on January 01, 2016 for all laboratories relative to individualized quality control measures (IQCP).

Under CLIA, IQCP is optional and it could be recommended that state regulations could be optional too.

If a lab does not choose to voluntarily it would refer to regular CLIA regulations.

Each laboratory determines its own individualization and implementation of their own quality control plan.

The uniformity lies with standardization of calibration and verification of instruments utilized in that specific laboratory.

It was suggested that surveyors make recommendations for board review at a future date to assess where the state rules could be amended without dilution of the intent of the state's regulations.

Counsel suggested the formulation of a policy to be utilized until the determination of and if a regulatory change in state rules could be accessed.

Motion: Table To have counsel present a policy during the January meeting for review pertaining to CLIA/IQCP.

**Motion: Ms. Kenwright**

**Second: Ms. Walton**

**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 was tabled pending the formulation of an advisory task force at a later date. The delay caused by a lack of staff to afford maximum time and effort toward the discussion and dissemination of materials necessary for a complete review.

Tabled until formulation of task force.

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

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

**1: Mid-South Transplant Foundation, INC.  
Memphis, TN 38018**

This licensed facility requested another appearance before the board for a modification of previous exemptions granted in (2009 and 2012) to allow a Certified Organ Procurement Specialist to perform and report Blood Gass and Troponin utilizing the Abbott i-Stat instrument and methodologies.

**Documentation received in the month of September requested a postponement in a return appearance to assimilate further information concerning the subject.**

No Action Taken

**2: Wayne Medical Center  
103 JV Mangubat Drive  
Waynesboro, TN 38485**

Board members reviewed this exemption request to permit ABG-endorsed Licensed Respiratory Therapists to perform and report blood gases and coximetry throughout the hospital facility with the specimens performed in the Respiratory Care Department and not at the bedside. The instrument and methodology utilized in the performance of these tests is the Roche Cobas B221.

**Motion to approve:** Ms. Walton

**Second:** Ms. Dolsen

**Exemption:** Approved

**3. North Knoxville Medical Center  
7565 Dannaer Drive  
Powell, TN 37849**

This request was for Licensed Registered Nurses (RN's) to perform and report activated clotting times (ACT's) in the Heart Catheterization Unit utilizing the Hemachron Signature Elite instrument and methodology.

**Motion:** Ms. Dolsen

**Second:** Ms. Kenwright

**Exemption:** Approved

**4. University Medical Center  
1411 Baddour Parkway  
Lebanon, TN 37087**

This facility made the following request for POCT exemptions:

1-Request to premit Licensed Registered Nurses (RN's) to perform and report activated clotting times (ACT's) in the Operating Rooms utilizing the Hemochron Signature Elite POC Analyzer/JACT-LR (ACT-LR) cuvettes in the INTENSIVE CARE UNIT.

**Motion to approve:** Ms. Dolsen

**Second:** Ms. Walton

**Exemption Request:** Approved.

2-To permit Licensed Registered Nurses (RN's) to perform and report activated clotting times (ACT's) utilizing the Hemochron Signature Elite POC Analyzer/JACT-LR (ACT-LR) cuvettes in the SURGICAL DEPARTMENT.

**Motion:** Ms. Kenwright

**Second:** Dr. Davis

**Exemption:** Approved.

3-Request to permit Licensed Registered Nurses (RN's) and Cardiovascular Invasive Specialists (RCVIS) to perform and report activated clotting times (ACT's) in the CATHERIZATION LABORATORY utilizing the Hemochron Signature Elite POC Analyzer/JACT-LR (ACR-LR) cuvettes.

**Motion:** Ms. Kenwright

**Second:** Mr. Johnson

**Exemption:** Approved.

**5. Methodist Lebonheur Healthcare  
Germantown Hospital  
7691 Poplar Avenue  
Germantown, TN 38138**

This facility request was to permit Respiratory Therapists, Registered Nurses (RN's), Radiology Technicians, Perfusionists, and Cardiovascular Technologists to perform and report activated clotting times (ACT's) in the following arenas utilizing the Hemochron Signature Elite.

