

INVESTIGATOR'S LABORATORY MANUAL

Duke Clinical Research Institute
PROTOCOL: CALERIE, Amendment 1.4

"Comprehensive Assessment of Long-term Effects of Reducing Intake of Energy (CALERIE)"

Esoterix Study Number: 100545

Courier: Federal Express

Courier Telephone: 800-463-3339

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THIS CURRENT VERSION DATED: 07-25-08 REPLACES ALL PRIOR VERSIONS

Revision Highlights:

- Revised Ambient shipping for CBC
- Modified packaging instruction for COMBO shipments
- (Please contact Esoterix with any questions)

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1.0 Study Plan

Overview of Laboratory Measurements

			Schedule of Assessments										
Visit Name			Screen	SCR- RPT	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Off Schedule /Repeats
Test/Panel	Collection Tube	Specimen Type	S	O	S	S	S	S	S	S	S	S	O
Serum Pregnancy, Qualitative (All Females)	6.0 mL SST	Serum in Transfer Tube	X	O									O
					Chemistry, Fasting	X	X	X	X	X	X	O	
Lipids Panel, Fasting	8.5 mL SST	Serum in Transfer Tube											O
CRP-hs		Serum in Transfer Tube Chilled			X				X		X		O Chilled
Insulin, Fasting		Serum in Transfer Tube Chilled			X Chilled					X Chilled		X Chilled	
Hematology Panel (CBC+Diff)	4.0 mL EDTA Lavender Tube	Whole Blood EDTA tube	X	O	X	X	X	X	X	X	X	X	O
		2 prepared Slides											
Urinalysis	Urine in BD® Urine Collection Cup	8.0 mL Urine Vacutainer tube with Preservative	X	O	X	X	X	X	X	X	X	X	O
Anemia Surveillance (Iron+CBC)	6.0 mL SST	Serum in Transfer Tube											O
	4.0 mL EDTA Lavender Tube	Whole Blood EDTA tube											

X or S: Scheduled
O: Optional

2.0 Visit Tables

THE FOLLOWING TABLE DETAILS SPECIMEN REQUIREMENTS FOR EACH TEST (AT ANY VISIT):

TEST	COLLECT	PREPARE & SUBMIT SAME DAY	SHIPPING TEMP	COURIER
*Serum Pregnancy, Qualitative	6.0 mL SST	Serum in Transfer Tube (Can share Chemistry tube if collected together)	Ambient	FedEx
**Chemistry, Fasting	6.0 mL SST	Serum in Transfer Tube	Ambient	FedEx
**Lipids Panel, Fasting	6.0 mL SST	Serum in Transfer Tube	Ambient	FedEx
CRP-hs	6.0 mL SST	Serum in Transfer Tube	CHILLED (or frozen)	FedEx
**Insulin, Fasting	6.0 mL SST	Serum in Transfer Tube	CHILLED (or frozen)	FedEx
Hematology Panel (CBC+Diff)	4.0 mL EDTA tube	Whole Blood EDTA Tube + 2 prepared Slides	Ambient	FedEx
Urinalysis	Urine in BD [®] Urine Collection Cup	8.0 mL BD [®] Urine Vacutainer Tube with Preservative	Ambient	FedEx
Anemia Surveillance (Iron+CBC)	6.0 mL SST	Serum in Transfer Tube	Ambient	FedEx
	4.0 mL EDTA Tube	Whole Blood EDTA Tube		

NOTE: Any serum tests combined with Insulin testing MUST be shipped CHILLED (or on dry ice).

*All Female Subjects will have the Serum Pregnancy test at Screen visit.

**Subject should be fasting for 12+ hours before collecting the Lipids Panel, and 8+ hours before collecting Chemistry or Insulin.

3.0 Supplies

- Visit-specific specimen collection kits (includes test request forms, specimen labels, and specimen containers). Urine collection cups and extra blood collection tubes are provided with the Bulk supplies.
- **Sites are responsible for re-ordering of supplies. Keep track of the Expiration date on the outer kit label.**
- **Please allow 5-7 business days for assembly and delivery of additional supplies.**
- Copy, Complete, and Fax the Supply Re-order Form provided in Appendix C (at the back of this Manual) or contact ESOTERIX for re-supply of kits by calling Marina Rivera directly at 877-788-8861 x5809 or by email (preferred): riveram@labcorp.com

4.0 Tube Specific Collection Procedures

- See General Venipuncture Guidelines on following page.

4.1 **6.0 or 8.5 mL SST – Chilled or Ambient**

- Gently invert sample 8 - 10 times to mix clot activator. Allow blood to clot for 30 minutes in upright position.
- Centrifuge at 1100 - 1300 x g for 10 – 15 minutes. (Refer to centrifuge chart following, if needed.)
- Transfer serum into transfer vial(s) using pipette. Each aliquot should contain at least 1.5 - 2.5 mL of serum. Do not submit hemolyzed samples.
- Refrigerate transfer tubes until time to ship.
- Ship **INSULIN/CRP** specimens **chilled** on 2 Frozen gel packs (or on dry ice). Refer to Sections 7.0 & 8.0.
- Ship all other **serum** tests **ambient** (or chilled). Refer to Sections 7.0 & 8.0.
- Ship on day of collection.

4.2 **4.0 mL EDTA tube (with or without Slides) – Ambient**

- Gently invert sample 8 - 10 times.
- Slides are not required for the CBC-only done at Anemia Surveillance visits.
- Use pencil to identify the slides with the patient ID and collection date.
- Prepare 2 blood smears with Diff-Safe and air-dry. Place into holder and seal. (See Blood Smear instructions that follow.)
- Do not open the EDTA tube. Remove Diff-Safe before shipping.
- Hold Lavender tube & slides at room temperature until time to ship.
- **Ship specimens ambient** (See Sections 7.0 & 8.0).
- Ship on day of collection.

4.3 **8.0 mL Urine Vacutainer tube with Preservative – Ambient**

- Collect the midstream portion of the first morning sample into the “BD® Urine Collection Cup”.
- Using “Sharps” precautions for the Collection Cup, transfer the urine into the 8.0 mL Urine Vacutainer tube (See instructions that follow).
- Do not open the Vacutainer.
- When urine flow stops, gently invert tube 8-10 times.
- Using a completed patient ID label, identify the tube.
- Refrigerate urine tube until time to ship.
- **Ship specimens ambient** (See Sections 7.0 & 8.0).
- Ship on day of collection.

General Venipuncture Guidelines (to avoid pre-analytical errors)

Recommended Order of Draw (to avoid cross contamination by anticoagulant)

- SST serum tubes
- EDTA tubes

Prevention of Backflow (to guard against possible adverse patient reactions)

- Place the patient's arm in a downward position.
- Hold tube with stopper uppermost.
- Make sure additives do not touch stopper or end of needle during venipuncture.

