

Final Order No. DOH-09-2157-DS-MOA
FILED DATE - 10/21/09
Department of Health

By: Agency Agency Station

STATE OF FLORIDA BOARD OF CLINICAL LABORATORY PERSONNEL

IN RE: PETITION FOR DECLARATORY STATEMENT

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FINAL ORDER

This matter came before the Board of Clinical Laboratory Personnel (hereinafter the "Board") on October 16, 2009, at a duly noticed telephone conference call board meeting, for consideration of the above-referenced Petition for Declaratory Statement. The Notice of Petition for Declaratory Statement was published on September 25, 2009, in Vol. 35, No. 38, of the Florida Administrative Weekly. Petitioner was neither present nor represented by counsel.

Petitioner submitted a chart with a listing of various tests performed in a Donor Testing

Laboratory and requested that the Board specify the license category that a medical technologist

must have to perform the listed tests.

FINDINGS OF FACTS

- 1. Petitioner is licensed as a Clinical Laboratory Supervisor by the Board.
- 2. The petition failed to set forth any particular circumstances to which the referenced rule was to be applied.

CONCLUSIONS OF LAW

- 1. The Board of Clinical Laboratory Personnel has authority to issue this Final Order pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.
 - 2. Section 120.565, Florida Statutes, reads in part as follows:
 - (1) Any substantially affected person may seek a declaratory statement regarding an agency's opinion as to the applicability of a statutory provision, or of

any rule or order of the agency, as it applies to the petitioner's particular set of circumstances.

- (2) The petition seeking a declaratory statement shall state with particularity the petitioner's set of circumstances and shall specify the statutory provision, rule, or order that the petitioner believes may apply to the set of circumstances
- 3. Rule 28-15.001, Florida Administrative Code states:

A declaratory statement is a means for resolving a controversy or answering questions or doubts concerning the applicability of statutory provisions, rules, or orders over which the agency has authority. A petition for declaratory statement may be used to resolve questions or doubts as to how the statutes, rules, or orders may apply to the petitioner's particular circumstances. A declaratory statement is not the appropriate means for determining the conduct of another person.

Because the petition fails to specify or describe Petitioner's specific or particular circumstances, the Board is unable to provide a response.

Based on the foregoing, the Board hereby **DENIES** Lucinda Olivio's petition for declaratory statement.

DONE AND ORDERED this 25 day of

BOARD OF CLINICAL LABORATORY PERSONNEL

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

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 Florida District Court of Appeal in the 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 has been furnished by U.

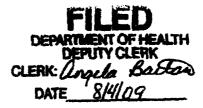
S. Mail to: Lucinda Olivio, Quality Assurance Manager, Florida Blood Services, Inc., 10100 Dr.

Martin Luther King Jr. Street North, St. Petersburg, Florida 33716; 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 October, 2009.

Deputy Agency Clerk





Petition for Declaratory Statement Before the Board of Clinical Laboratory Personnel

July 28, 2009

Lucinda Ann Olivio
Quality Assurance Manager
Florida Blood Services, Inc.
10100 Dr. Martin Luther King Jr. Street North
St. Petersburg, FL 33716
(727) 568-1203
Fax (727) 568-2177

The declaratory statement is sought on 64B3-10.005 Scope of Practice Relative to Specialty of Licensure (3) through (8).

Please clarify the licensure that is required to work in a Donor Testing Laboratory. Listed below are tests performed in a donor testing lab. Please specify the license category (Hematology, Clinical Chemistry, Microbiology, Immunohematology or Serology) that a Medical Technologist must have in order to perform the testing listed. And please indicate if a "Blood Bank" specialty license can be substituted for the required license.

TEST	METHODOLOGY	LICENSE REQUIRED TO PERFORM TESTING	CAN A "BLOOD BANK" SPECIALTY BE SUBSTITUTED? (YES or NO)
WNV	NAT or PCR		
HIV/HCV/HBV (Multiplex and discriminatory)	NAT or PCR		
HBsAg	EIA or ChLIA		
Anti-HBc	EIA or ChLIA		
Anti-HIV-1/2	EIA or ChLIA	Andrews (Temple of the place) and the place of the place	
Anti-HTLV-I/II	ChLIA		
Anti-HCV	EIA or ChLIA		
Anti-T. cruzi (Chagas)	EIA	andre skiednissen stelle t men en ge <u>en skiednissen spelanten o</u> n men en en en	
Anti-HLA Class I and Class II	EIA		



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ABO and Rh	Automated Serologic]	
(Including Weak D)	Agglutination		
	Gel Technology		
1	Manual Tube Method		
Antibody Screen	Automated Serologic		
Thinoday Solden	Agglutination	1	
	Gel Technology		
	Manual Tube Method		
	Manual Tube Method		
DAT	Manual Tube		
DAI	Manual Tube		
Crmbilio	Automotivi		
Syphilis	Automated	1	
	Microhemagglutination		
	Manual card method		
	(RPR)		
	EIA		
Anti-CMV	Automated		
	Manual Card Method		
Hematology Cell Counts	Automated Impedance/		
	Optical or Photometry		
White Blood Cell Counts	Flow Cytometry		
	Tion Cytomony		
Factor VIII/	Automated Light		
Fibrinogen	Emitting Diode Mode		
pH Determination	H+ Determination		
pri Determination	11 Determination		
RIBA HCV SIA	Enyzme Immunoblot		
THE TOTAL TOTAL	Assay		
Inno-LIA HTLV I/II			
IIIKO-LIX HILV VII	Line Immunoassay		
UDa A a Navrtuslimetin	FIA CLIVA		
HBsAg Neutralization	ElA or ChLIA		
IIII I III			
HIV-1 WB	Western Blot		
HIV-1 IFA	Immunofluorescence		
	Assay		
Cholcrsterol Testing	Automated		
Serum Indicies (Hemoglobin,	Automated		
Lipemia, Bilirubin)			
			L i



Key:

WNV = West Nile Virus

NAT = Nucleic Acid Testing

PCR = Polymerase Chain Reaction

HIV = Human Immunodeficiency Virus

HCV = Hepatitis C Virus

HBV = Hepatitis B Virus

EIA = Enzyme Immunoassay

ChLIA = Chemiluminescent Immunoassay

HBsAg = Hepatitis B Surface Antigen

HBc = Hepatitis B Core Antigen

HIV-1/2 = Human Immunodeficiency Virus Type 1 and Type 2

HTLV-I/II = Human T-Lymphotropic Virus Type I and Type II

DAT = Direct Antiglobulin Test

CMV = Cytomegalovirus

RIBA SIA = Recombinant Immunoblot Assay Strip Immunoassay

Thank you in advance for your help. If further clarification of the question is needed, please feel free to call or email me at the above addresses.

Respectfully,

Lucinda Ann Olivio, MT (ASCP)

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