

WELCOME FROM YOUR PROJECT TEAM!

LabCorp Clinical Trials has been selected by University of California San Francisco to perform the DNA Extraction for Protocol POINT NCT00991029.

As such, we have the pleasure of providing you and your team with all the necessary information and instructions in order to make our collaboration as successful as possible.

The LabCorp team members designated for this study are identified below. We encourage you to contact us as frequently as necessary to answer any questions and address any concerns. We are here to provide all needed study assistance and support.

Your Site Support Associate will be your first avenue of communication on most study related items.

LabCorp Clinical Trials operates Monday through Friday between 8:00 AM and 6:00 PM Eastern Standard Time (EST). All calls received after business hours, on holidays, or on weekends will be forwarded to the Clinical Trials voice mailbox. If a message is left during this time, your call will be returned promptly on the next business day. There is also an on-call phone (919-602-2139) which is carried by our Site Support Team for EMERGENCIES ONLY. Emergency on-call hours extend from 6:00 PM to 10:00 PM EST, Monday through Friday, and 9:00 AM to 5:00 PM (EST) on Saturdays and Sundays.

All individuals associated with the clinical portion of this study should carefully review all applicable instructions and procedure descriptions prior to submitting or collecting samples. If there are any questions or concerns, please contact your Site Support Associate, listed below.

We wish you great success with your study and look forward to the receipt of your samples.

Sincerely, Melanie Little Project Manager

		TEL:	1-877-788-8861
Site Support Associate	Site Support US	FAX:	1-512-225-1273
		E-MAIL:	MonitoringUS@covance.com
		TEL:	1-919-474-4357
Project Manager	Melanie Little	FAX:	1-919-474-4385
		E-MAIL:	Melanie.little@covance.com
		_ 10/ 021	

LabCorp Clinical Trials – Cranford, New Jersey: 1-877-788-8861



LABORATORY MANUAL ~ Canada Sites ONLY

University of California San Francisco POINT NCT00991029



Sponsor:

University of California San Francisco 675 Nelson Rising Lane, Room 402A San Francisco, CA 94158

Central Laboratory Facilities:

LabCorp Clinical Trials Center for Esoteric Testing 1447 York Court Burlington, NC 27215 USA LabCorp Clinical Trials LabCorp CMBP 1904 Alexander Drive RTP, NC 27709 USA LabCorp Biorepository 724 Chipola Street Kannapolis, NC 28083 USA



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SUMMATION OF CHANGES

Description of Change	Section	Date Added	Version
Initial Release	N/A	May 2013	1.0
Updated contact title (from Monitor to Site Support Associate)	Entire Document	12-Nov-2013	2.0
Updated contact information (replaced Rosanna Mantini with Ajesh Raju)	Welcome Page	12-Nov-2013	2.0
Replaced packaging illustration (from Esoterix to current inventory)	Action Plan	12-Nov-2013	2.0
Updated example	Chapter 2	12-Nov-2013	2.0
Replaced packaging illustrations to reflect current inventory	Chapter 4	12-Nov-2013	2.0
Updated holiday schedule	Appendix 2	12-Nov-2013	N/A
Updated RTP CLIA certificate	Appendix 4	12-Nov-2013	N/A
Updated Dr. Hancock's CV	Appendix 5	12-Nov-2013	N/A
Updated Shipment Alert Form contact information (replaced Rosanna Mantini with Ajesh Raju)	Appendix 6	12-Nov-2013	N/A
Updated Project Manager (Ajesh Raju to Melanie Little) and Site Support Associate (Brittney Whitworth to Jaeson Hackett)	Welcome Page, Appendix 6	05-Aug-2015	3.0
Revised Chapter numbers and Appendix numbers	Table of Contents	05-Aug-2015	3.0
Updated formatting for the Schedule of Assessments and removed the internal LabCorp mnemonics	Chapter 1	05-Aug-2015	3.0
Removed 2013 and 2014 holidays	Appendix 2	05-Aug-2015	N/A
Updated RTP CAP and Burlington CAP/CLIA	Appendix 4	05-Aug-2015	N/A
Updated CVs	Appendix 5	05-Aug-2015	N/A
Removed Jaeson Hackett as SSA and added Site Support US.	Welcome Page and App. 6	17-Mar-2016	4.0
Updated US PM email address.	Welcome Page	17-Mar-2016	4.0
Added updated CLIA for RTP	Appendix 4	17-Mar-2016	N/A
Removed 2015 Holiday Scheduled	Appendix 2	17-Mar-2016	N/A
Removed SSA and PM information from bottom of Shipment Alert Form as this information is no longer needed.	Appendix 6	17-Mar-2016	N/A
Added updated CV for RTP	Appendix 5	17-Mar-2016	N/A
Removed old Baseline +DNA + Plasma requisitions and added updated requisitions to reflect the 5 digit ID	Chapter 2	15-Apr-2016	4.0

ACTION PLAN



Courier Information



Select the Correct Sampling Kit



Complete the Laboratory Requisition Form



Collect and Prepare the Specimens



Package for Transport



Result Report

For the transportation of samples from your site to the lab, one or more couriers may have been selected. If you receive additional or supplemental information with courier instructions, please review the material and then file in Chapter 1.

Organize pickup with the selected courier company

- Latest Booking Time: This time is provided by the courier company and is the latest possible time to arrange a pickup of samples for that day. To ensure the timely pickup <u>and</u> delivery of your samples to the central laboratory, it is imperative to alert the courier company <u>before</u> this "Latest Booking Time".
- **Booking Number:** Once you have scheduled your pickup, you should be given a booking or pickup number. Please document this number as confirmation of your request.
- Latest Pickup Time: This is the latest possible time during a day for the courier to collect the samples from your site and meet the specified delivery time to the central laboratory. This time is based on the routine service provided.
- **Problems with Pickup:** If you experience any problem with the pickup of your samples (e.g. courier is not showing up), **please contact LabCorp immediately.** Be prepared to provide the booking number and the airway bill number so we can work with the courier company to resolve the problem. <u>Do not wait</u> until the next day to inform LabCorp of the issue, as this can delay the processing of your samples and possibly compromise the integrity of the specimens.

Dry Ice

• If dry ice is needed for the transport of samples, ordering details can be found in Chapter 1.

Holidays

- Please check your local holidays before shipping samples, as customs and courier services may not be operational prior to, during or following an observed holiday in your country.
- The LabCorp facilities are closed on Sundays, and on certain holidays (See Appendix 1).
- It is advisable to avoid shipments immediately prior to any of the dates listed in Appendix 1. To ensure a timely delivery, please schedule your shipment no later than 3 days before any holiday.

FOR SPECIFIC COURIER INFORMATION REGARDING YOUR STUDY, PLEASE REFER TO CHAPTER 1.

- You were provided with sampling kits and some bulk supplies.
- Each kit contains the required materials to collect, prepare, and return the samples to LabCorp Clinical Trials.
- The requisition form and barcode labeled items, included inside each kit box, are preprinted and contain the <u>same</u> barcode number. Do not transfer the contents between kits.
- All label information must be completed prior to shipping the samples.

PLEASE MAKE SURE YOU HAVE SELECTED THE CORRECT SAMPLING KIT:

- Check <u>PROTOCOL</u>
- Check <u>KIT TYPE</u>
- Check EXPIRATION DATE

If the incorrect sampling kit is selected for the visit, samples may be missing or drawn unnecessarily. Verification of those samples in question may delay the reporting of results.

