Tennessee Medical Laboratory Board Meeting October 2016 Minutes

Date:	October 20, 2016
Time	09:04 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.ACytotechnologist, Board Chair Patti J. Walton, MT-Hospital/Lab Manager/Adm. Dir, Vice-Chair Kathleen Kenwright, MT- Medical Technologist, Educators Carla M. Davis, MD-Pathologist Jason S. Nolan, MD-Pathologist, Non-Educator Tereyo M. Cox, MT-Medical-Technologist, General Mark A. Calarco, DO, Independent Lab Manager/Administrator Stephanie Dolsen, MT- Medical Technologist Supervisor Michael Johnson, MT-Medical Technologist Generalist Gaye G. Jolly, MT-Hospital Administrator
Members Absent:	Royce Joyner, MD-Pathologist Educator 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, 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 bebbie Haggard, Medical Technologist Consultant/Surveyor, West Tennessee
Staff Absent:	All staff present for the meeting.
CLIA Manager/Representative:	Sandra Bogard, MT CLIA Manager

Presiding Officer:	Cheryl Arnott, S.ACytotechnologist, Chairman
Call To Order:	The meeting was called to order at 9:03 am CDT by Board Chair Cheryl Arnott.
Introductions of Board Members:	Board members and staff made their introductions to the record.
Introductions of Staff: Quorum:	Eleven board members were present which constituted a quorum.
Approve Minutes:	
P & E Committee Meeting	A motion to approve the August 17, 2016 Personnel & Education Committee minutes was made by: Ms. Kenwright Second: Dr. Nolan Committee Minutes: Approved.
Full Board Meeting	A motion to approve the August 18, 2016 Board meeting minutes was made by: Mr. Johnson Second: Ms. Dolsen Board Minutes: Approved.
Board Reports:	
Ratification of Initial Determinations of the P&E	Ms. Kenwright reported the actions of the Board's Personnel & Education Committee meeting, October 19, 2016.
Committee Meeting:	Motion to ratify Committee actions: Ms. Walton Second: Mr. Johnson Report: Ratified as presented.
Contested Case	Margrette Youssef
	Nashville, TN Medical Laboratory Technician
	TN License 37221
	Administrative Judge: Summers Docket 17.08-139702A
	Administrative Law Judge Summers appeared before the board to state the orders for this case on today's schedule just came across her desk this morning without sufficient time to complete the process for the case to be presented during this meeting.
	The petitioner, Ms. Youssef, had obtained an attorney the middle of this month, therefore Judge Summers asked for a continuance until the January 27, 2017 meeting.
	Joint motion for agreement; case will be presented January, 2017.
Consent, Agreed, Compliance	No other action was taken.

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	
Presen	tations to	o the Board:		
Tennessee Professional Peer Assistance Program (TNPAP):	Mr. Mike Harkreader TNPAP Director			
):	The statistical report for July 1, 2016-September 30, 2016 was presented to board members with zero (0) individuals being monitored.		
		One referral was made by an employer for impairment and positive urine drug screen in the workplace.		
			One TNPAP evaluation was performed with one individual consenting to treatment. Since September another individual will be signing a monitoring agreement today with this advocacy agency.	
			Mr. Harkreader explained a service upgrade incorporating the advantage of having on line meetings with clients, monitors, support group and facilitator as the overall progress and participation with clients and staff. These groups are available on- line and in person. Individuals under contract with TNPAP are continuously monitored for laboratory evaluations of participation in the absence of diversionary practices and are also monitored for attendance and involvement in assigned meetings.	
			Motion to accept the TN PAP report: Ms. Dolsen Second: Mr. Johnson Report accepted as presented by Mr. Harkreader.	
			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: <u>www.TNPAP.org</u>	