Cardiac Cath Laboratory

**Motion:** Dr. Calarco

**Second:** Ms. Kenwright

**Exemption:** **Approved**

Cardiac Step-Down Units

**Motion:** Ms. Kenwright

**Second:** Mr. Johnson

**Exemption:** **Approved**

Intensive Care Units

**Motion:** Dr. Davis

**Second:** Ms. Walton

**Exemption:** **Approved**

Cardiovascular Intensive Care Units

**Motion:** Mr. Johnson

**Second:** Ms. Walton

**Exemption:** **Approved**

Surgical Departments

**Motion:** Ms. Kenwright

**Second:** Ms. Dolsen

**Exemption:** **Approved**

**6. Williamson Medical Center  
4321 Carothers Parkway  
Franklin, TN 37067**

The exemption request was to allow Licensed Registered Nurses (RN's) to perform and report activated clotting times (ACT's) in the Surgery Department of this hospital utilizing the ITC Hemochron Signature Elite instrument and methodology.

**Motion:** Ms. Kenwright

**Second:** Dr. Calarco

**Exemption:** Approved.

Note: Ms. Walton excused herself from the discussion and vote.

**7. Methodist University Hospital  
1265 Union Avenue  
Memphis, TN 38104**

1-This request is an extension of an exemption request approved during the July 2008 board meeting for Registered Nurses (RN's), Licensed Practical Nurses (LPN's), Respiratory Therapists, Cardiovascular Technicians, and Registered Radiology Techs to perform and report activated clotting times in the same locations listed below; this current request is for the addition of the following tests to the previous exemption: same individuals, same locations; different testing procedures + instrument. The tests are: sodium, potassium, chloride, CA+, BUN, creatinine, total CO<sub>2</sub>, hemoglobin and hematocrit utilizing the i-STAT instrument and methodologies in the:

Cardiovascular Units    Surgical Settings    Medical ICU  
Cardio Step-Down    Special Radiology Units

**Motion:** Ms. Kenwright

**Second:** Ms. Walton

**Exemption:** Approved.

2-Permit Registered Nurses (RN's), Licensed Practical Nurses (LPN's), Respiratory Therapists, Cardiovascular Technologists and Registered Radiology Technicians to perform and report: sodium, potassium, chloride, CA+, BUN, creatinine, Total CO<sub>2</sub>, hemoglobin, and hematocrit testing procedures utilizing the i-STAT instrument and methodologies in the:

Endoscopy Procedure Area    ECMO Unit    Transplant ICU  
Neuro Trauma    Critical Care Units    3-East ICU

**Motion:** Ms. Walton

**Second:** Dr. Calarco

**Exemption:** Approved

3-Request to permit Registered Nurses (RN's), Licensed Practical Nurses (LPN's), Perfusionists, Cardiovascular Technologists, EMT-IV and Radiology Techs to perform and report activated clotting times (ACT's) and PT/INR testing procedures utilizing the Hemochron Signature Elite instrument in the following locations:

CVICU    Medical ICU    3-East ICU    Stroke Center    ECMO  
Cath Lab    Cardiac Step-Down    Emergency Department  
Perioperative Unit I    Interventional Radiology Unit  
Surgical ICU    Neuro Trauma ICU

**Motion:** Ms. Kenwright

**Second:** Mr. Johnson

**Exemption:** Approved

4-Request to permit CRNA's and Perfusionists to perform and report delta thromboelastometry in the Perioperative Department utilizing the Rotem *delta* instrument and methodologies. Used during surgery and transplant procedures. Instrument is portable and not stationary as is the TEG, which will continue to be used. New Instrument: New Request; Instrument cannot be used on anyone under 21 at this time per manufacturer directions.

**Motion:** Granted Pending Further Review: Trial Study

**Second:** Ms. Kenwright

Exemption Request Denied based on new instrument on market and necessity of additional correlation studies on specific data related to test and testing procedures on patients and the clinical outcome of the tests to be reported back to board members during the April 2016 meeting to review the tracings and give an overall view of the instrument and procedure.

5-This exemption request was to permit Registered Nurses (RN's), EMT's, Registered Respiratory Therapists, Certified Respiratory Therapists and Licensed Practical Nurses to perform and report: hemoglobin, hematocrit, platelet counts and white blood counts in the designated biological containment area located on the ground floor of the hospital. The room will be utilized ONLY for possible Ebola or other infectious-type patients.