Venipuncture Technique and General Collection Instructions

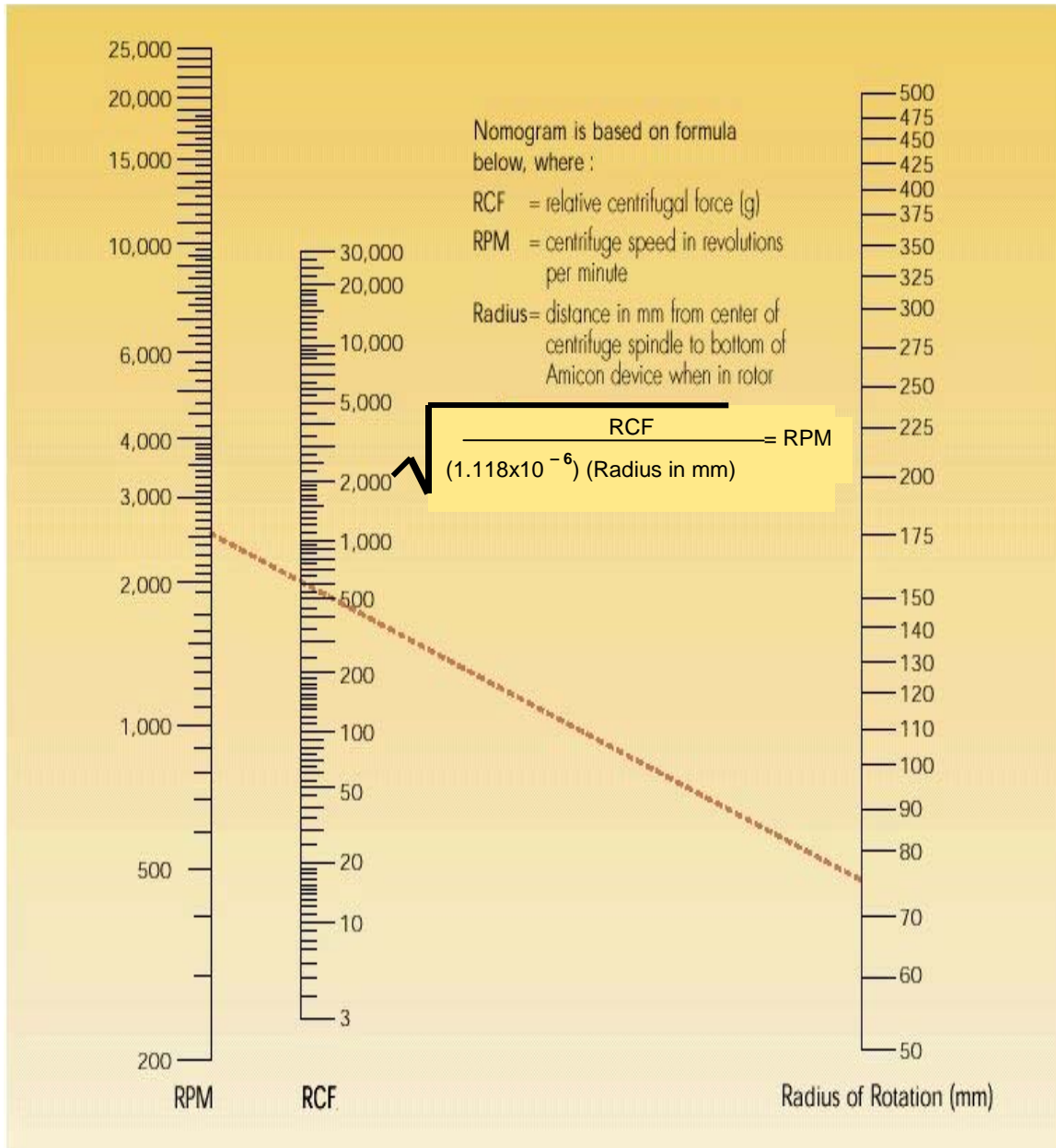
- Gather all supplies required for collection. Identify tubes with patient info. Assemble needle into holder.
- Apply tourniquet about 3-4 inches above the selected venipuncture site. The preferred site is the median cubital vein. The tourniquet should be on the arm no longer than one minute.
- Place patient's arm in a downward position.
- Prepare site with antiseptic. Allow to air dry. Do not palpate area after cleansing.
- Place tube into holder without puncturing stopper, and remove needle shield.
- Perform venipuncture. Press tube forward until stopper has been penetrated.
- Confirm correct position of needle cannula in vein. Avoid "fishing" as this can lead to hemolysis or insufficient sample.
- If necessary, hold tube in place to ensure complete vacuum draw and a properly filled tube.
- Remove filled tube and place new tube into holder.
- While drawing second tube, gently invert first tube 8 to 10 times to mix. Do not shake. Clot activator additive in plastic SST tubes also requires mixing.
- When last tube is removed and mixed, remove needle from vein and apply pressure to site with a dry sterile swab. Apply bandage if desired.
- Dispose of needle and holder per your facility's policy and guidelines.

Additional tips to avoid pre-analytical variability in samples

- Be sure to identify the correct patient. Correctly label that patient's samples using tubes, labels, and requisition from the same kit. Do not "borrow" from other kits. You may borrow from bulk supply.
- Do not use tubes after their expiration date. Most tubes expire in 6-12 months. Take note of kit expiration dates.
- Overfilling or underfilling of tubes (including urines) will result in an incorrect sample-to-additive ratio and may lead to incorrect analytic results or may cause displacement of stopper.
- Possible contributors to hemolyzed samples are prolonged tourniquet time, using a small-bore needle, or an improper venipuncture indicated by a slow blood flow.
- Recommended needle gauge sizes are 19 through 23.
- SST tubes must be allowed to clot for a minimum of 30 minutes to a maximum of 2 hours before centrifugation. Minimum time is preferred. Exceeding maximum time may contribute to inaccurate test results.
- Proper barrier formation in SST tube requires centrifuging for 10-15 minutes at 1100-1300 g-force (RCF -relative centrifugal force).
- Centrifuge temperature should be ambient (25 C), not refrigerated.
- Be sure centrifuge is balanced and properly sized to the sample tubes to avoid tube breakage.
- Allow centrifuge to self-brake, and come to a complete stop.
- The SST sample should not be re-centrifuged once the barrier is formed. If necessary, aspirate serum into a clean test tube and re-spin.