Financial Report	The financial report was given by Mr. Butch Jack, Fiscal Officer. The report is a draft and subject to re-review; additional changes will be presented during upcoming meetings.	
	Mr. Jack gave the year end fiscal report ending June 30, 2016.	
	The cumulative carryover for that time period was \$1,612,056.30.	
	Motion to accept report: Ms. Kenwright Second: Ms. Dolsen	
	Report accepted as presented with no changes. (Copy of report on file in administrative office)	
Investigations Report Nichelle Dorroh Presentation/Discussion	Personnel: Two (2) open complaints are currently in investigations, with current monitoring of five (5) complaints. Four (4) complaints have been closed since the last report in August.	
	Facilities: Two (2) complaints were closed; one with a letter of warning and the second with a letter of concern.	
	Motion To Accept Report: Mr. Johnson Second: Ms. Walton Report accepted as given by Ms. Dorroh.	
Compliance Orders	There were 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:

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

Consider Rule Making for 1200- 06-011(22) and 1200-06-03- .08(d) (5) relative to pathologists reading	Ms. Arnott, board chair, gave the report of the activities of the task force meeting held on August 25, 2016. The committee decided all laboratory reports must have an appropriate chain of custody for specimen processing; this chain of custody includes: specimen processed per histopathology at one
slides/location of diagnosis.	location and actual reading of specimen at another physical location. The report must contain information for "technical" services (histopathology) as well as information of the physical location where the slide is read "professional" services. The laboratory where either laboratory function is performed (technical or professional) must be licensed for the practice of pathology.
	The task force also recommended a review of the scope of practice for cytotechnologists. Board members agreed for this review to take place in 2017.

Motion: Mr. Johnson Second: Dr. Nolan Minutes were approved.

Task Force minutes are on board's web site.

Legislative Report Ben Simpson DOH Commissioner's Office Legisla <mark>t</mark> ive Liaison	Mr. Simpson gave board members a summary of the legislative actions from the 2016 legislative session.These actions are presented to the public as "informational".The documents can be found in their entirety on the med lab web page:	
	 Public Chapter 154 Electronic Records Access/Commissioner. Public Chapter 502 Joint Gov Operations Committee Rule Stay. Public Chapter 711 30 Bed or Less Lab Personnel Qualifications. Public Chapter 912 Non-resident Office Based Opioid Facilities. Public Chapter 1033 Licensure of Pain Clinics. Public Chapter 763 Caps Retired/Relapsed Reinstatement Fee. Public Chapter 719 Prohibits Denial of License for Possession of a Felony. Public Chapter 1083 Medical Testing on Cannabis Products.* 	
	*Summary of all chapters are on board's web page	
	Motion: Ms. Kenwright	
	Second: Dr. Calarco Report accepted as given by Mr. Simpson	
Esoteric Laboratories Information Motion	Board members reviewed a memorandum based on information relative to the testing procedures, analytes and methodologies pertaining to the licensure of esoteric laboratories. This information must become part of the initial application review information submitted before an "esoteric" laboratory license can be issued. The purpose of the document is to ascertain true esoteric values for personnel and laboratory testing parameters in the clinical arena.	
	The memo is now included in the application packet for esoteric laboratories. No action taken on this matter.	

<u>Ratifications:</u> 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: TriStar Southern Hills Medical Center 391 Wallace Road Nashville, TN 37211 Teresa Jenkins, MT Administrative Lab Director
- 2: Wellmont Holston Valley Medical Center 130 W. Ravine Road Kingsport, TN 37660

LaDonna Compton Point of Care Coordinator

3. Erlanger East Laboratory 1755 Gun Barrel Road #101 Chattanooga, TN 37421

> Rita Stewart Point of Care Coordinator

This request was for Respiratory Therapists (ABG-endorsed) to perform and report blood gases and associated parameters throughout the facility utilizing the i-STAT instrument and methodologies.

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

The request permits licensed Nurses (RN's, LPN's) & EMT's to perform and report lactate analyses throughout the medical center utilizing the StatStrip-Lactate system.

Motion to approve exemption: Ms. Dolsen Second: Dr. Nolan Request Approved

Three exemption requests were presented by this facility:

Request #1-Permits Registered Nurses, Licensed Respiratory Care Therapists, Registered Radiological Technologists, Registered Cardiovascular Invasive Specialists, and Cardiovascular Technologists to perform and report co-oximetry results on the AVOXimeter in the Cardiovascular Interventional Radiology Unit.

