CENTERS FOR MEDICARE & MEDICAID SERVICES CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
OKLAHOMA BLOOD INSTITUTE SYLVAN N GOLD
OKLAHOMA BLOOD INSTITUTE
1001 N LINCOLN BOULEVARD
OKLAHOMA CITY, OK 73104-3299

LABORATORY DIRECTOR

JAMES W SMITH MD

CLIA ID NUMBER

37D0470358

EFFECTIVE DATE

07/27/2013

EXPIRATION DATE

EFFECTIVE DATE

07/26/2015

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CIVIS CENTERS for MEDICAND SERVICES

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Judith A. Yost, Director Division of Laboratory Services Survey and Certification Group Center for Medicaid and State Operations

308 Certs2_070313

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	
BACTERIOLOGY (110)	03/01/2004	1	
VIROLOGY (140)	03/08/2007		
SYPHILIS SEROLOGY (210)	07/27/1995		
GENERAL IMMUNOLOGY (220)	07/27/1995		
HEMATOLOGY (400)	07/27/1995		
ABO & RH GROUP (510)	07/27/1995		
ANTIBODY TRANSFUSION (520)	06/27/2002		
ANTIBODY IDENTIFICATION (540)	07/27/1995		
COMPATIBIL!TY TESTING (550)	07/27/1995	J	

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.HHS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

State of California Department of Public Health CLINICAL LABORATORY LICENSE

In accordance with the provisions of Chapter 3, Division 2 of the Business and Professions Code, the persons named below are hereby issued a license authorizing operation of a clinical laboratory at the indicated address or other site(s) on file with the department.

OKLAHOMA BLOOD INSTITUTE 1001 NORTH LINCOLN BLVD OKLAHOMA OK 73104

OWNER(S):

OBI HOLDING COMPANY JOHN ARMITAGE MD JAMES SMITH MD RANDY STARK KIM VAN ANTWERPEN CHARLES MOONEY **DIRECTOR(S):**

JAMES SMITH MD

Lab ID Number: COS 00800359

Effective Date: August 01, 2014 Valid Until: July 31, 2015 CLIA Number: 37D0470358 Beatrice R. O'Keefe, Division Chief

Laboratory Field Services

FOR FDA USE ONLY

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION **BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING**

1. REGISTRATION NUMBER	3. REASON FOR SUBMISSION						
FEI: 1626009	.1 ANNUAL REGISTRATION						
CFN: 1626009	2 NITIAL REGISTRATION						

