Final Order No. DOH-09-2156-DS -MQA	
FILED DATE -	10121109
Department of Health	
	R. A.
By: Angela	Daitoli
Deputy Agency Clerk	

STATE OF FLORIDA BOARD OF CLINICAL LABORATORY PERSONNEL

IN RE: THE PETITION FOR DECLARATORY STATEMENT OF LINDA VALDES, MS, MT(ASCP)

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 via telephone conference call on October 16, 2009, the Board considered Linda Valdes' Petition for Declaratory Statement. The Petition was filed with the Department of Health on September 1, 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: "Can laboratory assistants (unlicensed laboratory personnel) create a slide for cytology procedures or FNA's (at patient's bedside?)".

No comments to the petition were received. Petitioner was present with Martha Herstek. 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 35/38 published on September 25, 2009.

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

3. Petitioner is licensed as a Clinical Laboratory Personnel Supervisor.

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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 unlicensed persons cannot take a specimen and create a

slide from that specimen.

5. The Board's response to the Petition is with regard only to the question propounded

by Petitioner in her 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.

De DONE AND ORDERED, this 20 day of _____

BOARD OF CLINICAL LABORATORY PERSONNEL

Joe Baker, Jr. Executive Director on behall 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.

<u>CERTIFICATE OF SERVICE</u>

I HEREBY CERTIFY that a true and correct copy of the foregoing was furnished by U.S. Mail to: Linda Valdes, MS, MT(ASCP), System Laboratory Administrative Coordinator – Regulations/Safety, Florida Hospital Laboratory, 601 E. Rollins Street, Orlando, Florida 32803; 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 $\partial I - O C + O$

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Deputy Agency Clerk

FILED DEPARTMENT OF HEALTH DEPUTY CLERK CLERK Angela Batton DATE 9-1-09

FLORIDA HOSPITAL LABORATORY

601 E. Rollins St. Orlando, FL 32803 (407) 303-1925

Petition for Declaratory Statement Before the Florida Board Of Clinical Laboratory Personnel

August 28, 2009

Linda Valdes, MS, MT(ASCP) System Laboratory Administrative Coordinator -Regulations/Safety (407) 303-5600 x1105960 (407) 408-5655 linda.valdes@fihosp.org

Department of Health Agency Clerk's Office 4052 Bald Cypress Way, Bin #A02 Tallahassee, Florida 32399-1703

Dear Sir or Madam:

Question concerning Manual Pretesting rule 64B-2.003 (19):

Can laboratory assistants (unlicensed laboratory personnel) create a slide for cytology procedures or FNA's (at the patient's bedside)? According to the rule they can stain, but can they also take a specimen and actually create a slide from that specimen, then stain the slide.

Please contact me at 407 303 5600, x1105960 or email at <u>linda.valdes@fihosp.org</u> if additional information or documentation is needed.

Sincerely,

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Linda Valdes, MS, MT(ASCP) System Laboratory Administrative Coordinator-Regulations/Safety

Operated by the Seventh-day Adventist Church