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Final Order No. DOH-09-1983-DS -MQA
FILED DATE - 9-15-09
Department of Health
By: Angela Barton
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF CLINICAL LABORATORY PERSONNEL

IN RE: THE PETITION FOR DECLARATORY STATEMENT OF INTEGRATED REGIONAL LABORATORIES, LLC and MIAMI BEACH HEALTHCARE GROUP, LTD., d/b/a AVENTURE HOSPITAL AND MEDICAL CENTER

FINAL ORDER

THIS MATTER came before the Board of Clinical Laboratory Personnel, pursuant to Section 120.565, Florida Statutes. At a duly-noticed public meeting held on August 14, 2009, in Orlando, Florida, the Board considered Integrated Regional Laboratories, LLC's (Petitioner) Petition for Declaratory Statement. The Petition was filed with the Department of Health on July 10, 2009. The Petitioner is requesting that the Board issue a Declaratory Statement interpreting the applicability of Rule 64B3-2.003(19), Florida Administrative Code. The question presented to the Board was whether a person who places a whole blood specimen into the Biosite Triage® testing cartridge has to be licensed by the Board. No comments to the petition were received. Petitioner was represented by Richard Ellis, Attorney at Law. Having considered the Petition, the presentation of Petitioner, and relevant statutes and rules, the Board issues the following:

FINDINGS OF FACT

1. The Petition was duly filed and noticed in the Florida Administrative Law Weekly; Volume 35/29 published on July 24, 2009.

2. The Petition is attached hereto and incorporated herein by reference.

3. Petitioner, IRL, provides clinical laboratory management services for 13 hospital clinical laboratories in South Florida.

4. Biosite, Inc., is a vendor of blood-testing technology; including the Biosite Triage® testing cartridge.

5. Petitioner is asking whether a person not licensed by the Board, e.g., an emergency responder, could collect the blood specimen and place in the specimen in the cartridge. The blood specimen would be placed in an analyzer by a person licensed by the Board or authorized pursuant to Rule 59A-7.034(5)(a), Florida Administrative Code.

CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter pursuant to section 120.565, and Chapter 483, Florida Statutes.

2. Section 483.803(4), Florida Statutes, states:

> "Clinical laboratory personnel" includes a clinical laboratory director, supervisor, technologist, blood gas analyst, or technician who performs or is responsible for laboratory test procedures, but the term does not include trainees, persons who perform screening for blood banks or plasmapheresis centers, phlebotomists, or persons employed by a clinical laboratory to perform manual pretesting duties or clerical, personnel, or other administrative responsibilities, or persons engaged in testing performed by laboratories regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2).

3. Rule 64B3-2.003(19), Florida Administrative Code, states:

> Manual Pretesting procedures means collecting and labeling specimens; initially separating specimens by centrifugation prior to testing; receiving specimens and requisitions, processing, sorting, accessioning, prior to testing and delivering specimens to the appropriate testing sites; specimen processing for storage and shipping to a reference laboratory; routine hematology and microbiology slide preparation from a primary sample; loading automated strainers; loading specimens onto automated sampling or processing systems; cytopreparatory staining; measuring and aliquoting specimens; and direct primary inoculation of microbiology cultures. Placement of specimens onto an automated instrument or system is considered a manual pretesting duty, provided it does not include any activity that initiates the analytic process.

4. It is the Board's opinion that only licensed or otherwise authorized personnel may introduce a whole blood specimen into a Biosite Triage® testing cartridge.

5. The Board's response to the Petition is with regard only to the question propounded by Petitioner in its Petition and only applies to the facts set forth therein.

This Order shall become effective upon filing with the Clerk of the Department of Health.

DONE AND ORDERED, this 14th day of July, 2009.