2. U.S. LICENSE NUMBER

.2 INITIAL REGISTRATION .3 🗹 CHANGE IN INFORMATION



	/00														
PLEASE READ INSTRUCTIONS CAREFULLY. Be sure to indicate any changes in your egal name or actual location in item 4, and any changes in your mailing address in item 5. Print all entries and make all corrections in red ink, if possible. Enter your phone number in item 8.3 and the phone number of your actual location in item 4.1. Sign the orm and return to FDA. After validation, you will receive your Official Registration for the ensuing year.							nd can 303(a) DIS	DISTRICT OFFICE: Dallas							
ENTER ALL CHANGES IN RED INK AND CIRCLE.	9. TYPE OF OWNERSHIP 10. TYPE ESTABLISHMENT (Chec					(Check all bo	ck all boxes that describe routine or autologous operations.)								
I. LEGAL NAME AND LOCATION (Include legal name, number and street, city, state, country, and post office code)	.1 ☐ SINGLE PROPRIETORSHIP .2 ☐ PARTNERSHIP .1 ☑ COMMUNITY (NON-HOSPITAL) .2 ☐ HOSPITAL BLOOD BANK														
Oklahoma Blood Institute Oklahoma Blood Institute Sylvan N. Goldman Center 1001 N. Lincoln Blvd. Oklahoma City, OK 73104-3299	.3 CORPORATION profit non-profit4 COOPERATIVE ASSOCIATION .5 FEDERAL (non-military) .6 U.S. MILITARY .7 STATE .8 COUNTY/MUNICIPAL/HOSPITAL AUTHORITY .9 OTHER (Specify):				.3 PLASMAPHERESIS CENTER .4 PRODUCT TESTING LABORATORY a. INDEPENDENT — ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK .5 HOSPITAL TRANSFUSION SERVICE a. — APPROVED FOR MEDICARE REIMBURSEMENT — NOT APPROVED FOR MEDICARE REIMBURSEMENT 6 COMPONENT PREPARATION FACILITY										
4.1 PHONE 405-297-5700 5. OTHER NAMES USED AT THIS LOCATION (Include trade name, doing-business-		.7 _ .8 _	.7 COLLECTION FACILITY .8 DISTRIBUTION CENTER .9 BROKER/WAREHOUSE U.S. LICENSE NUMBER OF PARENT FIRM												
as, previous names, and other firms co-located. If applicable, include registration number.)				.10	OTHER (Sp	ecify) :		-							
Oklahoma Blood Institute (OBI) Oklahoma Blood Institute Legacy Building 901 N. Lincoln Blvd. Oklahoma C	11. PRODUCTS X ALLOGENEIC AUTOLOGOUS DIRECTED		COLLECT	MANUAL APHERESIS (.2)	AUTOMATED APHERESIS (.3)	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS (.9)				
 MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) 	WHOLE BLOOD	1	x	(in)	(17)		x	X	()	X	X				
Oklahoma Blood Institute	RED BLOOD CELLS (RBC)	2		No. of the least	х	х	х	х		х	х				
ATTN: Marta Payne	RBC FROZEN	3				х	х	х		х	х				
Sylvan N. Goldman Center	RBC DEGLYCEROLIZED	4				x	х	х		х	х				
1001 N. Lincoln Blvd.	RBC REJUVENATED	5						х							
Oklahoma City, OK 73104-3299	RBC REJUVENATED FROZEN	6				х	х	х		х	х				
,,	RBC REJUVENATED DEGLYCEROLIZED	7				х	х	х		х	х				
	CRYOPRECIPITATED AHF	8				х				х	х				
 U.S. AGENT (Include name, institution name if applicable, number and street, city, state, and zip code) 	PLATELETS	9			x	х	х	х		х	х				
state, and zip code)	LEUKOCYTES/GRANULOCYTES	10			х	х				х	х				
	PLASMA	11			х					х	х				
	PLASMA CRYOPRECIPITATE REDUCED	12			х	х				х	х				
	FRESH FROZEN PLASMA	13			х	х				х	х				
	LIQUID PLASMA	14				x				х	х				
	THERAPEUTIC EXCHANGE PLASMA	15													
7.1 E-MAIL ADDRESS	SOURCE LEUKOCYTES	16				x				х	х				
7.2 PHONE	SOURCE PLASMA	17													
3. REPORTING OFFICIAL'S SIGNATURE	RECOVERED PLASMA	18				x				х	х				
M_{\bullet} C	BLOOD PRODUCTS FOR DIAGNOSTIC USE	19	х			х				х	х				
Montafore	BLOOD BANK REAGENTS	20	U TO SE												
8.1 TYPED NAME Marta Payne	OTHER Platelets Washed	21				x		х		х	х				
8.2 E-MAIL ADDRESS mapayne@obi.org															
8.3 PHONE 405-297-5700 8.4 DATE 43/15															

See Instructions for OMB Stalement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,