Motion: Ms. Walton Second: Mr. Johnson Request: Approved

Request #2-Permits Registered Nurses, Licensed Respiratory Care Therapists, Registered Radiological Technologists, Registered Cardiovascular Invasive Specialists, and Cardiovascular Invasive Specialists to perform and report sodium, potassium, chloride, CO2, Ca+, glucose, BUN, creatinine, lactate, hematocrit, blood gases and activated clotting time in the Cardiovascular Interventional Radiology Unit utilizing the i-STAT instrument.

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

Request #3-Permits Registered Nurses and Paramedics* to perform and report sodium, potassium, chloride, CO2, blood gases, Ca+, glucose, BUN, creatinine, lactate, hematocrit and troponin utilizing the i-stat campus wide. Motion: Ms. Walton Second: Dr. Nolan Request: Approved *Paramedics must be part of a Rapid Response Team

4.	Baroness Erlanger Hospital 975 East Third Street	Board members granted this request to permit licensed Registered Nurses to perform and report WBC's in the Special Pathogens Unit (Ebola Unit) utilizing the HemoCue WBC system.
	Chattanooga, TN 37403	Motion: Mr. Johnson Second: Ms. Walton
	Rita Stewart, MT	Request: Approved
	Point of Care Coordinator	
5.	TriStar Centennial Medical Center	Two (2) request were presented for board review:
	2300 Patterson Street Nashville, TN 37203	Request #1-Permits licensed Nurse Practitioners (APRN's) to perform and report wet preps and KOH values in the Women's OB Emergency Department.
	Mollie Wynn, MT	Motion: Ms. Dolsen
	Point of Care/QC	Second: Ms. Kenwright
	Coordinator	Request: Approved
		Request #2-Permits licensed Physicians Assistants (PA's) to perform and report wet preps and KOH values in the Women's OB Emergency Department.
		Motion: Ms. Walton

Second: Ms. Jolly Request: Approved

Direct more than three (3) Laboratories

Stuart Bogema,PhD,MBA,DABCC,FABFT	Dr. Bogema appeared before the board to request an exemption to direct a fourth (4 th) laboratory in Tennessee.	
	He currently directs the following laboratories:	
	1-Asperio Laboratory-Thompson Station, TN 37179 2-Insight Diagnostics-Franklin, TN 370654 3-Vision Laboratory Solutions-Franklin, TN 37067 (Esoteric Lab) 4-Vision Laboratory Solutions-Franklin, TN 37037 (Non-esoteric)	
	Dr. Bogema was not approved to direct the non-esoteric Vision Laboratory Solutions and therefore this request was not acted upon by board members.	
	No further action was taken on this request.	
	See: Initial Lab Approval-Vision Laboratory Solutions-Franklin, TN 37037 (non-esoteric)	

RECEIVE REPORTS AND /OR REQUESTS:

Board Director's Report	Ms. England gave the board director's report for the quarter April 01, 2016 thru July 31, 2016. The report included a statistical report of activities of licensure for personnel and laboratory facilities.		
	Included in this report was a change for a couple of board dates in 2017 to Thursday and Friday. Everyone was cautioned to check the internet for all scheduled meetings.		
	Motion to accept Director's report: Ms. Dolsen Second: Mr. Johnson Report accepted as given (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			
	No requests were made to add to the waived test list.		
Review/Discuss Approval Licensure of Medical Laboratory Director			
	No director files were presented to board members for review during this meeting.		
Regional Surveyors Reports Complaint Investigations and proficiency testing (East, West and Middle TN)			
ETRO Report	East TN Regional Office: April 01-July 31, 2016		
Taylor Carpenter MT-Consultant	Unsuccessful Proficiency Testing: Two (2) 1-Analyte: T3 (Triiodothyronine) ; Acceptable plan of correction submitted to surveyor, and 2-Analyte: Bacteriology: Acceptable plan of correction submitted to surveyor. Complaint Investigations: Zero (0)		
MTRO Report Richard Carroll MT-Consultant	Middle TN Regional Office: April 01-July 31, 2016 Unsuccessful Proficiency Testing: Three (3) 1 st Unsuccessful; citations pending. 2 nd Unsuccessful: Zero Complaint Investigations: Zero (0)		