The instrument utilized in the performance of these tests is the QBC Star Dry Hematology Analyzer. New Instrument.

**Motion:** Ms. Walton To Deny

**Second:** Ms. Dolsen

Exemption: Denied based on incomplete correlation studies, reference ranges comparison with primary analyzer and also specific personnel involved with testing.

Members requested facility return in January with complete packet to include specific requested information.

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

This exemption request was to permit License Registered Nurses (RN's) and Licensed Practical Nurses (LPN's), and Paramedics to perform and report PT/INR analyses throughout the facility, utilizing the i-STAT instrument to be utilized **during stroke assessment crisis.**

**Motion:** Ms. Dolsen  
**Second:** Dr. Calarco  
**Exemption:** Approved.

**9**      **Diagnostic Laboratories**  
**Vanderbilt University Medical**  
**Center\***  
**22<sup>nd</sup> & Pierce 4065 TVC**  
**Nashville, TN 37232-5310**

Exemption requests extension of testing arenas and tests performed by Licensed Perfusionists (previously granted in October 2004), to the following areas utilizing the GEM 4000:

VUMC Peri-Operative Services

**Motion:** Ms. Walton  
**Second:** Dr. Calarco  
**Exemption:** Approved

VUMC Cath Laboratory/MCCH@VUMC\* Emergency Dept.

**Motion:** Ms. Walton  
**Second:** Dr. Calarco  
**Exemption:** Approved.

VUMC Cardiac Cath Laboratory/MCCH@VUMC

**Motion:** Ms. Walton  
**Second:** Dr. Calarco  
**Exemption:** **Approved.**

Peri-Operative Services/MCCH@VUMC

**Motion:** Ms. Walton  
**Second:** Dr. Calarco  
**Exemption:** Approved.

Extracorporeal Circuit Membrane Oxy. Units (ECMO)/MCCH  
@VUMC

**Motion:** Ms. Walton  
**Second:** Dr. Calarco  
**Exemption:** Approved.

\*Monroe Carroll, Jr. Children's Hospital at Vanderbilt University  
Medical Center (VUMC) Nashville, TN

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

No requests for this meeting.

**RECEIVE REPORTS AND /OR  
REQUESTS:**

**Board Director's Report**

Ms. England gave her report for the quarter July 1, 2015 thru September 30, 2015.  
The report included a statistical report of activities of licensure for personnel and laboratory facilities.

**Motion to accept Director's report:** Dr. Davis

**Second:** Ms. Kenwright

Report accepted as given:

*(Copy of report is on file in the Administrative Office)*

**REINSTATEMENT OF LICENSES**

Nothing to present

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

Nothing to present

**LEGISLATIVE UPDATE**

Public notice information from the 2015 legislative session was included in the report by Devin Wells, Board Counsel.

**Office of General Counsel's  
Report: Mr. Devin Wells**

No current open case is currently in the Office of General Counsel at this time.

Mr. Wells gave the legislative report of the past happenings affecting all of the health licensure professions in the Department of Licensure and Regulation: Public Chapter 154 (Medical Records Review), Public Chapter 94 (Abuse/Neglect Abuse Records), Public Chapter 502 (Government Operations Committee Rule Stay)

Complete information of rules on web page.

Rules rewrite are still currently in process of internal review.

**Motion:** Ms. Dolsen

**Second:** Ms. Walton

**Report: Accepted As Presented.**

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

Vickie S. Baselski, Ph.D.  
Memphis, TN 38103  
Director: Public Health Laboratory

Dr. Baselski appeared before the board to answer questions concerning her qualifications to become a public health laboratory director.

Review of her application was affirmative in compliance with qualifications for licensure.

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

Catherine S. Brown, Ph.D.  
St. Simmons Island, GA 31522  
Director: Clinical Chemistry

Dr. Brown was present to answer questions from board members and is certified by the American Board of Clinical Chemistry.

**Motion:** Dr. Calarco  
**Second:** Ms. Dolsen  
**Approved.**

Jess G. Evans, Ph.D.  
Eads, TN 38028  
Director: General

Dr. Evans appeared before the board to request licensure as a clinical laboratory director-generalist. He is boarded by the American Board of Bioanalysis with a BCLD designation.