Centrifugation

Guidelines for the Conversion of relative Centrifugal Force (g) to RPM



How to prepare Blood Smears using the Diff-Safe Dispenser

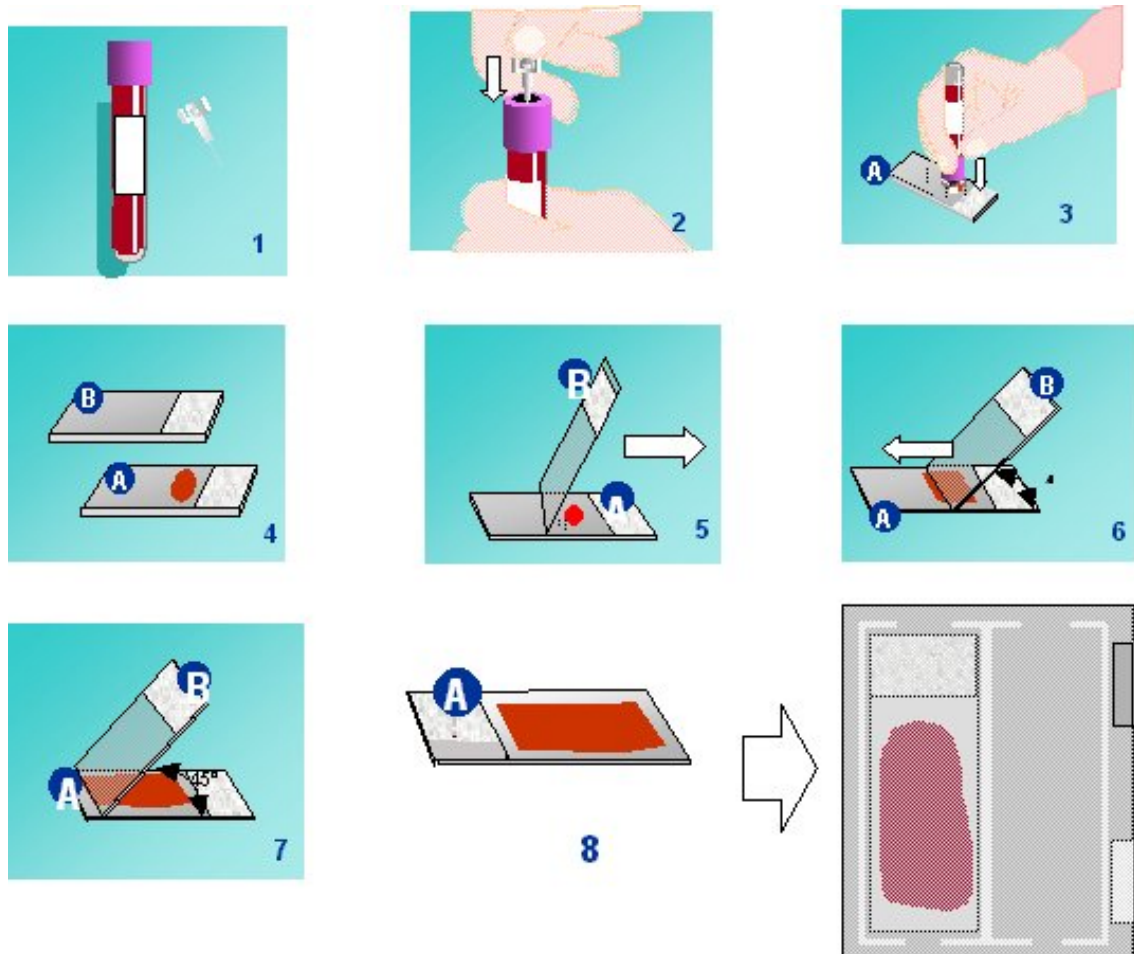
In the kit, Esoterix provided you with a “Diff-Safe” blood dispenser for making the Blood smears.

The Diff-Safe blood dispenser is comprised of a base of plastic and a blunt-ended stainless steel cannula. The device is not sterilized.

The device is intended as a safe means to puncture a closed collection tube and to obtain a drop of blood without the need to remove the stopper. The device produces a uniform drop of blood suitable for making a smear.

Warnings

- Wear Gloves. Do not open the tube (opened tubes will leak in transit).
- Do not insert Diff-Safe when tube is upside down.
- This is a single use device and is not designed for use with multiple specimens or to be cleaned and reused. Use for only one sample and then discard.
- Remove the Diff-Safe blood dispenser from the collection tube before returning the tube to Esoterix.



Materials needed:

Two clean grease-free glass collection slides with frosted ends in a transport holder, Diff-Safe blood dispenser, EDTA Blood collection tube.

- Using a soft pencil, write the patient initials/ID and collection date on the frosted end of the slides. Handle slides only by the frosted ends or by the edges. Place the collection slide frosted side up and to your right on a flat surface.
- After mixing the blood gently by inverting the tube 5-7 times, insert the Diff-Safe dispenser through the stopper of the tube held in upright position. Turn the tube upside down and press moderately against the slide. The drop of blood should be in the centerline, approximately ¼ inch from the frosted end.
- The instant the drop appears, discontinue pressure. If the drop fails to appear, check if the Diff-Safe is properly inserted or if the specimen is clotted.



- Hold the spreader slide at a 45° angle, approximately ¼ inch away from the drop of blood on the slide. This angle prevents the white cells from bunching along the edges.
- Draw the spreader slide steadily back toward the drop of blood. When the slide contacts the drop, the blood will start to spread to the edges of the spreader slide.



- Keep the spreader slide at a 45° angle, maintaining light but firm pressure with the spreader slide against the collection slide. Push the spreader slide rapidly over the entire length of the collection slide, pulling a thin smear of blood behind it. A feathered edge usually characterizes a good blood smear.
- Allow the blood smear to air dry. Do not blow on the slide. Do not apply fixative. After the slide is completely dry, place it in the labeled slide holder for transport to Esoterix.

Special Notes on Slide Preparation:

- Slides must not be touched on any area except the long slide edges or frosted ends.
- Prepare the smear immediately, as soon as the drop of blood has been placed on the slide. Any delay will result in abnormal distribution of the white cells, with many of the larger white cells accumulating at the thin edge of the smear. Rouleaux of the red cells (stacking like piles of coins) and platelet clumping will also occur.

Criteria of a good blood smear:

- Should be about 1½ inches long, and the entire smear should cover approximately half of the area of the entire slide.
- Should not extend to the edges of the slide.
- Should be free of waves, holes and ridges, and it should have a smooth appearance and feathered edge.
- Should be properly identified.

Common causes of a poor blood smear:

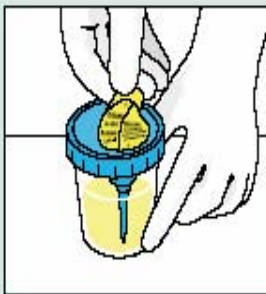
- Too long delay in transferring the drop of fresh blood from collection tube to slide.
- Drop of blood too large or too small (usually too large).
- Spreader slide pushed across the slide in a jerky manner.
- Greasy or dirty slides, or use of a spreader slide with a chipped or unpolished end.
- Failure to keep the entire edge of the spreader slide against the slide while making the smear.
- Failure to keep or have the spreader slide at approximately a 45° angle. (Increasing the angle results in a thick smear, while a smaller angle will produce a thin smear).
- Failure to push the spreader slide completely across the flat side.
- Failure to mix the sample well.

Using the BD[®] Urine Collection System

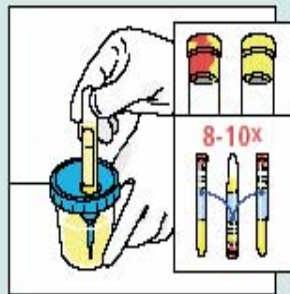
Guidelines for the collection of Urine using a Vacutainer Urine tube with preservative

- Do not open the tube. Urine collection cups are provided with your supplies (outside the kits) and **MUST** be used to get the urine into the Vacutainer tube.
- Minimum acceptable urine sample volume is 7.0 mL.

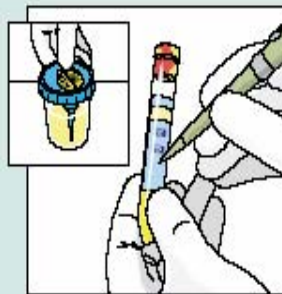
UA Preservative or Plain UA Tube Only



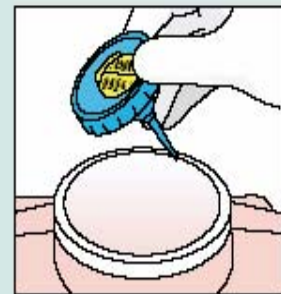
1. Peel back protective sticker to expose rubber-covered cannula.



2. • Push UA Preservative Tube (cherry red/yellow top) or plain UA Tube (yellow top) into integrated transfer port.
 - Hold in position until flow stops.
 - Remove tube.
 - Invert UA Preservative Tube 8-10 times to mix the sample.



3. • Place protective sticker back over the integrated transfer port.
 - Label filled tube with patient's name, the date/time of specimen collection and any other data required by your institution.