In case your kits are about to expire

Order new kits using the reorder form provided in Appendix 5. Expired kits can be destroyed as per local regulations.

In case you have an unsuccessful collection

Should an item be broken or wasted, replace it with an item from the bulk supplies. There are additional bar-coded labels in each collection kit. Affix one of the extra bar-coded labels in a way that can be easily scanned (e.g. lengthwise for a tube). Make sure the "Lot Expiration" barcode is not covered. Complete the information required on the label, including the name of the procedure required.

Reordering supplies

To reorder supplies, make a copy of the study-specific Reorder Form provided in Appendix 5. Complete the Supply Reorder Form and fax to the fax number listed on top of the form.

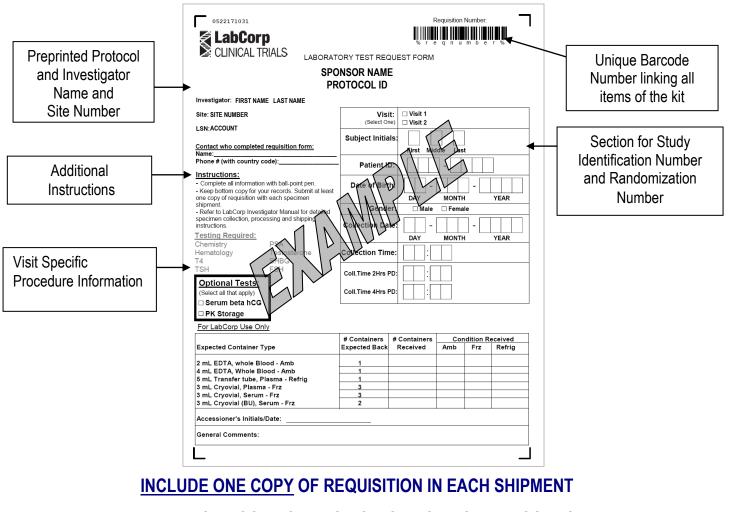
When reordering supplies, please allow a minimum of 5 to 7 working days for assembly and delivery of your supplies.

FOR EXAMPLES OF STUDY-SPECIFIC REQUISITION FORMS, PLEASE REFER TO CHAPTER 3.

The Laboratory Requisition Form is included in the sampling kit

- Specimens submitted for DNA Extraction/plasma storage **must** have an accompanying requisition form.
- The <u>barcode number</u> on the requisition form **must match** the <u>barcode number</u> on the preprinted label.
- The <u>subject and collection information</u> on the requisition form **must match** the <u>subject information</u> on the label.
- The subject information must be written legibly and completely.
- All requested <u>subject and collection information</u> must be entered for each visit to ensure proper sample processing within the laboratory.

<u>NOTE</u>: If there are any discrepancies as outlined above, verification from your facility will be required.



RETAIN ONE COPY OF REQUISITION FOR YOUR RECORDS

COMPLETE ALL INFORMATION AS REQUESTED ON THE REQUISITION

1. Use the International Date Format: (ex. 15-OCT-2012)

For month format (MMM), please use following abbreviations:

JAN (January)	JUL (July)
FEB (February)	AUG (August)
MAR (March)	SEP (September)
APR (April)	OCT (October)
MAY (May)	NOV (November)
JUN (June)	DEC (December)

- 2. Use the 24 Hour Time Format: (ex. 14:30)
- 3. IF APPLICABLE:
 - Be sure to mark the correct Visit.
- 4. Please do not insert any information into the "For LabCorp Use Only" section.

- All samples must arrive with a matching requisition enclosed in the specimen bag.
- All samples must be identified with the corresponding Barcode/Subject Label.
- Specimen Requirements have been carefully determined. It is critically important that the instructions in this manual and on the lab requisition form are followed precisely. Examples of Specimen Requirements may include:
 - Sample Type (e.g. serum, plasma, whole blood, urine, tissue)
 - Tube/Container Type (e.g. Red Top Tube [no preservative], Sodium Heparin, Formalin)
 - Temperature (e.g. Ambient, Refrigerated, Frozen)
 - Amount of sample (e.g. minimum required or full draw no short samples)

NOTE: Shipments are subject to local, national, and international laws and regulations. Individuals preparing shipments are responsible for ensuring all applicable requirements, laws and certifications are met. The shipment boxes, provided to you by LabCorp or the courier, are compliant with International Air Transport Association (IATA) guidelines.

The technical information presented in this manual does <u>not</u> qualify as regulatory training or certification. Any questions regarding certification in the preparation, handling or shipment of dangerous goods should be directed to the appropriate authorities or regulatory agencies.

For a list of the IATA approved training schools, please contact your local office (details can be found at <u>www.iata.org/about/offices</u>) or the IATA main facility in Montreal, Canada (+ 1 514 874 0202).

- All study related data will be forwarded as per specifications from the sponsor.
- Any missing information or discrepancies could delay the transfer of data.

FOR STUDY-SPECIFIC RESULT REPORTING, PLEASE REFER TO CHAPTER 6.



University of California San Francisco POINT NCT00991029



Study-specific Instructions ~ Canada Sites ONLY ~





SCHEDULE OF ASSESSMENTS

Visit Name/Visit Number					Baseline DNA + Plasma	
	Visit Type					
Test Panel/Name	Specimen Type	Sample Tube/ Cryovial Samples permitted to be				
rest Fanel/Name	Specimen Type	Collection Tube	(Coming back)	batched		
Plasma- storage	Diserve		6 x 2ml Cryovial	Var	F	
DNA Extraction- Buffy coat	Plasma	10 ml EDTA 10 ml Cryovial ¹		Yes ²	F	

¹Following centrifugation at the site, plasma is transferred to 2ml Cryovials and frozen on-site. The remaining RBCs and buffy coat is transferred from the 10ml EDTA to a 10ml Cryovial and is frozen and shipped along with 2ml Cryovials.

²Samples can be batched at the site and shipped every 3 months only if the samples are stored at -70°C to -90°C. Ship the specimens on dry ice within 4 days of collection if they were stored frozen in a **-20°C,-30°C or -40°C freezer**.

Notes:

S: Scheduled / F: Frozen

TEST REQUISITION EXAMPLE







LABORATORY TEST REQUEST FORM

Investigator:

Site:	V	isit: Baselin	e DNA	+ Plas	ma	
LSN:						
Contact who completed requisition form: Name:	Subjec	t ID:				
Phone #: (with country code-International sites only)	Randomizatio	n #·		7		
Instructions:	Randomizatio					
 Complete all information with ball-point pen. Keep bottom copy for your records. Submit at least one copy of requisition with each specimen shipment. Refer to LabCorp Investigator Manual for detailed 	Collection D	ate:	MONT	 н	YEAR	
 Specimen collection, processing and shipping instructions. ENSURE PATIENT CONSENT FORM IS SIGNED 	Coffection Ti (84 vr clock)	me:	MM			
BEFORE SAMPLES ARE COLLECTED.						
IMPORTANT: When aliquoting plasma from EDTA tube, do NOT pipette buffy coat and ensure it remains in the EDTA tube.	Was a refrigerated centrifuge used? Yes No At what freezer temperature were samples stored?					
After plasma is transferred equally into 6 x 2ml cryovials, transfer the packed RBCs & buffy coat from		□ -20°C				
the EDTA tube into the 10mL cryovial. Complete	□ -70°C					
information on all tube labels & freeze all cryovials. Empty EDTA tube can be discarded.		□ Other:	_°C (ent	er tempe	rature)	
Testing Required: DNA Extraction	Site Comment:					
For LabCorp Use Only		(Not entered into	b LabCorp d	atabase)		
	# Containers	# Containers	Cor	dition R	eceived	
Expected Container Type	Expected Back	Received	Amb	Frz	Refrig	
10 mL Cryovial, Buffy Coat - Frz	1					
2 mL Cryovial, Plasma - Frz	6					
Accessioner's Initials/Date:						
General Comments:						
LabCorp BVBA Clearstone Central Laborator Intercity Business Park (China) Inc.,203-204 Shidao - Generaal De Wittelaan L11 A2 2 Tongji Middle Road, BDA 2800 Mechelen Belgium Belging 100176 PR China	Soloon Black 33, #03	ntral Laboratories (Sir 06, Marsiling Industria entral Industrial Estate	al Estate Roa	d 3 - 750 W	rd. NJ 07016	



SPECIMEN COLLECTION AND PREPARATION General Reminders

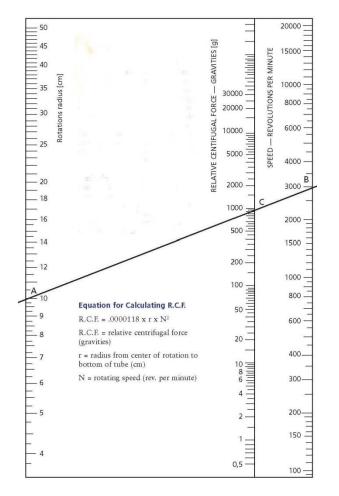
- Throughout specimen collection and handling, proper universal precautions should be practiced. Precautions such as collection gloves, protective eye wear, and lab coats should be worn throughout the collection and specimen handling procedure. Particular caution should be observed during venipuncture.
- Confirm that Informed Consent for the biomarkers study was obtained.



SPECIMEN COLLECTION AND PREPARATION

CENTRIFUGATION

Guidelines for the Conversion of Relative Centrifugal Force (g) to RPM (Rotations per Minute)



Radius (cm)	G-force	RPM
10	1200	3280
12	1200	2990
14	1200	2770
16	1200	2590
18	1200	2440
20	1200	2310
22	1200	2200
24	1200	2110
26	1200	2030
28	1200	1950
30	1200	1890

Radius (cm)	G-force	RPM
10	1500	3660
12	1500	3340
14	1500	3090
16	1500	2890
18	1500	2730
20	1500	2590
22	1500	2470
24	1500	2360
26	1500	2270
28	1500	2190
30	1500	2110

Note: If you need further assistance, please call your LabCorp Site Support Associate.



SPECIMEN COLLECTION AND PREPARATION

NOTE: Instructions outlined below are for DNA+Plasma portion of the study.

VISITS	PROCEDURES	COLLECTION TUBES	INSTRUCTIONS / STABILITY	TUBES TO BE SENT BACK	SHIPPING TEMP.	SHIPPING Frequency / Courier / Location
Baseline DNA + Plasma	Plasma Storage		 -Completely fill the lavender top EDTA tube. -Gently invert the tube at least 6-8 times immediately after collection to avoid clotting. -Complete the label with the SubjID (Subject ID) and Random# (Randomization #). -Fill out the Laboratory Request Form. -Separate the plasma from the cells by centrifuging at 1000 <i>x g</i> for 15 minutes. -Refrigerated centrifuge is preferred. Centrifuge within 30 minutes to 1 hour of collection. -Using a pipette included in the sampling kit, transfer 0.7 mL of plasma from the lavender top EDTA tube into each of the six Cryovial aliquot tubes. -Be careful not to disturb the buffy coat layer between the blood cells and the plasma. (NOTE: Buffy coat is critical for DNA extraction and if no buffy coat present, no DNA or minimal DNA is extracted). * -Secure caps on the plasma Cryovial aliquot tubes. -Complete labels for the aliquot tubes with the SubjID (Subject ID) and Random# (Randomization Number). -Transfer leftover blood cells and buffy coat into the 10 mL Cryovial. -Complete label for 10ml Cryovial with the SubjID (Subject ID) and 	Six 2 mL Cryovials	FROZEN	Ship the specimens on dry ice within 4 days of collection if the leftover cells and plasma are frozen in a -20°C, -30°C or -40°C freezer. Specimens can be stored in a -70°C to - 90°C freezer for up to three months before shipping on dry ice.
	DNA Extraction Buffy coat	10 mL EDTA Tube	 Complete laber for Tomic Cryovial with the Subjic (Subject ID) and Random# (Randomization Number). -Make sure all tubes and containers are tightly closed to avoid leakage during transport. -Insert all tubes into Aqui Pak (6 place tube holder in absorbent material), place inside largest compartment of specimen bag and seal. Insert a copy of the completed requisition form in the outer pocket of the specimen bag. (Retain one copy for your records.) IMMEDIATELY PLACE THE SPECIMEN BAG IN THE FREEZER. During freezer storage, specimens should remain in the plastic specimen bags in an upright position. NOTE: The 10 mL Cryovial containing the buffy coat and extracted plasma will be shipped together on dry ice. 	10 mL Cryovial (contains RBCs & Buffy Coat)		Monday through Thursday ONLY via FedEx to Research Triangle Park, NC

* If you accidentally draw up some of the buffy coat layer into one of the pipettes, please make a note on the Laboratory Requisition Form. This may affect the accuracy of biomarker levels.



SPECIMEN PACKAGING FOR TRANSPORT

Study-specific ATTENTION POINTS:

- All samples have to be identified with the corresponding Barcode/Subject Label.
- All tubes must be tightly closed to avoid leakage during transport.
- Samples of multiple subjects may be shipped in one container and should remain in their individual specimen bags, along with corresponding requisition forms.
- Check local and national holidays (See Appendix 1).
- ➢ In the event samples cannot be shipped on the Day of Collection (or outside cut-off times):
 - For sites participating in the DNA + Plasma portion of study and WITHOUT* a -70°C to -90°C freezer, store all samples at -20°C, -30° or -40°C and ship within 4 days of collection
 *Note: Sites with a -70°C to -90°C freezer can keep samples on site for up to 3 months before shipment to LabCorp on dry ice.

> You must fill out all FedEx air waybills completely

- Air waybills are provided and are pre-printed with site and LabCorp information. (See Chapter 1 -Courier Services)
- > Sign and Date where indicated.
- > Retain a copy for your records.