1. REGISTRATION NUMBER (FDA Establishment Identifier)

FEI: 0001626009

b. X ANNUAL REGISTRATION / LISTING DISTRICT: Dallas PRINTED BY FDA:04-DEC-2014

2. REASON FOR SUBMISSION

2. REASON FOR SUBMISSION

a. INITIAL REGISTRATION / LISTING

VALIDATION—FOR FDA USE ONLY
VALIDATED BY FDA:27-NOV-2014

AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)			c. CHANGE IN INFORMATION					TION	PRINTED BY FDA.04-DEC-2014					
PART I - ESTABLISHMENT INFORMATION	PART II - P	PART II - PRODUCT INFORMATION						00+	₹70-	m031-				
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps										FR	EGU EDI	PERS.	
a. BLOOD FDA 2830 NO. FEI: 0001626009		Establishment Functions						CT/Ps CRIBER 1271.1	CAL CAL	CT/Ps JLATE 3S OF OGIC,	14. PROPRIETARY			
b. DEVICES FDA 2891 NO.	Types of HCT / Ps		Types of HCT / Ps Recover Screen Test Package P	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	NAME(S)			
c. DRUG FDA 2656 NO.													S	
PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Oklahoma Blood Institute Sylvan N Goldman Center Oklahoma Blood	a. Bone				х						х	х	х	
Institute	b. Cartilage				X						X	X	X	
1001 N Lincoln Blvd. Oklahoma City, Oklahoma 73104-3299					X						Х	x	x	
	d. Dura Mater				X						X			
a. PHONE 405-297-5700 EXT	e. Embryo	X SIP X Directed X Anonymous			X						x	х	х	
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. c. TESTING FOR MICRO-ORGANISMS ONLY 5. ENTER CORRECTIONS TO ITEM 4	f. Fascia				X						X	х	X	
	g. Heart Valve				X						х			
	h. Ligament				X						x	x	х	
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte	X SIP X Directed X Anonymous			x						х	х	х	
Sylvan N. Goldman Center-Oklahoma Blood Institute Attn: Marta Payne	j. Pericardium				X						X	x	X	
Oklahoma Blood Institute 1001 N. Lincoln Blvd. Oklahoma City, Oklahoma 73104-3299	k. Peripheral Blood Stem	X Autologous X Family Related X Allogeneic	x	x	x	x	х	X	X	x	x		х	Hematopoietic Progenitor Cell
• Province to the control of the con	I. Sclera				X						x	X	х	
a. PHONE 405-297-5700 EXT 7. ENTER CORRECTIONS TO ITEM 6	m. Semen	X SIP X Directed X Anonymous			х						x	X	x	
b. PHONE	n. Skin				X						x	x	x	1.72
	o. Somatic Cell Therapy Products	X Autologous Family Related Allogeneic			х						х	x	x	
8. U.S. AGENT	p. Tendon				X						х	X	х	
	q. Umbilical Cord Blood	X Autologous Family Related Allogeneic			х						x	x	x	
a. E-MAIL	r. Vascular Graft				x					İ	x	x	x	
9. REPORTING OFFICIAL'S SIGNATURE	s.										,	-		
a. TYPED NAME Marta Payne	t				-									
b. E-MAIL mapayne@obi.org	u.											Collection of		
c. TITLE Regulatory Coordinator d. DATE 26-NOV-2014	v.													

State of California Department of Public Health CLINICAL LABORATORY LICENSE

In accordance with the provisions of Chapter 3, Division 2 of the Business and Professions Code, the persons named below are hereby issued a license authorizing operation of a clinical laboratory at the indicated address or other site(s) on file with the department.

VIROMED LABORATORIES, (LABCORP)

1447 YORK COURT
BURLINGTON NC 27215

OWNER(S):

LABORATORY CORPORATION OF AMERICA HOLDINGS

DIRECTOR(S):

CHARLES P CARTWRIGHT PHD

Lab ID Number: COS 00800057

Effective Date: May 06, 2014
Valid Until: May 05, 2015
CLIA Number: 24D0400424

Beatrice R. O'Keefe, Division Chief

Laboratory Field Services

CENTERS FOR MEDICARE & MEDICAID SERVICES CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS VIROMED LABORATORIES INC 1447 YORK COURT BURLINGTON, NC 27215 CLIA ID NUMBER 24D0400424

EFFECTIVE DATE

02/28/2015

LABORATORY DIRECTOR

EXPIRATION DATE

CHARLES P CARTWRIGHT DIREC

02/27/2017

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Karen W. Dyer, Acting Director Division of Laboratory Services Survey and Certification Group Center for Clinical Standards and Quality

371 Certs2_020315

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialtics/subspecialtics you are certified to perform and their effective date:

LAB CERTIFICATION (CODE) BACTERIOLOGY (110)	EFFECTIVE DATE 01/22/2010	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
VIROLOGY (140)	01/22/2010		,
SYPHILIS SEROLOGY (210)	01/22/2010		
GENERAL IMMUNOLOGY (220)	01/22/2010		

CENTERS FOR MEDICARE & MEDICAID SERVICES CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS

LABORATORY CORPORATION OF AMERICA 13112 EVENING CREEK DR SOUTH STE 200 ATTN QA SAN DIEGO, CA 92128

LABORATORY DIRECTOR

JENNY R GALLOWAY M.D.