BOARD OF CLINICAL LABORATORY PERSONNEL

Joe Baker, Jr., Executive Director
on behalf of Roger Bertholf, Ph.D., CHAIR

NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the Florida Appellate District where the party resides. The Notice of Appeal must be filed within thirty (30) days of rendition of the order to be reviewed.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was furnished by U.S. Mail to: **Integrated Regional Laboratories, LLC, and Miami Beach Healthcare Group,** LTD, by sending same to their counsel of record, **Richard Ellis**, Rutledge, Ecenia & Purnell, Post Office Box 551, Tallahassee, Florida 32302-0551; and by interoffice mail to **Deborah B. Loucks**, Assistant Attorney General, PL-01 The Capitol, Tallahassee, Florida 32399-1050, and **Angela Southwell**, Office of the Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050, on Sept. 15, 2009.

Angel Sanders

Deputy Agency Clerk

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK
DATE 7-10-09

STATE OF FLORIDA
BOARD OF CLINICAL LABORATORY PERS

In the Matter of:

INTEGRATED REGIONAL LABORATORIES, LLC and MIAMI BEACH HEALTHCARE GROUP, LTD. d/b/a AVENTURA HOSPITAL AND MEDICAL CENTER, Petitioners.

Case No.: 2009_____

Petition for Declaratory Statement Before the State of Florida Board of Clinical Laboratory Personnel.

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PETITION FOR DECLARATORY STATEMENT

INTEGRATED REGIONAL LABORATORIES, LLC ("IRL") and MIAMI BEACH HEALTHCARE GROUP, LTD. d/b/a AVENTURA HOSPITAL AND MEDICAL CENTER ("Aventura"), pursuant to Section 120.565, Florida Statutes, and Chapter 28-105, Florida Administrative Code, hereby petition the State of Florida Board of Clinical Laboratory Personnel (the "Board") for a declaratory statement concerning Rule 64B3-2.003(19), Florida Administrative Code, and state as follows:

Name, address, and telephone number of Petitioners and representative

1. IRL is a licensed clinical laboratory located at 5361 N.W. 33rd Avenue, Fort Lauderdale, Florida 33309, phone number (954) 777-0018.

2. Aventura is a licensed acute care hospital with a licensed clinical laboratory located at 20900 Biscayne Blvd., Aventura, Florida 33180, phone number (305) 682-7000.

3. IRL and Aventura are represented by the undersigned counsel in this proceeding, whose name, address, phone number, and fax number are given below.

Subject matter of Petition

4. The subject matter of this Petition is Rule 64B3-2.003(19), Florida Administrative Code.

Description of how the Rule affects Petitioners

5. IRL provides clinical laboratory management services for thirteen different hospital clinical laboratories in South Florida including, but not limited to, Aventura. IRL has a substantial interest in ensuring the lawful compliance of its management services with rules of the Board. Those rules include Rule 64B3-2.003(19), Florida Administrative Code.

6. Aventura holds a clinical laboratory license for its hospital clinical laboratory and is subject to Rule 59A-7.035, Florida Administrative Code (Staffing Requirements), which generally requires the use of licensed clinical laboratory personnel. Aventura has a substantial interest in ensuring that its clinical laboratory testing procedures comply with rules of the Board. Those rules include Rule 64B3-2.003(19), Florida Administrative Code.

7. Section 483.803(4), Florida Statutes, defining the term "Clinical laboratory personnel," excludes "persons employed by a clinical laboratory to perform manual pretesting duties..." Rule 64B3-2.003(19), Florida Administrative Code, defines the term "Manual Pretesting" as follows:

> Manual Pretesting procedures means collecting and labeling specimens; initially separating specimens by centrifugation prior to testing; receiving specimens and requisitions, processing, sorting, accessioning, prior to testing and delivering specimens to the appropriate testing sites; specimen processing for storage and shipping to a reference laboratory; routine hematology and microbiology slide preparation from a primary sample; loading automated stainers; loading specimens onto automated sampling or processing systems; cytopreparatory staining; measuring and aliquoting specimens; and direct primary inoculation of microbiology cultures. Placement of specimens onto an automated instrument or system is considered a manual pretesting duty, provided it does not include any activity that initiates the analytic process.