5. • Remove lid from cup and dispose in a sharps collector.
 - Dispose of urine according to your facility's policy.
 - Dispose of collection cup as a biohazard.

5.0 Specimen Labeling

5.1 Example label

- All specimens must be labeled using the labels provided by Esoterix.
- The information on the label must match the information on the requisition form.
- Some labels are TEST SPECIFIC. Please use the correct tube.
- An example of the label is provided below:

Subj. ID: _____
Visit: _____
Collection Date/Time: _____
EDTA – Lavender Top

01100001234
DCRI CALERIE

5.2 Label Instructions

- Write the subject's ID # in the spaces provided. Be sure all 6 numbers are entered.
- Enter VISIT (Month 1, Off Schedule, etc)
- Enter DATE of collection.
- Enter TIME of collection: using the 24-hour clock (e.g. 13:00 not 1:00).
- **Use permanent waterproof ink (fine indelible marker or ball point pen) when completing labels.**

6.0 Completing Test Request Forms

6.1 Test Request Forms are Provided in the kits by ESOTERIX and customized with:

- Investigator's name
- Site Number
- ESOTERIX study number
- Bar Code - Site and Visit-type Specific
- Visit choices for each kit-type

6.2 The Following Information Must Be Filled In On All Requisition Forms:

- Subject ID number (## - ## ##)
- Subject Date of Birth (dd-MMM-yyyy)
- Subject Gender (male/female)
- **Fasting Status** (Fasting / Non-fasting)
 - **Chemistry / Insulin requires 8+ hours of fasting**
 - **Lipids Panel requires 12+ hours of fasting**
- Date Drawn (dd-MMM-yyyy)
- Time Drawn (Use 24 hour clock, e.g. 13 not 1:00 PM)
- Visit – mark the appropriate box
- Off Schedule Testing: – Select which Optional test is being submitted.

Note: The info on the requisition must match exactly what is written on the tube!

6.3 Test Request Form Submission

- Send in the **Top and Middle** copies with samples
- Retain the **Bottom** copies for your files

7.0 Specimen Packaging

UPDATE FOR AMENDMENT 1.4 - **Insulin & CRP** at Baseline / Month 12 / Month 24

How to package **Chilled** + **Ambient** samples in Combo-Shippers

- For each Combo Shipment use: 1 @ Box with Styrofoam Container plus Cardboard Insert
1 @ Foil Zip-Loc Pouch
2 @ Frozen Gel Packs
1 @ Small Ambient Kit Box (with Biohazard Bags & Absorbent Pads)



Combo-Shipper



Foil Pouch



Frozen Gel Packs



Small Ambient Kit Box

- **Freeze the 2 gel packs** (provided in the Kit) at -20°C for 24 - 48 hours before refrigerated transport.
- Serum Insulin/CRP samples must be received COLD at Esoterix or they will arrive out of stability. *(If you anticipate an extended delay in shipping this sample, hold frozen at -20°C or -70°C with a copy of the requisition. Also, before shipping, note the storage temperature on requisition and the length of time the sample was stored.)*
- The Lavender tube, Slides, and Urine must be shipped ambient on day of collection.
- If properly bagged, you may ship more than one subject in each Combo-Shipper.

7.1 **COMBO SHIPMENTS** = CHILLED + AMBIENT

CHILLED Specimens

- Place each refrigerated serum transfer tube inside a bubble wrap sleeve.
- Place the bubble wrap sleeves containing specimens into the biohazard bag with an absorbent pad and seal.
- Place one copy of the completed test request form into the plastic specimen bag pouch (retain bottom copy for your files).
- Insert **2 Frozen gel packs and specimen bag** into foil pouch and seal zipper strip. If the zipper strip fails to stay closed, please tape or staple the closure edge.
- Place foil pouch into Styrofoam container and replace cover.
- **Do not apply dry ice stickers to Combo-Shipper** (unless shipping on dry ice).
→ **If you plan to ship on dry ice, please contact Esoterix for specific instruction.**

AMBIENT Specimens

- Place Lavender & Urine tubes inside bubble wrap sleeves.
- Place the bubble wrap sleeves, slide holder, & absorbent pad into the plastic biohazard bag and seal.
- Place one copy of the completed test request form in the specimen bag pouch (retain bottom copy for your files).
- Place specimen bag into the original Small Ambient Kit Box and close.
- Insert Small Ambient Kit Box into cardboard insert provided with Combo-Shipper.
- Place cardboard insert (containing kit box) on top of large Styrofoam container in Combo-Shipper.
- Seal Combo-Shipper and attach completed FedEx documents (see Section 8.0).
- **Do not apply dry ice stickers to Combo-Shipper. Do not ship CBC/Urine on dry ice!**

7.2 AMBIENT ONLY SHIPMENT [Screen] [Months 1,3,6,9,18]
[Off Schedule-Repeats or Anemia Surveillance]



Small Ambient Kit Box
or Large Kit Box with
Styro Insert



FedEx Diagnostic Pak

NOTE: If your kit box has gel packs, remove and save for future use (or ship AMBIENT gel packs with the ambient specimens to help insulate package).

- Place ambient sample tubes inside bubble wrap sleeves.
- Place the bubble wrap sleeves, slide holder, & absorbent pad into the biohazard bag and seal.
- Place two copies of the completed test request form in the specimen bag pouch (retain bottom copy for your files).
- Place specimen bag into the original Kit Box and close.
- Place the closed kit box into the FedEx Diagnostic Pak and seal.
- Complete FedEx documents and attach to outside of FedEx Diagnostic Pak (see airbill instructions in Section 8.0).

7.3 CHILLED ONLY SHIPMENTS [Off Schedule for Repeat Insulin or CRP]



Frozen Gel Packs



Large Ambient Kit Box
with Styrofoam Insert



FedEx Diagnostic Pak

- Place each refrigerated serum transfer tube inside a bubble wrap sleeve.
- Place the bubble wrap sleeves containing specimens into the plastic biohazard bag with an absorbent pad and seal.
- Place two copies of the completed test request form in the specimen bag pouch (retain bottom copy for your files).
- Place **specimen bag and 2 frozen gel packs** into Styrofoam insert of Large Kit Box, replace Styrofoam cover, and close Large Kit Box.
- Place the closed kit box into the FedEx Diagnostic Pak and seal.
- Complete FedEx documents and attach to outside of FedEx Diagnostic Pak (see airbill instructions in Section 8.0).

8.0 Shipping Specimens Via Federal Express

IMPORTANT NOTE: Samples should be shipped on the day of collection, Monday through Friday. Samples arriving beyond their limit of stability must be redrawn at the discretion DCRI.

→ These instructions do NOT apply to any shipment containing dry ice.

8.1 Completing FedEx Airbills (Refer to the example airbill & label following)

- Fill out one domestic airbill for each package:
Enter collection date
Verify:
 - FedEx Account Number: **1893-5431-2** (Third party billing)
 - Billing Reference Number: **CALERIE 303-8754**
 - Shipping Address:
ESOTERIX CLINICAL TRIALS SERVICES
Attn: David Burgos
750 Walnut Ave
Cranford, NJ 07016
Telephone Number: 908-709-5706
 - Airbill is marked for “**Priority Overnight**” Delivery.
- If shipping on Friday is unavoidable, be sure to mark the airbill for “Saturday Delivery” and apply Saturday Delivery stickers to the package.