	WTRO Report Karon Hathcoat	West TN Regional Office: April 01-July 31, 2016	
	MT-Consultant	Unsuccessful Proficiency Testing: Zo Complaint Investigations: Zero (0)	
		Motion to accept regional reports : Second: Ms. Dolsen Reports accepted as presented	Mr. Johnson
Board Ra Initial Lic	atification of Laboratory cense:		
1	aboratory Corp. of America 528 Bridgewater Lane #1 ingsport, TN 37660	Medical Laboratory Director:	Susan Rollins, MD Anatomic/Clinical Pathology Cytopathology
		Specialties:	Hematology, Clinical Chemistry, Urinalysis
		Surveyor:	Julia Daniels, MT Consultant II/ETRO
		Motion: Ms. Walton	
		Second: Dr. Calarco License Approved	
Jo 21	ioReference Laboratories, Inc. @ ohn Macey, M.D. 201 Murphy Avenue #307 ashville, TN 37203	Medical Laboratory Director:	Rajendra Persad, MD Anatomic/Clinical Pathology Hematology
		Specialty:	Collection Station
		Surveyor:	Richard Carroll, MT Consultant II/MTRO
		Motion: Dr. Calarco Second: Mr. Johnson License Approved.	
3	ision Laboratory Solutions-E 25 Seaboard Lane #110 ranklin, TN 37067	Medical Laboratory Director:	Stuart Bogema, PhD Director: Toxicology
		Specialty:	Esoteric Toxicology
		Surveyor:	Richard Carroll, MT Consultant II/MTRO

Dr. Bogema discussed laboratory operations in this facility with board members. Members determined this laboratory met requirements for an esoteric toxicology laboratory.

Motion: Ms. Walton Second: Dr. Calarco License Approved

Vision Laboratory Solutions-R 325 Seaboard Lane #110 Franklin, TN 37067 McKenzie, TN 38201 Medical Laboratory Director

Stuart Bogema, PhD Director: Toxicology

Richard Carroll, MT Consultant II/MTRO

Specialties:

General Immunology, Clinical Chemistry, Urinalysis, Endocrinology, Hematology

Surveyor:

After discussion with Dr. Bogema, board members determined that Dr. Bogema was licensed in Tennessee as a Director in Toxicology (BCLD) and could not qualify to direct this laboratory. Board members considered the denial*of this license request, however a motion was made to table the application until the January 2017 meeting pending the compliance with 1200-06-01 **Rules and Regulations Governing** Medical Laboratories per qualifications to be a director in a laboratory with the specialties for which the license is sought.

	*Motion to deny license: Dr. Calarco Second-Ms. Walton License: Denied	
	Motion to withdraw denial Motion: Ms. Walton Second: Mr. Johnson Motion withdrawn	
	Motion to table until January: Mr. Johnson Second: Ms. Walton Application tabled until the January meeting.	
Sano Informed Prescribing, LLC 393 Nichol Mill Lane #14 Franklin, TN 37067	Medical Laboratory Director	Tara Chang, MD Anatomic/Clinical Pathology
	Specialty:	Esoteric Toxicology
	Surveyor:	Richard Carroll, MT Consultant II/MTRO
	Motion: Dr. Calarco Second: Ms. Walton Opposed: Ms. Kenwright License Approved	
Crestar Labs, LLC-R 2001 Campbell Station PKY STE C-2 Spring Hill , TN 37174	Medical Laboratory Director:	Marc J. Rumpler, PhD Director: Toxicology (HCLD)
	Specialties:	Hematology, Toxicology (non- esoteric), Molecular Diagnostics
	Surveyor:	Richard Carroll, MT Consultant II/Surveyor MTRO
	Motion to table this initial license based on director qualifications (HCLD) to direct clinical specialties other than toxicology.	
	Motion: Dr. Calarco Second: Ms. Walton Tabled until the January 2017 meeting.	