> Forward Shipment Alert Form

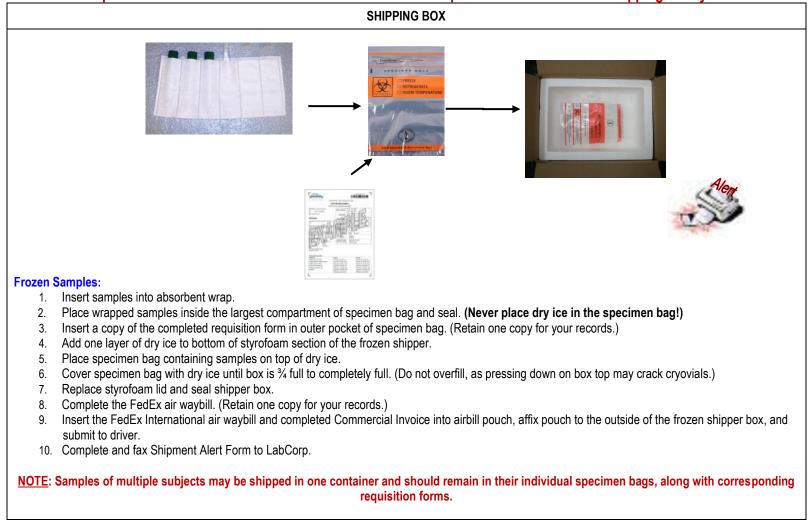
- > On the day that you ship your specimens, make a copy of the Shipment Alert Form located in Appendix 5.
- > Complete and fax the Shipment Alert Form to the **attention of your Site Support Associate**.



SPECIMEN PACKAGING FOR TRANSPORT

Non-Infectious FROZEN Shipment - Monday through Thursday ONLY

Ship the specimens on dry ice within 4 days of blood draw if the leftover cells and plasma are frozen in a -20°C, -30°C or -40°C freezer. Specimens can be stored in a -70°C to -90°C freezer for up to three months before shipping on dry ice.







LabCorp will not perform any testing. Extracted DNA samples and frozen plasma aliquots will be shipped to Mayo Clinic for analysis.

When contacting LabCorp, ALWAYS have the Requisition Number available, since this is the LabCorp primary identifier.

FEDERAL EXPRESS COURIER INFORMATION



Federal Express is selected for the transport of your biological samples. Federal Express airbills, with pre-printed site and LabCorp information, have been provided.

Web-site Address:

You can track your shipment by entering your airbill number on the following web site: www.fedex.com.

Dry Ice: (if applicable)

Sites are responsible for providing their own dry ice. Dry ice will not be provided by courier services. Obtain dry ice from a local vendor - you may access <u>www.dryiceinfo.com</u> for local vendor locations.

For Specimen Packaging and Transport instruction, please refer to Chapter 4

Note:

Federal Express will not accept any shipment without the outer cardboard box. LabCorp supplies a bulk supply of cardboard/styrofoam shippers at initiation. If you need to replenish your supply of styrofoam shippers, please contact your LabCorp Site Support Associate or complete and fax the Supply Reorder Form located in Appendix 6.

REMINDER: Specimens can only be shipped to LabCorp Clinical Trials MONDAY THROUGH THURSDAY

If you experience problems with the pickup of your samples, contact your LabCorp Site Support Associate immediately. Please be prepared to provide the booking and air waybill numbers.

NOTE: Shipments are subject to local, national, and international laws and regulations.

Individuals preparing shipments are responsible for ensuring all applicable requirements, laws and certifications are met. The shipment boxes, provided to you by LabCorp or the courier, are compliant with the International Air Transport Association (IATA) guidelines.

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For a list of IATA approved training schools, please contact your local office (details can be found at <u>www.iata.org/about/offices</u>) or the IATA main facility in Montreal, Canada (+ 1 514 874 0202).



FEDERAL EXPRESS COURIER INFORMATION

AIRBILLS:

FedEx International Air Waybill for shipments

"Date" of shipment must be indicated





FEDERAL EXPRESS COURIER INFORMATION

Enter FedEx AIRBILL # and DATE OF EXPORTATION COMMERCIAL INVOICE Frozen Shipments to LabCorp Clinical Trials INTERNATIONAL (NOTE: ALL SHIPMENTS MUST BE ACCOMPANIED AIRBILL NO BY AN INTERNATIONAL AIRBILL) DATE OF EXPORTATION EXPORT REFERENCES (ie., ORDER NO., INVOICE NO., ETC.) LSN: ###### SHIPPER/EXPORTER (COMPLETE NAME AND ADDRESS) CONSIGNEE (COMPLETE NAME AND ADDRESS) LabCorp Clinical Trials Attn: CT Specimen Management Evonne Anderson 1904 Alexander Orice Research Triangle Park NC 27709 United States Phone # 800-533-056 COUNTRY OF EXPORT HER T SIGNEE (PL) MEAND SS) COUNTRY OF MANUFACTURE United States COUNTRY OF ULTIMATE DESTINATION United States MARKS NO. OF TYPE OF TOTAL UNIT OF GOODS OTY υом WEIGHT FULL NO.S PKGS PAC VALUE VALUE Human Bological Substance Category BUN3373 (blood or serurh or urine or other body fluids 1 Ea Lbs. \$.16 \$5.00 Calton 1 r biopsies) kg. Inst. 650 NON-INFECTIOUS HUMAN SERUM SAMPLES FOR RESEARCH PURPOSES ONLY. UN3373 - BIOLOGICAL SUBSTANCE CATEGORY B Dry Ice Class 9 UN1845 Pkg. Inst. 904 Lbs. TOTAL τοται TOTAL WEIGHT NO OF INVOICE PKGS VALUE \$5.00 1 Lbs. CHECK ONE □ F.O.B. □ C & F C.I.F.

THESE COMMODITIES ARE LICENSED FOR THE OLTIMATE DESTINATION SHOWN. DIVERSION CONTRARY TO UNITED STATES LAW IS PROHIBITED. I DECLARE ALL THE INFORMATION CONTAINED IN THIS INVOICE IS TO BE TRUE AND CORRECT SIGNATURE OF SHIPPER/EXPORTER:

(PRINT NAME & TITLE AND SIGN)



US HOLIDAYS OBSERVED BY LABCORP CLINICAL TRIALS

- LabCorp will be closed on the following Holidays, and also on Sundays.
- Please keep these dates in mind as you prepare to schedule subjects for specimen collection.
- Remember to contact the courier for their list of holidays and days of reduced services.

HOLIDAY	2016		
New Year's Day	Friday, January 1		
Memorial Day	Monday, May 30		
Independence Day	Monday, July 4		
Labor Day	Monday, September 5		
Thanksgiving Day	Thursday, November 24		
Christmas Day	Sunday, December 25 (observed Monday, Dec. 26)		

HOLIDAY	2017	2018
New Year's Day	Sunday, January 1 (observed Monday, Jan. 2)	Monday, January 1
Memorial Day	Monday, May 29	Monday, May 28
Independence Day	Tuesday, July 4	Wednesday, July 4
Labor Day	Monday, September 4	Monday, September 3
Thanksgiving Day	Thursday, November 23	Thursday, November 22
Christmas Day	Monday, December 25	Tuesday, December 25



REFERENCE RANGE

NOT APPLICABLE



A valid Laboratory Accreditation is provided with the initial supply.