8.2 Calling Federal Express to Schedule a Sample Pick-Up

- Call FedEx early on the day of shipment to arrange a pick-up time.

Reminders:

- Copy & complete the **Shipment Alert Form (Appendix B)**. Fax to Esoterix on the day of shipment.
- Avoid specimen collections and shipping near weekends and holidays! Verify with FedEx that your ship date and time can be serviced.
- Samples delayed in shipment may arrive beyond stability and/or temperature requirements and may need to be re-collected at the sponsor’s discretion.
- Esoterix operations are closed on Sundays and Holidays and samples cannot be received.

Air waybill for shipments within the United States

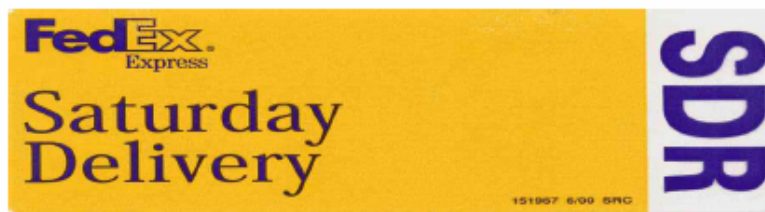
Section #6
For Friday shipments: mark **"SATURDAY Delivery"**

Date of shipment must be indicated

The image shows a FedEx USA Airbill form with several sections:

- Sender's Information:** Sender's Name, Company, Address, City, State, ZIP, Phone.
- Recipient's Information:** Recipient's Name, Company, Address, City, State, ZIP, Phone.
- Service Selection:**
 - 4a Express Package Service:** FedEx Priority Overnight, FedEx Standard Overnight, FedEx 2Day, FedEx Next Business Day, FedEx First Overnight.
 - 4b Express Freight Service:** FedEx 3Day Freight, FedEx 2Day Freight, FedEx 1Day Freight.
- 5 Packaging:** FedEx Envelope/Letter, FedEx Pak.
- 6 Special Handling:**
 - SATURDAY Delivery:** Includes FedEx Priority Overnight, FedEx 2Day, FedEx 3Day Freight, FedEx 4Day Freight, FedEx 5Day Freight.
 - SUNDAY Delivery:** Includes FedEx Priority Overnight, FedEx 2Day, FedEx 3Day Freight, FedEx 4Day Freight, FedEx 5Day Freight.
 - HOLD at FedEx Location:** Includes FedEx Priority Overnight, FedEx 2Day, FedEx 3Day Freight, FedEx 4Day Freight, FedEx 5Day Freight.
 - HOLD at Recipient:** Includes FedEx Priority Overnight, FedEx 2Day, FedEx 3Day Freight, FedEx 4Day Freight, FedEx 5Day Freight.
- 7 Payment:** Bill to me, Recipient, Third Party, Credit Card, Cash/Check.
- 8 Release Signatures:** Shipper, Addressee, Receiver, Driver, Other.

Handwritten annotations include a blue circle around the 'Date' field and a blue arrow pointing from the 'SATURDAY Delivery' checkbox to the text 'Section #6 For Friday shipments: mark SATURDAY Delivery'. The tracking number 0133643387 is printed at the bottom.



Note:

This manual does not qualify as certification on IATA regulations for training in the shipment of dangerous goods. For a complete listing of IATA approved training schools, refer to page 765 in the IATA Dangerous Goods Regulations Book found on-line at www.iataonline.com or contact IATA at 1-305-264-7772.

9.0 Results

- Esoterix results will be faxed to all the sites within 48-72 hours after samples have been received (if there are no demographic corrections needed).
- Sites will be called with Esoteric Standard Panic Ranges (see Appendix A, Reference Range Chart)
- The Esoterix Clinical Trials Department operates between 8:30 AM – 6:00 PM (ET), Monday-Friday. During holidays and weekends, a message can be left on your Esoterix Project Monitor's voicemail system. Your call will be returned on the next business day.
- In case of after-hours emergency, a Clinical Trials Representative may be contacted directly at 1-908-334-9490 weekdays between 6:00 PM and 10:00 PM (ET) and on weekends between 8:00 AM - 5:00 PM (ET).

People involved in this study should carefully review all instructions provided in this manual, as well as the content of the initial supply shipment. If there are any questions concerning the supplies, the procedure for filling out the Esoterix request forms, sample requirements, results, or specimen shipping, please contact any of the team members noted below.

Please provide your protocol #, Sponsor, and Investigator's name when calling or leaving messages.

Marina Rivera	Project Monitor	Tel. :	908-709-5809
	(Primary contact)	Fax :	512-225-1273
		Email :	riveram@labcorp.com
<hr/>			
Linda Evanello	Project Manager	Tel. :	908-709-5879
		Fax :	512-225-1273
		Email :	evanell@labcorp.com
<hr/>			
Lawrence Frascella	Assistant Project Manager	Tel. :	908-709-5708
		Fax :	512-225-1273
		Email :	frascel@labcorp.com
<hr/>			
Other numbers :	Esoterix- Main Clinical Trials		877-788-8861

Appendix A

Alert & Reference Ranges

ALERT RANGES FOR CALERIE

Test	Gender & Age	Panic Alert-Low	Panic Alert-High	Units
Hematology Panel				
White Blood Count (WBC)	F/M	< 2.5	> 20.0	x10 ³ /uL
Red Blood Count (RBC)	F/M	< 2.75	> 7.00	x10 ⁶ /uL
Hemoglobin	F/M	< 7.0	> 25.0	g/dL
Hematocrit	F/M	< 18.0		%
Platelets	F/M	< 30.0	> 1000	x10 ³ /uL
Neutrophils (Absolute)	F/M	< 1.0	> 14.0	X10 ³ /uL
Chemistry Panel				
Glucose	F/M	< 40	> 500	mg/dL
BUN	F/M	< 2	> 75	mg/dL
Creatinine	F/M	< 0.3	> 15.0	mg/dL
Uric Acid	F/M		> 15.0	mg/dL
Sodium	F/M	< 120	> 160	mEq/L
Potassium	F/M	< 2.5	> 6.5	mEq/L
Calcium	F/M	< 7.0	> 13.0	mg/dL
Magnesium	F/M	< 1.0	> 3.5	mg/dL
Iron	F/M	< 10	> 260	ug/dL
Creatine Phosphokinase (CPK)	F/M		> 500	IU/L
Total Bilirubin	F/M		> 12.0	mg/dL
Alkaline Phosphatase	F/M		> 1000	IU/L
AST (SGOT)	F/M		> 500	IU/L
ALT (SGPT)	F/M		> 500	IU/L
GGT	F/M		> 650	IU/L