(Emphasis added)

8. Biosite, Inc. is a vendor of blood-testing technology designed to quickly produce quantitative results as an aid in determining acute illness such as myocardial infarction (heart attack) and congestive heart failure. By this Petition, IRL and Aventura seek to determine whether non-licensed personnel could, consistent with the last sentence of Rule 64B3-2.003(19), introduce a whole blood specimen into a Biosite Triage® testing cartridge for cardiac markers, which specimen would subsequently be placed in the analyzer by personnel licensed under Chapter 64B3, Florida Administrative Code, or authorized under Rule 59A-7.034(5)(a), Florida Administrative Code (Alternate Site Testing). If permissible, the use of non-licensed personnel would reduce the "turnaround" time otherwise needed for critical laboratory tests, and would hasten necessary medical interventions. Specimen collection and introduction of the whole blood specimen into the Biosite Triage® testing cartridge could be performed by emergency responders while en route to the hospital with the patient, and under the direction of the emergency department physician.

9. For reference, Biosite gives the following narrative description of its Triage technology on its website (www.biosite.com):

- Biosite's protein array is comprised of two components: the protein array device, and the Triage Meters.
- When a sample of blood is added to the protein array, a fibrous filter contained within the array separates red blood cells from plasma.
- The plasma then exits the filter and flows into a region of higher capillarity called the Sample Reaction Barrier.
- The plasma then enters a Reaction Chamber of lower capillarity, which contains reagents in a dry form. The plasma reconstitutes the reagents to form a reaction mixture. The reagents include antibodies bound to fluorescence energy transfer particles (FETL).
- A time gate delays the flow of plasma out of the Reaction Chamber to define an incubation time. This time gate is composed of hydrophobic surfaces that prevent fluid

flow. These surfaces are converted into hydrophilic surfaces by the proteins in the sample, allowing the reaction mixture to flow into a Diagnostic Lane.

- The Diagnostic Lane is a capillary channel containing discrete zones of immobilized antibodies to the analytes. Any analytes bound to FETL from the reaction mixture will bind to the immobilized antibodies as the reaction mixture moves through the Diagnostic Lane. Excess plasma from the blood filter washes unbound FETL from the Diagnostic Lane.

- The fluorescence at each discrete zone is measured by a handheld fluorometer called the Triage Meters. When inserted into the Triage Meters, the protein array device is scanned by a laser diode. The FETL fluorescence emission is detected by a photodiode in a high gain circuit. The fluorescence intensity is integrated over each discrete zone to give a quantitative measurement of the analyte concentrations.

Images of the cartridge and handheld fluorometer cannot be reproduced in this Petition, but may be viewed at Biosite's website.

WHEREFORE, IRL and Aventura respectfully request that the Board issue a declaratory statement concerning whether non-licensed personnel may, consistent with Rule 64B3-2.003(19), Florida Administrative Code, introduce a whole blood specimen into a Biosite Triage® testing cartridge for cardiac markers.

RESPECTFULLY SUBMITTED this 8th day of July, 2009.

STEPHEN A. ECENIA
RICHARD M. ELLIS
Rutledge, Ecenia & Purnell
119 South Monroe St., Suite 202
Post Office Box 551
Tallahassee, FL 32302-0551
Ph. (850) 681-6788
Fax (850) 681-6515

Attorneys for IRL and Aventura

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the original of this Petition for Declaratory Statement was Hand-Delivered to R.S. Power, Agency Clerk, Florida Department of Health, 4052 Bald Cypress Way, Tallahassee, Florida 32399, and Joe Baker, Jr., Executive Director, Board of Clinical Laboratory Personnel, 4052 Bald Cypress Way, Tallahassee, Florida 32399 this 8th day of July, 2009.

Attorney