For online accreditation information, access:

http://www.covance.com/customers/investigators/investigator-tools-and-resources/accreditations-and-certifications.html





Accredited Laboratory



The College of American Pathologists

certifies that the laboratory named below

Laboratory Corporation of America Center for Molecular Biology & Pathology Research Triangle Park, North Carolina Arundhati Chatterjee, MD

LAP Number: 7182269 AU-ID: 1396239 CLIA Number: 34D1008914

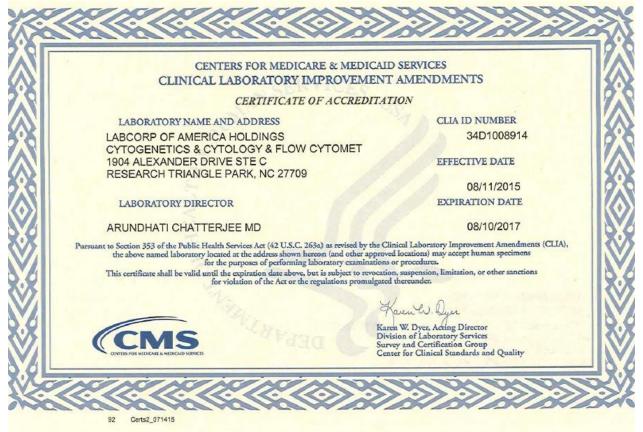
has met all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to May 24, 2016 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

RMScanlan Chair, Commission on Laboratory Accreditation

Merbelson, FCAP President, College of American Pathologists





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:

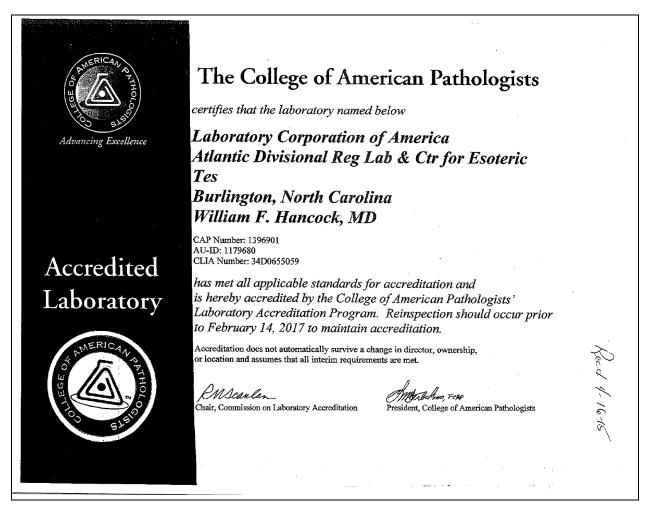
LAB CERTIFICATION (CODE) GENERAL IMMUNOLOGY (220) ROUTINE CHEMISTRY (310) HEMATOLOGY (400) CYTOGENETICS (900) EFFECTIVE DATE 04/09/2007 09/14/2009 06/18/2010

08/11/2003

LAB CERTIFICATION (CODE)

EFFECTIVE DATE

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.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.



APPENDIX







CV MEDICAL DIRECTOR

Name: Arundhati Chatterjee

Education:					
<u>High School</u> Name of High School			<u>Atter</u> From	nded To	Graduate
Multipurpose Government	High School		1965	1967	Yes
<u>College</u> Name of College or Unive	rsity	Major	<u>Atter</u> From	nded To	Degree
Bethune College, Calcutta	, India	Physics, Chemistry, Biology, English	9/67	8/68	Premedical
Calcutta Medical College University of Calcutta, We	st Bengal, India	Medical Studies	1968	1975	MBBS
Job Experience:					
Institution	Title	Job Duti	es	From	<u>To</u>
LabCorp CMBP RTP, NC	Medical Director	Biochemical Geneti Identity, Histology Molecular Genetics	Oncology,	9/07	Present
	Subspecialty Medica Director	l Uropatholo	ogy	5/04	Present
	Subspecialty Medica Director	l Uropathology/Cyto	opathology	5/04	9/07
	Pathologist and Director of Cytopathology and Surgical Pathology	Anatomic and Clinic	al Pathology	1994	5/04
Womack Army Medical Center, Fort Bragg, NC	Staff Pathologist and Chief, Clinical Pathology	Anatomic and Clinic	al Pathology	1 988	1993
Roche Biomedical Laboratories, Fayetteville, NC and Pinehurst, NC	Director of Cytopathology Laboratory	Cytopathol	ogy	1990	1994

Awards, Licenses, Board Certifications:

<u>Award, Certification</u> American Board of Pathology	<u>Date</u> 7/98 5/87	Certification Number	<u>Specialization</u> Cytopathology Anatomic and Clinical Pathology
North Carolina	1987	32199	
South Carolina	2004	27328	
Arizona	1985	15613	

Laboratory Corporation of AmericaTMHoldings (LabCorp) Center for Molecular Biology and Pathology 1912/1904 Alexander Drive

page 1 of 1

Research Triangle Park, NC 27709

Signature A. Cuaumple Effective:1/4/2016 _Review Date_1/8/16

CV MEDICAL DIRECTOR



Thay 7, 2015

GEORGE C. MAHA, JD, Ph.D., MT(ASCP) Ph.D. Medical Geneticist (ABMG) Associate Vice President Laboratory Director Laboratory Corporation of America™ Holdings DNA Identification Testing Division 1440 York Court Burlington, North Carolina 27215-3361 Telephone 1-336-436-7307 Fax 336-436-7384 E-mail: Mahag@LabCorp.com (November 2014)

Education

SCHOOL	DATES	DEGREE/PROGRAM
Upper Dublin Senior High School Fort Washington, PA	1969-1972	Diploma
St. Louis University St. Louis, Missouri	1972-1976	BA (Biology)
Department of Biology St. Louis University St. Louis, Missouri	1976-1979	MS
Biological Station University of Montana Flat Head Lake, Montana	1977	Summer Session
Department of Genetics and Development University of Illinois Urbana, Illinois	1978-1982	Ph.D.
University of Maryland College Park	1982	Continuing Education (Microbiology)
Malcolm Grow USAF Medical Center Department of Pathology Andrews AFB, Maryland	1982-1983	Biomedical Laboratory Internship
North Carolina Central University School of Law Durham, North Carolina	1991 – 1995	JD
Michigan State University East Lansing, Michigan	2006	Continuing Education (Molecular Biology)

CV MEDICAL DIRECTOR- continued



APPE

Admitted to the North Carolina Bar (1995)

Ph.D. Medical Geneticist (1987) - American Board of Medical Genetics

Laboratory Director (1987) - New York State Department of Health

Medical Technologists (1983) - American Society of Clinical Pathologist

Organizations

American Society of Clinical Pathology (ASCP)

American Association of Blood Banks (AABB) Member Parentage Testing Program Unit 1999-2003 Chair, Relationship Testing Standards Program Unit 2004 – 2008 Consultant, Relationship Testing Standards Program Unit 2009 – Present

College of American Pathologists Consultant, Histocompatibility/Identity Testing Committee 2009 – 2011 Member, Histocompatibility/Identity Testing Committee 2012 - Present

American Bar Association (ABA) - Vice Chair, Paternity Committee 1996 - 1997

National Conference of Commissioners on Uniform State Laws Observer to revision of the Uniform Parentage Act - 1997 - 2000

Positions Held

Laboratory Director, May 2000 – Present Technical Leader, November 2004 - Present Associate Vice President, May 2008 - Present DNA Identification Testing Division Laboratory Corporation of America Holdings 1440 York Court, Burlington, NC 27215-2230

Director of Laboratory Operations, January 1993 - 2000 HLA & Department of Parentage Evaluation Laboratory Corporation of America Holdings (Formerly Roche Biomedical Laboratories, Inc.) 1440 York Court, Burlington, NC 27215-2230