CLIA ID NUMBER
05D0571200

EFFECTIVE DATE

02/28/2015 EXPIRATION DATE

02/27/2017

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Karen W. Dyer, Acting Director Division of Laboratory Services

Survey and Certification Group Center for Clinical Standards and Quality

1243 Certs2_020315

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE) EFFECTIVE DATE
BACTERIOLOGY (110)	10/17/2006	ANTIBODY TRANSFUSION (520) 09/03/2010
MYCOBACTERIOLOGY (115)	07/10/2006	ANTIBODY NON-TRANSFUSION (530) 08/30/1995
MYCOLOGY (120)	09/12/2008	ANTIBODY IDENTIFICATION (540) 05/19/2009
PARASITOLOGY (130)	10/24/2002	
VIROLOGY (140)	09/06/2012	
SYPHILIS SEROLOGY (210)	08/30/1995	
GENERAL IMMUNOLOGY (220)	08/30/1995	
ROUTINE CHEMISTRY (310)	08/30/1995	
URINALYSIS (320)	10/24/2002	
ENDOCRINOLOGY (330)	08/30/1995	
TOXICOLOGY (340)	04/10/2003	
HEMATOLOGY (400)	08/30/1995	
ABO & RH GROUP (510)	08/30/1995	



Dear Laboratory Director:

Attached below is your clinical laboratory license. Your license is void after the expiration date below.

Expiration Date: May 15, 2015

LABORATORY CORPORATION OF AMERICA 13112 EVENING CREEK DR S STE 200 SAN DIEGO CA 92128-4108 DISPLAY:

State law requires that the clinical laboratory license shall be conspicuously posted in the clinical laboratory.

CHANGE OF LABORATORY NAME,
DIRECTOR, OWNER AND/OR ADDRESS:

State law requires that the laboratory owner and/or the director notify this office within 30 days of any change in ownership, name, location, or laboratory directors. YOUR LICENSE ALSO WILL BE AUTOMATICALLY REVOKED 30 DAYS AFTER A MAJOR OWNER AND/OR DIRECTOR CHANGE.

You must submit a completed application for a new clinical laboratory license or registration within those 30 days or cease engaging in clinical laboratory practice. Mail written notification and/or application to the address indicated below,

California Department of Public Health Laboratory Field Services, Facility Licensing Section 850 Marina Bay Parkway, Building P, 1st Floor Richmond, CA 94804-6403

Thank you for your cooperation.

Lab 142 Labelin (11-12)

Total Here

Tear Here

State of California Department of Public Health

In accordance with the provisions of Chapter 3, Division 2 of the Business and Professions Code, the persons named below any hereby issued a license authorizing operation of a clinical laboratory at the angitated address or other site(s) operations with the magazine of a clinical laboratory.

LABORATORY CORPORATION OF MERICAL STREET OF THE SOUTH STREET OF TH

OWNER(S):

LABORATORY CORPORATION

DIRECTOR(S):

JERINY R GALLOWAY MD

Lab ID Number: CLF 00000072

Effective Date: May 16, 2014 Valid Until: May 15, 2015 CLIA Number: 05D0571200 Beatrice R. O'Keefe, Division Chief Laboratory Field Services