Protocol Reference Range Definitions

For ESN: 100545 Duke University, DCRI, CALERIE

Test Name	Test Code	Result Type	Unit	Sex	Age	Range	Activation Date
CRP-Repository	TCRPHS	Numeric	mg/L	Both	ALL	0.00 - 3.00	03/01/2007
CRP, high sensitivity	TCRPHS	Numeric	mg/L	Both	ALL	0.00 - 3.00	03/01/2007
eGFR	TGFRW	Numeric	mL/min/1.73*m ²	Both	ALL	60 (low)	01/14/2007
eGFR - If African American	TGFRB	Numeric	mL/min/1.73*m ²	Both	ALL	60 (low)	01/14/2007
Hematocrit_Surv.	HCT	String	%	Both	0d - 6d	53.0 - 65.0	06/02/2007
					6d - 28d	44.0 - 56.0	
					28d - 6m	39.0 - 52.0	
					6m - 11m	35.0 - 45.0	
					11m - 2y	30.0 - 42.0	
					2y - 4y	32.0 - 44.0	
					4y - 11y	33.0 - 45.0	
					11y - 17y	34.0 - 46.0	
				Female	17y - 150y	34.0 - 44.0	
Male	17y - 150y	36.0 - 50.0					
Hematology Slides Received	HEMSLD	String					
Hemoglobin_Surv.	HGB	String	g/dL	Both	0d - 6d	18.5 - 21.5	07/31/2007
					6d - 28d	15.5 - 18.5	
					28d - 6m	13.0 - 16.5	
					6m - 11m	12.0 - 14.0	
					11m - 2y	10.0 - 14.0	
					2y - 4y	11.2 - 14.3	
					4y - 11y	11.5 - 14.5	
					11y - 17y	11.6 - 14.8	
				Female	17y - 150y	11.5 - 15.0	
Male	17y - 150y	12.5 - 17.0					
Insulin	INSM	Numeric	uU/mL	Both	ALL	0.0 - 29.1	05/08/2008
Insulin-Repository	INSM	Numeric	uU/mL	Both	ALL	0.0 - 29.1	05/08/2008
IRON- Anemia Surveillance	TFE	Numeric	ug/dL	Both	0y - 3y	11 - 130	01/10/2006
					3y - 9y	11 - 150	
				Female	9y - 150y	35 - 155	
				Male	9y - 150y	40 - 155	
MCH_Surv.	MCH	String	pg	Both	0d - 6d	30.0 - 42.0	06/02/2007
					6d - 28d	30.0 - 42.0	
					28d - 6m	28.0 - 38.0	

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Protocol Reference Range Definitions

For ESN: 100545 Duke University, DCRI, CALERIE

Test Name	Test Code	Result Type	Unit	Sex	Age	Range	Activation Date
MCH_Surv.	MCH	String	pg	Both	6m - 11m	24.0 - 32.0	06/02/2007
					11m - 2y	24.0 - 32.0	
					2y - 4y	24.0 - 32.0	
					4y - 11y	23.0 - 33.0	
					11y - 17y	27.0 - 34.0	
					17y - 150y	27.0 - 34.0	
MCHC_Surv.	MCHC	String	g/dL	Both	0d - 6d	28.0 - 38.0	06/02/2007
					6d - 6m	29.0 - 37.0	
					6m - 11m	30.0 - 36.0	
					11m - 2y	30.0 - 37.0	
					2y - 17y	31.0 - 37.0	
					17y - 150y	32.0 - 36.0	
MCV_Surv.	MCV	String	fL	Both	0d - 6d	90 - 115	06/02/2007
					6d - 28d	88 - 110	
					28d - 6m	82 - 100	
					6m - 11m	77 - 98	
					11m - 4y	75 - 96	
					4y - 11y	78 - 96	
					11y - 150y	80 - 98	
Platelet Count_Surv.	PLT	String	10 ³ /uL	Both	0y - 17y	140 - 440	06/02/2007
					17y - 150y	140 - 415	
RBC_Surv.	RBC	String	10 ⁶ /uL	Both	0d - 6d	5.00 - 6.30	06/02/2007
					6d - 28d	4.70 - 5.90	
					28d - 6m	3.80 - 5.20	
					6m - 11m	3.70 - 5.20	
					11m - 2y	3.50 - 4.90	
					2y - 4y	3.70 - 5.00	
					4y - 11y	3.90 - 5.10	
					11y - 17y	3.80 - 5.20	
				Female	17y - 150y	3.80 - 5.10	
				Male	17y - 150y	4.10 - 5.60	
Serum Pregnancy, Qual.	THCGS	String		Both	ALL	Negative: <5 mU/mL of total HCG Borderline: 5-20 mU/mL of	07/27/2006

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Protocol Reference Range Definitions

For ESN: 100545 Duke University, DCRI, CALERIE

Test Name	Test Code	Result Type	Unit	Sex	Age	Range	Activation Date
						total HCG Positive: >20 mU/mL of total HCG	
WBC_Surv.	WBC	String	10 ³ /uL	Both	0d - 6d	9.00 - 30.00	06/02/2007
					6d - 28d	5.00 - 20.00	
					28d - 11m	6.00 - 17.50	
					11m - 2y	6.00 - 17.00	
					2y - 4y	5.00 - 14.50	
					4y - 11y	4.00 - 13.50	
					11y - 17y	4.00 - 12.50	
					17y - 150y	4.00 - 10.50	
Automated Diff							
Basophils, Absolute	BASOAA	String	10 ³ /uL	Both	0d - 6d	0.00 - 0.60	05/31/2007
					6d - 11m	0.00 - 0.40	
					11m - 17y	0.00 - 0.30	
					17y - 150y	0.00 - 0.20	
Basophils, Percent	BASOPA	Numeric	%	Both	0y - 17y	0 - 2	05/31/2007
					17y - 150y	0 - 3	
Eosinophils, Absolute	EOSNAA	String	10 ³ /uL	Both	0d - 6d	0.00 - 1.50	05/31/2007
					6d - 28d	0.00 - 1.00	
					28d - 24m	0.00 - 0.90	
					24m - 11y	0.00 - 0.70	
					11y - 17y	0.00 - 0.60	
					17y - 150y	0.00 - 0.40	
Eosinophils, Percent	EOSNPA	Numeric	%	Both	0y - 17y	0 - 5	05/31/2007
					17y - 150y	0 - 7	
Lymphocytes, Absolute	LYMPAA	String	10 ³ /uL	Both	0d - 6d	2.30 - 10.80	05/31/2007
					6d - 28d	2.20 - 10.60	

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Protocol Reference Range Definitions

For ESN: 100545 Duke University, DCRI, CALERIE

Test Name	Test Code	Result Type	Unit	Sex	Age	Range	Activation Date
Lymphocytes, Absolute	LYMPAA	String	10 ³ /uL	Both	28d - 6m	2.60 - 13.00	05/31/2007
					6m - 11m	2.60 - 13.00	
					11m - 2y	2.90 - 13.30	
					2y - 4y	1.80 - 9.40	
					4y - 11y	1.10 - 6.50	
					11y - 17y	1.10 - 5.90	
					17y - 150y	0.70 - 4.50	
Lymphocytes, Percent	LYMPPA	Numeric	%	Both	0d - 6d	26 - 36	05/31/2007
					6d - 28d	43 - 53	
					28d - 6m	44 - 74	
					6m - 11m	44 - 74	
					11m - 2y	48 - 78	
					2y - 4y	36 - 65	
					4y - 11y	28 - 48	
					11y - 17y	27 - 47	
17y - 150y	14 - 46						
Monocytes, Absolute	MONOAA	String	10 ³ /uL	Both	0d - 6d	0.40 - 3.90	05/31/2007
					6d - 28d	0.20 - 2.60	
					28d - 6m	0.20 - 2.30	
					6m - 11m	0.20 - 2.30	
					11m - 2y	0.20 - 2.20	
					2y - 4y	0.20 - 1.90	
					4y - 11y	0.20 - 1.80	
					11y - 17y	0.20 - 1.60	
					17y - 150y	0.10 - 1.00	
Monocytes, Percent	MONOPA	Numeric	%	Both	0y - 7d	4 - 13	05/31/2007
					7d - 14d	4 - 13	
					14d - 1m	4 - 13	
					1m - 6m	4 - 13	
					6m - 2y	4 - 13	
					2y - 12y	4 - 13	
					12y - 150y	4 - 13	
Neutrophils, Absolute	NEUTAA	String	10 ³ /uL	Both	0d - 6d	2.90 - 18.60	05/31/2007