Associate Director, June 1987 - December 1992 HLA & Department of Parentage Evaluation Roche Biomedical Laboratories, Inc., 1447 York Court, Burlington, NC 27215-2230

Chief, Medical Genetics Laboratory, October 1984 - June 1987 USAF Medical Genetics Center, Keesler AFB, MS

Chief, Clinical Laboratory Services, September 1983 - September 1984 USAF Regional Hospital, Incirlik, Turkey



CV MEDICAL DIRECTOR- continued

(Lecturer)

Teaching Experience

School	Dates	Course Taught
St. Louis University (Teaching Assistant)	1975-1978	General Biology Comparative Anatomy
St. Louis University (Lecturer)	1976-1977	General Biology
University of Illinois (Teaching Assistant)	1978-1982	Experimental Genetics General Genetics Evolution Genetics and Society Histology
University of Maryland, European Division (Lecturer)	1983-1984	Human Genetics General Biology
Embry-Riddle Aeronautical University (Lecturer)	1985	Flight Physiology
University of Southern Mississippi (Lecturer)	1987	Medical Genetics

Military Service

Captain, United States Air Force, Biomedical Science Corps 1982-1987 Honorable Discharge: June 30, 1987

Awards and Honors

United States Air Force Humanitarian Service Award United States Air Force Commendation Medal, First Oak Leaf Cluster

Significant Scientific Continuing Education

Bode Mid-Atlantic: DNA and Investigators Workshop, Crystal City, VA	2014
25 TH International Symposium on Human Identification, Phoenix, AZ	2014
24 TH International Symposium on Human Identification, Atlanta, GA	2013
AABB, 65 th Annual Meeting, Boston, MA	2012
23rd International Symposium on Human Identification, Nashville, TN	2012
American Academy of Forensic Sciences, Annual Scientific Meeting, Atlanta, GA	2012
22 nd International Symposium on Human Identification, National Harbor, MD	2011
AABB, 64 th Annual Meeting, San Diego, CA	2011
AABB, 63 rd Annual Meeting, Baltimore, MD	2010
15th National CODIS Conference, Reston, VA	2009
AABB, 62nd Annual Meeting, New Orleans, LA	2009

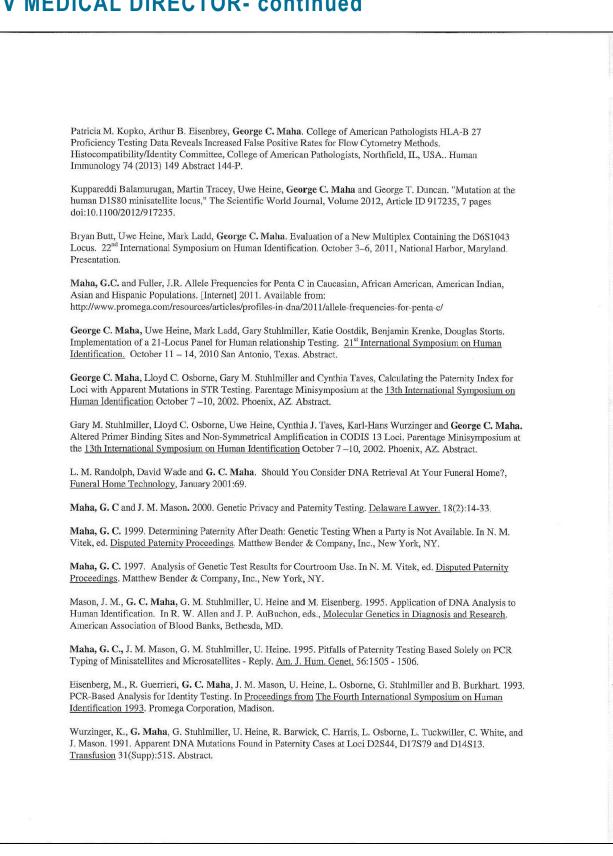
CV MEDICAL DIRECTOR- continued

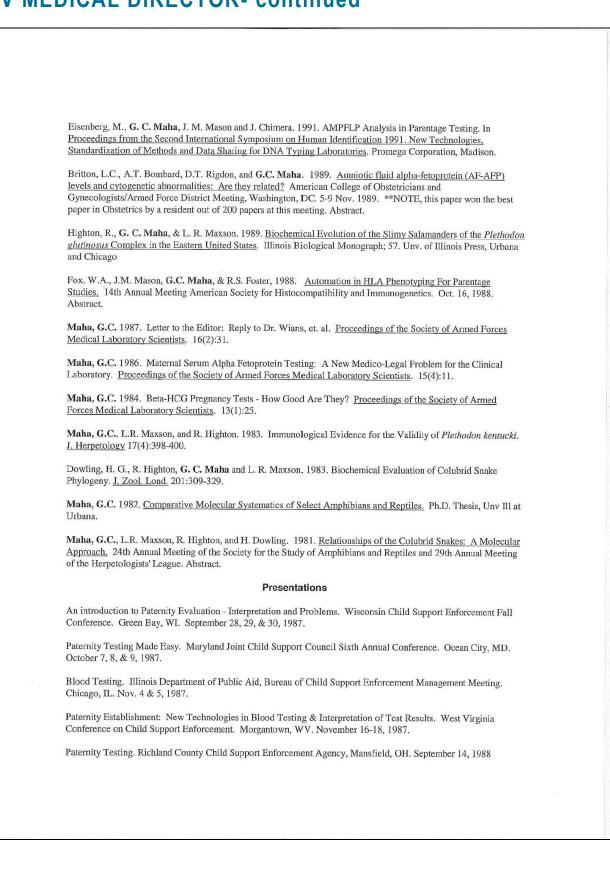
14th National CODIS Conference, Arlington, VA	2008
AABB, 61st Annual Meeting, Montreal, Quebec, Canada	2008
13 th National CODIS Conference, San Francisco, CA	2007
AABB, 60th Annual Meeting, Anaheim, CA	2007
AABB, 59th Annual Meeting, Miami, FL	2006
AABB, 58th Annual Meeting, Seattle, WA	2005
AABB, 57th Annual Meeting, Baltimore, MD	2004
American Association of Blood Banks, 56th Annual Meeting, San Diego, CA	2003
13th International Symposium on Human Identification, Phoenix, AZ	2002
American Association of Blood Banks, 55th Annual Meeting, Orlando, FL	2002
12th International Symposium on Human Identification, Biloxi, MS	2001
American Association of Blood Banks, 54th Annual Meeting, San Antonio, TX	2001
ASHI / SEOPF Regional Workshop, Raleigh, NC	2001
American Association of Blood Banks, 53rd Annual Meeting, Washington, DC	2000
10th International Symposium on Human Identification, Coronado Springs Resort, Orlando, Florida	1999
American Association of Blood Banks, 52nd Annual Meeting, San Francisco, CA	1999
Statistics and Population Genetics for Forensic Science, The Southern Association of Forensic Scientists, 1996 Fall Conference, Raleigh, North Carolina	1996
American Association of Blood Banks, 47th Annual Meeting, San Diego, California	1994
DNA Fingerprinting, NISS (National Institute of Statistical Science) Forum, Chapel Hill, North Carolina	1993
1991 International Symposium on Human Identification., Madison, Wisconsin	1991
41st Annual Meeting, The American Society of Human Genetics, Cincinnati, Ohio	1990
American Association of Blood Banks, DNA for Parentage Testing: Current State of the Art, Leesburg, Virginia	1989
The International Symposium on Human Identification, Data Acquisition and Statistical Analysis for DNA Typing Laboratories, Madison, Wisconsin	
DNA Genetic Testing: Forensic Implications For New Mexico, Family Law and Criminal Law Sections of the State Bar of New Mexico and the New Mexico Human Services Department,	
39th Annual Meeting, The American Society of Human Genetics, New Orleans, LA	1988
South-Eastern Organ Procurement Foundation, Histocompatibility Specialist Course, Phoenix, Arizona	1988
Vational Institutes of Health, Medical Genetics Course, The Foundation for Advanced Education in the Sciences, Inc., Bethesda, Maryland	1987