**Motion:** Ms. Kenwright  
**Second:** Dr. Davis  
**Approved.**

**Note:** Ms. Dolsen abstained from the discussion and vote.

Sheila Rochette, Ph.D.  
Cordova, TN 38018  
Director: Molecular Diagnostics

Dr. Rochette appeared before the board seeking to be licensed as a laboratory director in Molecular Diagnostics. Dr. Rochette is boarded by the American Board of Bioanalysis in Molecular Diagnostics.

**Motion:** Ms. Kenwright  
**Second:** Mr. Johnson  
**Approved.**

George J. Dizikes, Ph.D.  
Knoxville, TN 37918  
Director: Public Health Laboratory

Dr. Dizikes possesses his BS, Master, and Ph.D. degrees in Microbiology and is boarded by the American Board of Bioanalysis, holding a HCLD certification in General Knowledge and Molecular Diagnostics.  
After board review, the applicant was granted a license as a Public Health Laboratory Director.

**Motion:** Ms. Dolsen  
**Second:** Dr. Davis  
**Approved:**

### **Regional Surveyors Reports**

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

**ETRO Report**  
**Julia Daniels**  
**Taylor Carpenter**

East TN Regional Office: Julia Daniels for the third quarter of 2015.  
Unsatisfactory/ Unsuccessful Proficiency Testing: One (1)  
Complaint Investigations: Zero (0)

Ms. Carpenter gave the report:

**MTRO Report**  
**Richard Carroll**  
**Angie Sneed**

Middle TN Regional Office: Richard Carroll for the third quarter of 2015.  
Unsatisfactory/Unsuccessful Proficiency Testing: Zero (0)  
Complaint Investigations: Zero (0)

Mr. Carroll gave the report:

**WTRO Report**  
**Mary Hamblen**

West TN Regional Office: Karon Hathcoat for the third quarter of 2015.  
Unsatisfactory/Unsuccessful Proficiency Testing: One (1)  
Complaint Investigations: Zero (0)

Ms. Hathcoat gave the report.

**Move to accept report** : Ms. Walton

**Second:** Ms. Kenwright  
Reports accepted as presented.

### **Board Ratification of Laboratory Initial License:**

**BioReference Laboratories, Inc.**  
**1068 Cresthaven Road Suite 230**  
**Memphis, TN 38119**

**Medical Director:**

Rajendra Persad, M.D.  
Anatomic/Clinical Pathology  
Pathology-Hematology

**Specialties:**

Collection Station

**Surveyor:**

Mary J. Hamblen  
Consultant 2/Surveyor WTRO

**Motion:** Mr. Johnson

**Second:** Dr. Calarco

**License Approved**

Laboratory Corporation of America  
1526 Bridgewater Lane Suite 1  
Kingsport, TN 37660

**Medical Director:**

Susan Rollins, M.D.  
Anatomic/Clinical Pathology  
Cytopathology

**Specialties:**

Collection Station

**Surveyor:**

Julia Daniels  
Consultant 2/Surveyor ETRO

**Motion:** Ms. Kenwright

**Second:** Ms. Dolsen

**License Approved**

Saint Thomas Midtown Hospital  
200 Church Street  
Nashville, TN 37326

**Medical Director:**

Michael L. Lomis, M.D.  
Anatomic/Clinical Pathology  
Hematology

**Specialties:**

Point of Care Testing Only  
(Previously granted under  
original laboratory license)

**Surveyor:**

Richard Carroll, MT  
Consultant 2/Surveyor MTRO

**Motion:** Ms. Walton

**Second:** Dr. Calarco

**License Approved**

**OTHER BUSINESS:**

**Item 1**

**Clarification of questions submitted to director:**

**Statement of Next Meeting**

The next Board Meeting will be January 21, 2016, and will begin at 9AM CDT in the Iris Conference Room, Ground Floor, MetroCenter Complex, 665 Mainstream Drive, Nashville, TN 37243

**Record of Adjournment**

With no further business to discuss, the meeting was adjourned at 2:23 PM CDT.

**Motion to adjourn:** Ms. Kenwright

**Second:** Dr. Calarco

**Meeting Adjourned.**

**Cheryl Arnott  
Chairman  
Tennessee Medical Laboratory Board**

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**Date**