Integrity Laboratories, LLC 120 Center Park Drive #3 Knoxville, TN 37922	Medical Laboratory Director	Adel Shaker, MD Anatomic/Forensic Pathology
	Specialty:	Esoteric Toxicology
	Board members Dr. Shaker's discussed toxicology training during residency for anatomic pathology plus the addition of toxicology training/experience obtained in the practice of forensic pathology. Board members agreed the combination of training would allow sufficient expertise to direct this esoteric –toxicology laboratory.	
	Dr. Shaker qualifies as laboratory director for this esoteric lab- toxicology.	
	Surveyor:	Taylor Carpenter, MT Consultant I/Surveyor ETRO
	Motion: Dr. Calarco Second: Ms. Walton License Approve d	
Addiction Labs of America 500 Wilson Pike Circle #360 Franklin, TN 37207	Medical Laboratory Director	Edgar H. Pierce, Jr MD Anatomic/Clinical Pathology Blood Banking
	Specialties:	Hematology, Syphilis Serology, General Immunology, Clinical Chemistry, Urinalysis, Endocrinology, Toxicology, Molecular Genetics
	Surveyor:	Richard Carroll, MT Consultant II/Surveyor MTRO
	Motion: Mr. Johnson Second: Ms. Cox License approved	
	Abstain: Dr. Calarco	

Pure Diagnostics, LLC 6120 Shallowford Road #107 Chattanooga, TN 37421 Medical Laboratory Director

David Smalley, PhD Director General (BCLD)

Specialty:

Surveyor:

Toxicology

Taylor Carpenter, MT Consultant I/Surveyor ETRO

Motion: Mr. Johnson Second: Dr. Davis Licensed approved.

OTHER BUSINESS:

Item 1

A.	Reporting HIV/STD Positive Individuals to	Board clarification of items relating to operation of administrative office technicalities: Ms. England reported correspondence from the HIV/STD Division for DOH, stating that a few licensed collection stations were not reporting the identities of those individuals testing positive for HIV/STD events.
	DOH TCA 68-10-101	This subject was presented at the request of that agency as an FYI- awareness because that Division does not have regulatory authority over these facilities that are licensed by this board.
		I would refer to the Rules and Regulations Governing Medical Laboratories 1200-06-0312 Reportable Diseases giving regulatory authority to the TN Medical Laboratory Board.
		State surveyors were instructed to review the reporting processes for all facilities in submitting the appropriate information to the Department of Health HIV/STD Unit. If the reporting process is found to be out of compliance with the above named Rules and Regulations, a citation is to be given. No action was taken on this subject.
В.	Board Policy for American Society of Clinical Pathology ASCP International Examination	Board members reviewed a policy authorized by the Personnel and Education Committee during their meeting on October 19 th to approve this sponsored international examination as a pathway for licensure in Tennessee if all other regulatory requirements are met. It does not matter if exam is taken outside the United States or its territories ASCP recognize equivalency and so does the Board. This decision has no effect on other agencies deemed by this board to sponsor examinations for licensure in Tennessee.
		Motion: Mr. Johnson Second: Ms. Walton Policy Adopted.

	C.	Election of Officers 2017 Calendar Year	
			Board Chair: Patti Walton, MT Motion: Ms. Kenwright Second: Mr. Johnson
			Board Vice-Chair: Stephanie Dolsen, MT Motion: Kathy Kenwright Second: Dr. Calarco
			Chair-Personnel & Education Committee: Ms. Kenwright, MT Motion: Dr. Calarco Second: Dr. Davis
	D.	Review of Reimbursement for Board	All nominees were approved by acclimation. Ms. Arnott questioned and asked for a review of the fees for the reimbursement of lodging for overnight stay associated with board business.
		Members	Ms. England said she would look into the matter.
		Lodging Fee	However Ms. England noted fees are universal for all the Division of Health Licensure and Regulation's Boards regarding board members.
Statement of Next Meeting			The next Board Meeting will be January 27, 2017 and will begin at 9AM CST in the Iris Conference Rood, Ground Floor, MetroCenter Complex, 665 Mainstream Drive, Nashville, TN 37243
Record of Adjournment			With no further business to discuss, the meeting adjourned at 1:45pm CDT.
			Motion: Ms. Kenwright Second: Ms. Jolly Meeting Adjourned.