Abstracts and Publications

Erin M. Hall, James R. Fuller, Sarah E. Haugh, and **George C. Maha**. Use of PowerPlex® 18D in the Examination of Genomic Instability in the Short Tandem Repeat DNA Loci used for Human Cell Line Authentication Testing. 25TH International Symposium on Human Identification, Phoenix, AZ. Abstract 49.

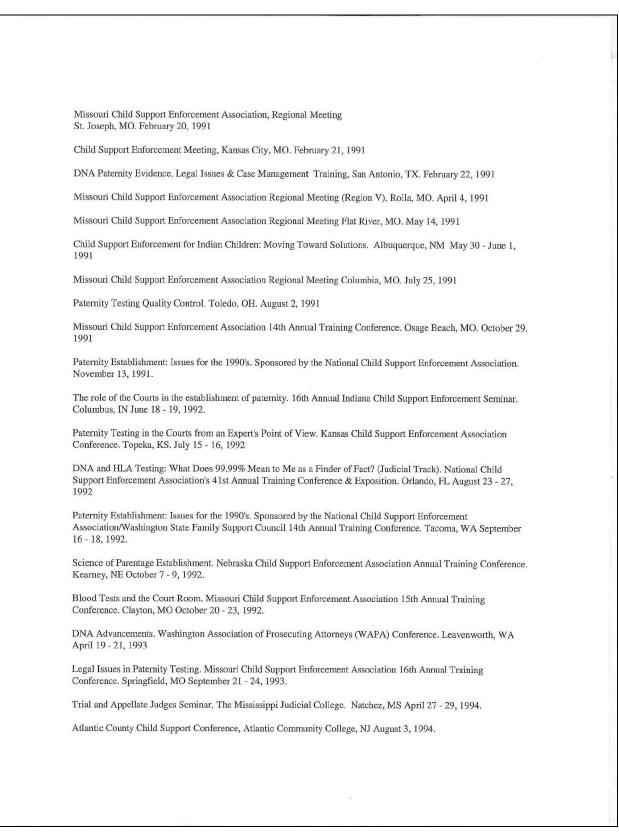
APPENDIX 5



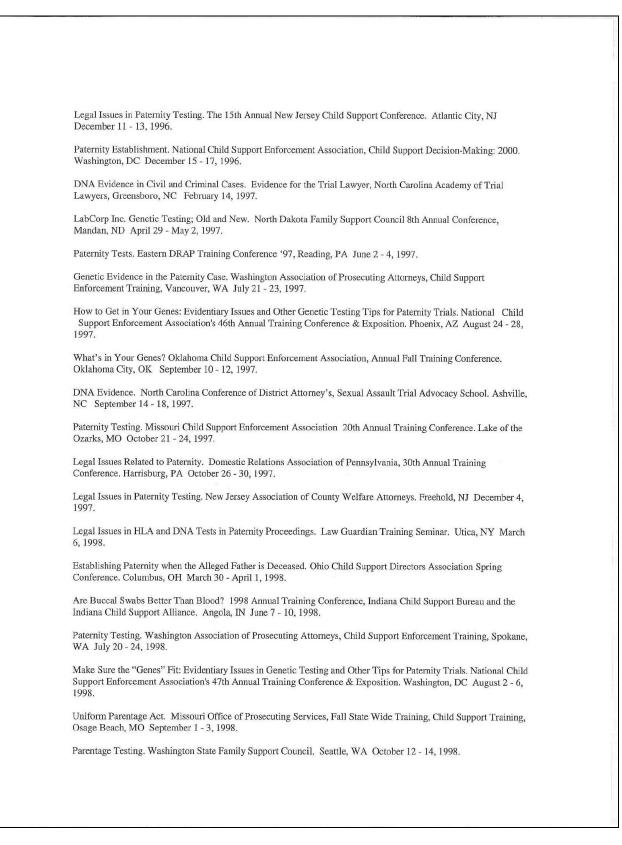




APPEN

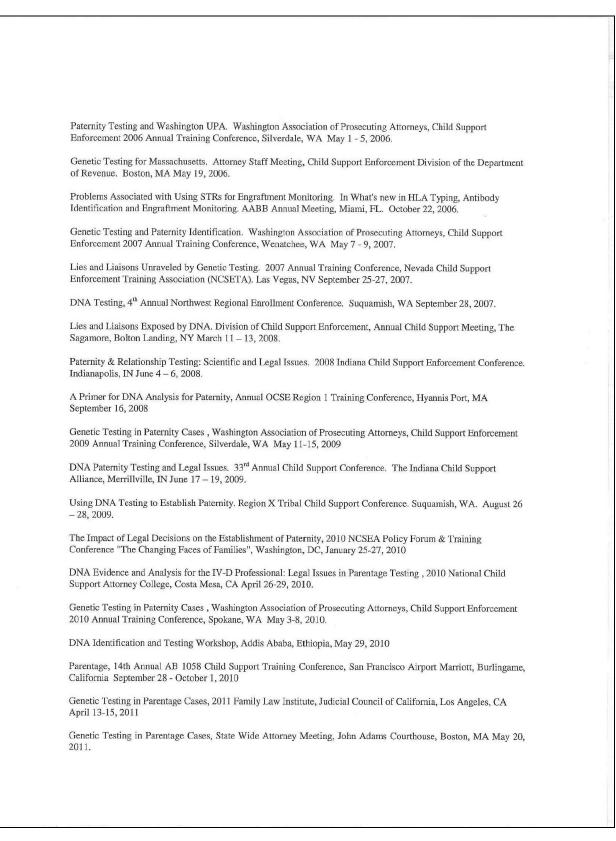














Paternity Forum: Beyond Biology, Bay Area Out Reach Conference for Child Support, San Francisco, CA June 7 – 9, 2011

DNA Paternity Testing, Indiana Child Support Conference, Indianapolis, IN June 15 - 17, 2011

Understanding DNA Results for the Courts, WICSEC 28^{th} Annual Training Conference, Austin, TX October 30 - November 3, 2011.

Legal Issues with Paternity Testing, 2012 Child Support Enforcement Conference, Indiana Department of Child Services, Merrillville, IN June 13-15 2012.

Relationship Testing Calculations: Standard Trio, Duo, RMNE and PE. AABB Audioconference. September 19, 2013. <u>http://www.aabb.org/events/audioconferences/Pages/descriptions.aspx#0919</u>

New Frontiers in Paternity Establishment. 10th Annual Child Support Conference, Rethinking Child Support: Who Moved Our Mission? Warwick, RI May 22, 2014.