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Protocol Reference Range Definitions

For ESN: 100545 Duke University, DCRI, CALERIE

Test Name	Test Code	Result Type	Unit	Sex	Age	Range	Activation Date
Neutrophils, Absolute	NEUTAA	String	10 ³ /uL	Both	6d - 28d	1.60 - 8.70	05/31/2007
					28d - 6m	1.50 - 6.70	
					6m - 4y	1.50 - 7.10	
					4y - 17y	1.50 - 7.80	
					17y - 150y	1.80 - 7.80	
Neutrophils, Percent	NEUTPA	Numeric	%	Both	0d - 6d	32 - 62	05/31/2007
					6d - 28d	32 - 44	
					28d - 6m	25 - 38	
					6m - 11m	25 - 41	
					11m - 2y	25 - 42	
					2y - 4y	30 - 49	
					4y - 11y	38 - 58	
					11y - 17y	38 - 63	
17y - 150y	40 - 74						
Nucleated RBC, Absolute	NRBCAA	String	10 ³ /uL				
Nucleated RBC, Percent	NRBCPA	Numeric	%				
Chemistry Panel							
Albumin	TALB	Numeric	g/dL	Both	0y - 2y	3.4 - 4.2	01/04/2006
					2y - 59y	3.5 - 5.5	
					59y - 69y	3.6 - 4.8	
					69y - 79y	3.5 - 4.8	
					79y - 89y	3.5 - 4.7	
					89y - 150y	3.2 - 4.6	
Alkaline Phosphatase	TALP	Numeric	IU/L	Female	0y - 1y	25 - 500	09/12/2006
					1y - 9y	100 - 400	
					9y - 14y	70 - 490	
					14y - 20y	45 - 300	
					20y - 60y	25 - 150	
					60y - 150y	25 - 165	
				Male	0y - 1y	25 - 500	
					1y - 9y	100 - 400	
					9y - 14y	150 - 530	
					14y - 20y	60 - 400	
20y - 60y	25 - 150						

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Protocol Reference Range Definitions

For ESN: 100545 Duke University, DCRI, CALERIE

Test Name	Test Code	Result Type	Unit	Sex	Age	Range	Activation Date
Alkaline Phosphatase	TALP	Numeric	IU/L	Male	60y - 150y	25 - 160	09/12/2006
ALT (SGPT)	TALT	Numeric	IU/L	Female	ALL	0 - 40	01/04/2006
				Male	ALL	0 - 55	
AST (SGOT)	TAST	Numeric	IU/L	Both	ALL	0 - 40	01/03/2006
Blood Urea Nitrogen	TBUN	Numeric	mg/dL	Both	0y - 89y	5 - 26	01/03/2006
					89y - 150y	12 - 36	
Calcium	TCAL	Numeric	mg/dL	Both	ALL	8.5 - 10.6	01/03/2006
Creatine Kinase	TCK	Numeric	IU/L	Female	ALL	24 - 173	01/04/2006
				Male	ALL	24 - 204	
Creatinine	TCRE	Numeric	mg/dL	Both	ALL	0.5 - 1.5	01/04/2006
Gamma Glutamyl Transferase	TGGT	Numeric	IU/L	Female	ALL	0 - 60	01/09/2006
				Male	ALL	0 - 65	
Glucose, Serum	TGLS	Numeric	mg/dL	Both	ALL	65 - 99	01/09/2006
Iron	TFE	Numeric	ug/dL	Both	0y - 3y	11 - 130	01/10/2006
					3y - 9y	11 - 150	
				Female	9y - 150y	35 - 155	
				Male	9y - 150y	40 - 155	
Magnesium	TMAG	Numeric	mg/dL	Both	ALL	1.6 - 2.6	01/09/2006
Potassium	TK	Numeric	mEq/L	Both	ALL	3.5 - 5.5	01/13/2006
Sodium	TNA	Numeric	mEq/L	Both	ALL	135 - 148	01/13/2006
Total Bili	TTBL	Numeric	mg/dL	Both	ALL	0.1 - 1.2	01/05/2006
Total Protein	TTP	Numeric	g/dL	Both	ALL	6.0 - 8.5	01/12/2006
Uric Acid	TUA	Numeric	mg/dL	Female	ALL	1.5 - 6.7	01/13/2006
				Male	ALL	2.2 - 8.7	
Hematology Panel							
Hematocrit	HCT	String	%	Both	0d - 6d	53.0 - 65.0	06/02/2007
					6d - 28d	44.0 - 56.0	
					28d - 6m	39.0 - 52.0	
					6m - 11m	35.0 - 45.0	
					11m - 2y	30.0 - 42.0	
					2y - 4y	32.0 - 44.0	
					4y - 11y	33.0 - 45.0	
					11y - 17y	34.0 - 46.0	
				Female	17y - 150y	34.0 - 44.0	
Male	17y - 150y	36.0 - 50.0					
Hemoglobin	HGB	String	g/dL	Both	0d - 6d	18.5 - 21.5	07/31/2007

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Protocol Reference Range Definitions

For ESN: 100545 Duke University, DCRI, CALERIE

Test Name	Test Code	Result Type	Unit	Sex	Age	Range	Activation Date
Hemoglobin	HGB	String	g/dL	Both	6d - 28d	15.5 - 18.5	07/31/2007
					28d - 6m	13.0 - 16.5	
					6m - 11m	12.0 - 14.0	
					11m - 2y	10.0 - 14.0	
					2y - 4y	11.2 - 14.3	
					4y - 11y	11.5 - 14.5	
					11y - 17y	11.6 - 14.8	
				Female	17y - 150y	11.5 - 15.0	
				Male	17y - 150y	12.5 - 17.0	
Mean Cell Volume	MCV	String	fL	Both	0d - 6d	90 - 115	06/02/2007
					6d - 28d	88 - 110	
					28d - 6m	82 - 100	
					6m - 11m	77 - 98	
					11m - 4y	75 - 96	
					4y - 11y	78 - 96	
					11y - 150y	80 - 98	
Mean Corpuscular Hemoglobin	MCH	String	pg	Both	0d - 6d	30.0 - 42.0	06/02/2007
					6d - 28d	30.0 - 42.0	
					28d - 6m	28.0 - 38.0	
					6m - 11m	24.0 - 32.0	
					11m - 2y	24.0 - 32.0	
					2y - 4y	24.0 - 32.0	
					4y - 11y	23.0 - 33.0	
					11y - 17y	27.0 - 34.0	
					17y - 150y	27.0 - 34.0	
Mean Corpuscular Hgb Conc	MCHC	String	g/dL	Both	0d - 6d	28.0 - 38.0	06/02/2007
					6d - 6m	29.0 - 37.0	
					6m - 11m	30.0 - 36.0	
					11m - 2y	30.0 - 37.0	
					2y - 17y	31.0 - 37.0	
					17y - 150y	32.0 - 36.0	
Platelet Count	PLT	String	10 ³ /uL	Both	0d - 1d	150 - 400	06/26/2006
					1d - 150y	150 - 400	
Red Blood Cells	RBC	String	10 ⁶ /uL	Both	0d - 6d	5.00 - 6.30	06/02/2007
					6d - 28d	4.70 - 5.90	
					28d - 6m	3.80 - 5.20	