No. 0186 P. 2/2

Jul. 8. 2014 9:35AM LabCorp

FORM APPROVED: OME No. 0910-0052. Expiration Date: March 31, 2015. See instructions for CMB Statement 1. REGISTRATION NUMBER 3. REASON FOR SUBMISSION FOR FDA USE ONLY DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FEI: 2183472 .1
ANNUAL REGISTRATION CFN: 2183472 2 INITIAL REGISTRATION 2. U.S. LICENSE NUMBER .3 CHANGE IN INFORMATION PLEASE READ INSTRUCTIONS CAREFULLY. Be sure to indicate any changes in your legal name or actual location in item 4, and any changes in your mailing address in item 6. Pinnt all entries and make all connections in red ink, if possible. Enter your phone number in kine 3 and the abone number of your actual location in item 4.1. Sign the form and return to FDA. After validation, you will receive your Official Registration for the form and return to FDA. After validation, you will receive your Official Registration for the This form is authorized by Sections 510(b), (j) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (j) and 374). Failure to report this information is a violation of Section 301(f) and (g) of the Act (Title 21, United States Code 331(f) and (g)) and can result in a fine of up to \$1,000 or imprisonment up to one year or both, pursuant to Section 303(a). PRINTED BY FDA: 18-NOV-2014

PRINTED BY FDA: 08-JAN-2015 PRINTED BY FDA: 08-JAN-2015 ENTER ALL CHANGES IN RED INK AND CIRCLE. 9. TYPE OF OWNERSHIP 10. TYPE ESTABLISHMENT (Chuck all boxes that describe routine or outologous operations.) LEGAL NAME AND LOCATION (Include legal name, number and street, city, state, country, and post office code) .: SINGLE PROPRIETORSHIP .: COMMUNITY (NON-HOSPITAL) BLOOD BANK 2. PARTNERSHIP 2 HOSPITAL BLOOD BANK .3 CORPORATION profit______ non-profit____ PLASMAPHERESIS CENTER Laboratory Corporation of America-ViroMed Laboratories .4☐ COOPERATIVE ASSOCIATION 452 PRODUCT TESTING LABORATORY 1447 York Court Burlington, NC 27215 .5 FEDERAL (non-military) a. ____INDEPENDENT ASSOCIATED W/ COMMUNITY of HOSPITAL BLOOD BANK .6 U.S. MILITARY .7 STATE .5 ... HOSPITAL TRANSFUSION SERVICE .8 COUNTY/MUNICIPAL/HOSPITAL AUTHORITY 9 OTHER (Specify): 6 COMPONENT PREPARATION FACILITY
7 COLLECTION FACILITY
8 DISTRIBUTION CENTER 4.1 PHONE 800-582-0077 U.S. LICENSE NUMBER OF PARENT FIRM 5. OTHER NAMES USED AT THIS LOCATION (Include trade name, doing-business-as, previous names, and other firms co-located. If applicable, include registration .9 BROKERWAREHOUSE .10 OTHER (Speaty): CCLLECT VANUAL AUTOMATED PREPARE LEUKOCYTES
RECUCED
RECUCED 11. PRODUCTS CETALCAREL DONOR RETESTED TEST (.7) (.9) 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if WHOLE BLCCO applicable, number and street, city, state, country, and post office code) Laboratory Corporation of America - ViroMed Laboratories RED BLOOD CELLS (RBC) RBC FROZEN ATTN: Michael Roberts 1447 York Court RBC DEGLYCEROLIZED Burlington, NC 27215 RBC REJUVENATED RBC REJUVENATED FROZEN RBC REJUVENATED DEGLYCEROLIZED CRYOPRECIPITATED AHE 7. U.S. AGENT (Include name, institution name if applicable, number and street, city, PLATELETS state, and zip code) LEUKOCYTES/GRANULOCYTES PLASMA x PLASMA CRYCPRECIPITATE REDUCED FRESH FROZEN PLASMA X LIQUID PLASMA x THERAPEUTIC EXCHANGE PLASMA 15 7.1 E-MAIL ADDRESS SOURCE LEUKOCYTES

17

18

19

20

21

х

x

SOURCE PLASMA

OTHER Serum

RECOVERED PLASMA

BLOOD BANK REAGENTS

BLOOD PRODUCTS FOR DIAGNOSTIC USE

8.2 E-MAIL ADDRESS robertm@labcorp.com

Maket

8.4 DATE

8. REPORTING OFFICIAL'S SIGNATURE

8.1 TYPED NAME Michael Roberts

Maken

8.3 PHONE 336-436-3555

7.2 PHONE