DNA Testing, 38th Annual Child Support Enforcement Conference, Florence, IN June 4 - 6, 2014.

Complex Relationship Statistics Workshop. Kelly Beatty, George Frech, Donna Housley, George C. Maha. 25TH International Symposium on Human Identification, Phoenix, AZ. October 29, 2014.



Court Appearances as an Expert (State, city and number of times)

Alabama	Anniston (1)
California	Los Angeles (2)
Colorado	Denver (1)
Connecticut	Hartford (1)
Florida	Miami (2), Quincy (2)
Illinois	Urbana (1), Wheaton (1)
Indiana	Bloomfield (1), Bloomington (1), Marion (2), Martinsville (1), New Castle (2), Nashville (1), Gary (1), Terre Haute (1)
Kentucky	Louisville (2), Bowling Green (1), Owensborough (1)
Maryland	Rockville (2)
Massachusetts	Dudley (1)
Missouri	Clinton (1), Columbia (2), Harrisonville (1), Independence (2), Jackson (1), Kansas City (2), Kennett (1), Liberty (1), Monticello (1), Rolla (1), St. Charles (2), St. Louis (8), Steeleville (1), Vienna (1)
Montana	Baker (1)
Nebraska	Kearney (2), Lincoln (2), Beatrice (1), Omaha (1)
New Jersey	Atlantic City (1)
North Carolina	Newbern (1), Newton (2)
Ohio	Canton (4), Kenton (1), Hillsborough (4), Eaton (1), Port Clinton (1), Toledo (4), Akron (3)
Oklahoma	Lawton (1), Oklahoma City (1)
Oregon	Burns (1)
Pennsylvania	Philadelphia (2), Easton (1), Lancaster (1), Lebanon (2)
South Carolina	Edgefield (1)
Vermont	Woodstock (1), St. Johnsberry (1)
Virginia	Fairfax (2)
Washington	Seattle (2)
West Virginia	Parkersburg (1)
Wisconsin	Wausau (1), Crandon (1), Appleton (1), Medford (2), Superior (1), Milwaukee (2)

FORMS



Supply Reorder Form

To reorder supplies, use the LabCorp study-specific reorder form on the following page. Please make copies as needed.

Complete the Supply Reorder Form and fax to the fax number listed on top of the form.

Please allow a minimum of 6 to 8 business days for the assembly and delivery of reordered supplies.

Shipment Alert Form

On the day of sample shipment, please complete and fax the Shipment Alert Form to the fax number listed on the form.

Commercial Invoice

On the day of sample shipment, please complete Commercial Invoice and send with shipping documents.





Supply Reorder Form (Version 2.0 / 05-Aug-2015)

Sponsor: UCSF	Protocol: POINT NCT00991029	LSN: 101993
Site Number:	Investigator's Last Name:	
<u>By Fax</u> : 1-512-225-1273	Attn: Site Support US (1- monitoringUS@	

1. Kits - contain all supplies necessary to collect and process all Required and Optional testing for the specified visit

QUANTITY	KIT TYPE	
	Baseline DNA + Plasma	

2. Bulk - items may be used to replace damaged/expired items in the kits

QUANTITY	DESCRIPTION	CTX MNEMONIC	QUANTITY	DESCRIPTION	CTX MNEMONIC
	10 mL EDTA Plastic Tube	EDT10		Biohazard Bag	SPBAG
	2 mL Cryovial	CRYO2		Aqui Pak - 6 place tube holder in absorbent material	AQPK
	10 mL Cryovial	10CRY		Non Sterile Transfer Pipette	PIPST

3. Transport Material - items are NOT included in the kits and must be ordered separately

QUANTITY	DESCRIPTION	CTX MNEMONIC
	Styrofoam Insert for Large Kit Box	STYRO
	Frozen Shipping Container, Medium	FSCM
	FedEx Diagnostic Pak	FEDEX

		1 7	
	QUANTITY	DESCRIPTION	CTX MNEMONIC
		FedEx Airbill Pouch	POUCH
		FedEx Frozen International Airbill to RTP	FFIRT
		FedEx Saturday Delivery Labels	SADEL

SECTION TO BE COMPLETED BY THE	E SITE
Order Placed By :	Please do not
Order Date :	forget
Telephone Number :	
Date Supplies Required*:	

FOR LABCORP USE ONLY		
Date Received:		
Order Handled By:		
Date Input:		
SWO Number (CTX only):		
Expected Delivery Date:		

* ALLOW AT LEAST 6 TO 8 BUSINESS DAYS FOR DELIVERY OF SUPPLIES – Canada





SHIPMENT ALERT FORM



On the Day of Shipment, please complete this form and fax to:

LabCorp Clinical Trials FAX: 1-512-225-1273

ATTENTION: Site Support US

(Phone: 1-877-788-8861) monitoringus@covance.com

Sponsor / Protocol:	UCSF / POINT NCT00991029
Investigator Last Name:	
Site Number:	
Contact Person at Site:	
Phone Number:	
Date of Shipment:	// DD / MMM / YYYY
Number of Boxes Shipped to RTP, NC:	
FedEx Airbill Number(s):	

LSN: 101993



COMMERCIAL INVOICE Frozen Shipments to LabCorp Clinical Trials (NOTE: ALL SHIPMENTS MUST BE ACCOMPANIED INTERNATIONAL AIRBILL NO. BY AN INTERNATIONAL AIRBILL) DATE OF EXPORTATION EXPORT REFERENCES (ie., ORDER NO., INVOICE NO., ETC.) LSN: 101993 SHIPPER/EXPORTER (COMPLETE NAME AND ADDRESS) CONSIGNEE (COMPLETE NAME AND ADDRESS) LabCorp Clinical Trials Attn: CT Specimen Management Evonne Anderson 1904 Alexander Drive Research Triangle Park, NC 27709 United States Phone # 1-800-533-0567 IMPORTER - IF OTHER THAN CONSIGNEE COUNTRY OF EXPORT (COMPLETE NAME AND ADDRESS) N/A COUNTRY OF MANUFACTURE **United States** COUNTRY OF ULTIMATE DESTINATION **United States** MARKS/ NO. OF TYPE OF UNIT TOTAL FULL DESCRIPTION OF GOODS QTY. U.O.M WEIGHT NO.S PKGS PACKAGING VALUE VALUE Human Biological Substance Category B UN3373 (blood or serum or urine or \$5.00 1 other body fluids or biopsies) Ea Lbs. \$.16 1 Carton Pkg. Inst. 650 NON-INFECTIOUS HUMAN SERUM SAMPLES FOR RESEARCH PURPOSES ONLY. UN3373 -**BIOLOGICAL SUBSTANCE** CATEGORY B Dry Ice Class 9 UN1845 Pkg. Inst. 904 Lbs. TOTAL TOTAL NO OF INVOICE WEIGHT VALUE PKGS \$5.00 1 Lbs. CHECK ONE □ F.O.B. 🗹 C & F □ C.I.F.

THESE COMMODITIES ARE LICENSED FOR THE ULTIMATE DESTINATION SHOWN. DIVERSION CONTRARY TO UNITED STATES LAW IS PROHIBITED.

I DECLARE ALL THE INFORMATION CONTAINED IN THIS INVOICE IS TO BE TRUE AND CORRECT.

SIGNATURE OF SHIPPER/EXPORTER:

DATE:

(PRINT NAME & TITLE AND SIGN)