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Protocol Reference Range Definitions

For ESN: 100545 Duke University, DCRI, CALERIE

Test Name	Test Code	Result Type	Unit	Sex	Age	Range	Activation Date
Red Blood Cells	RBC	String	10 ⁶ /uL	Both	6m - 11m	3.70 - 5.20	06/02/2007
					11m - 2y	3.50 - 4.90	
					2y - 4y	3.70 - 5.00	
					4y - 11y	3.90 - 5.10	
					11y - 17y	3.80 - 5.20	
				Female	17y - 150y	3.80 - 5.10	
				Male	17y - 150y	4.10 - 5.60	
White Blood Cells	WBC	String	10 ³ /uL	Both	0d - 6d	9.00 - 30.00	06/02/2007
					6d - 28d	5.00 - 20.00	
					28d - 11m	6.00 - 17.50	
					11m - 2y	6.00 - 17.00	
					2y - 4y	5.00 - 14.50	
					4y - 11y	4.00 - 13.50	
					11y - 17y	4.00 - 12.50	
					17y - 150y	4.00 - 10.50	
					Lipid Panel		
HDL	THDL	Numeric	mg/dL	Both	ALL	40 - 59	01/09/2006
LDL (Calc.)	TL DLC	Numeric	mg/dL	Both	0y - 19y	0 - 109	01/09/2006
					19y - 150y	0 - 99	
Total Cholesterol	TCHL	Numeric	mg/dL	Both	0y - 19y	100 - 169	01/04/2006
					19y - 150y	100 - 199	
Triglycerides	TTRG	Numeric	mg/dL	Both	ALL	0 - 149	01/13/2006
Lipids-Repository							
Cholesterol-Repository	TCHL	Numeric	mg/dL	Both	0y - 19y	100 - 169	01/04/2006
					19y - 150y	100 - 199	
HDL-Repository	THDL	Numeric	mg/dL	Both	ALL	40 - 59	01/09/2006
LDL Calc-Repository	TL DLC	Numeric	mg/dL	Both	0y - 19y	0 - 109	01/09/2006
					19y - 150y	0 - 99	
Triglycerides-Repository	TTRG	Numeric	mg/dL	Both	ALL	0 - 149	01/13/2006
Manual Diff							

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Protocol Reference Range Definitions

For ESN: 100545 Duke University, DCRI, CALERIE

Test Name	Test Code	Result Type	Unit	Sex	Age	Range	Activation Date
Bands, Absolute	BANDAM	String	10 ³ /uL	Both	ALL	Not established	08/12/2003
Bands, Percent	BANDPM	String	%	Both	ALL	Not Established	06/22/2006
Basophils Manual Percent	BASOPM	String	%	Both	ALL	Not Established	06/22/2006
Basophils, Manual Absolute	BASOAM	String	10 ³ /uL	Both	0y - 150y	0.0 - 0.2	06/22/2006
Differential Comments	DIFCOM	String					
Eosinophils Manual Percent	EOSNPM	String	%	Both	ALL	Not Established	06/22/2006
Eosinophils, Manual Absolute	EOSNAM	String	10 ³ /uL	Both	0d - 1m	0.0 - 0.9	06/22/2006
					1m - 6m	0.0 - 0.2	
					6m - 2y	0.0 - 0.3	
					2y - 10y	0.0 - 0.7	
					10y - 21y	0.0 - 0.6	
					21y - 150y	0.0 - 0.5	
Lymphocytes Atypical, Absolute	LYMAAM	String	10 ³ /uL	Both	ALL	0.0 (high)	12/06/2002
Lymphocytes Atypical, Percent	LYMAPM	String	%	Both	ALL	0 (high)	12/06/2002
Lymphocytes Manual Percent	LYMPPM	String	%	Both	ALL	Not Established	06/22/2006
Lymphocytes, Manual Absolute	LYMPAM	String	10 ³ /uL	Both	0d - 4d	1.6 - 7.4	06/22/2006
					4d - 5d	1.6 - 6.0	
					5d - 1m	2.8 - 9.0	
					1m - 6m	2.9 - 9.1	
					6m - 1y	4.0 - 13.5	
					1y - 2y	4.0 - 10.5	
					2y - 4y	3.0 - 9.5	
					4y - 6y	2.0 - 8.0	
					6y - 10y	1.5 - 7.0	
					10y - 21y	1.5 - 6.5	
					21y - 150y	1.0 - 4.8	
Metamyelocytes, Absolute	METAAM	String	10 ³ /uL	Both	ALL	0.0 (high)	12/06/2002
Metamyelocytes, Percent	METAPM	String	%	Both	ALL	0 (high)	12/06/2002
Monocytes Manual	MONOPM	String	%	Both	ALL	Not	06/22/2006

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Protocol Reference Range Definitions

For ESN: 100545 Duke University, DCRI, CALERIE

Test Name	Test Code	Result Type	Unit	Sex	Age	Range	Activation Date
Percent						Established	
Monocytes, Manual Absolute	MONOAM	String	10 ³ /uL	Both	0d - 4d	0.0 - 2.0	06/22/2006
					4d - 1m	0.0 - 1.7	
					1m - 6m	0.0 - 0.7	
					6m - 2y	0.0 - 1.0	
					2y - 150y	0.0 - 0.8	
Myelocytes, Absolute	MYELAM	String	10 ³ /uL	Both	ALL	0.0 (high)	12/06/2002
Myelocytes, Percent	MYELPM	String	%	Both	ALL	0 (high)	12/06/2002
Neutrophils Manual Percent	NEUTPM	String	%	Both	ALL	Not Established	06/22/2006
Neutrophils, Manual Absolute	NEUTAM	String	10 ³ /uL	Both	0d - 1d	0-12 hr: 2.0-6.0 12-24 hr: 8.0-14.0	06/22/2006
					1d - 2d	7.0 - 13.0	
					2d - 4d	3.5 - 7.5	
					4d - 5d	1.8 - 6.5	
					5d - 1m	1.8 - 5.4	
					1m - 6m	1.0 - 8.5	
					6m - 4y	1.5 - 8.5	
					4y - 6y	1.5 - 8.0	
					6y - 10y	1.8 - 8.0	
					10y - 150y	1.8 - 7.7	
Nucleated RBC Manual Absolute	NRBCAM	String	10 ³ /uL	Both	ALL	0.0 (high)	12/06/2002
Nucleated RBC Manual Percent	NRBCPM	String	%	Both	ALL	0 (high)	12/06/2002
Platelet Assessment	PLTASS	String					
RBC Morphology	RBCMOR	String					
WBC Morphology	WBCMOR	String					
Urinalysis Macroscopic							
pH	TPH	Numeric	pH	Both	ALL	5.0 - 7.5	08/02/2006
Specific Gravity	TSG	Numeric	SGU	Both	ALL	1.005 - 1.030	08/02/2006
UA Blood	TBLD	String		Both	ALL	Normal = Negative	08/02/2006
UA Glucose	TGLUA	String		Both	ALL	Normal = Negative	08/02/2006
UA Ketones	TKET	String		Both	ALL	Normal =	08/02/2006

Note: All age ranges are inclusive on the low end and exclusive on the high (i.e. an age range of 18y - 50y includes patients from their 18th birthday up to their 50th birthday). All tests in the protocol are displayed, even if no reference range is defined.

Protocol Reference Range Definitions

For ESN: 100545 Duke University, DCRI, CALERIE

Test Name	Test Code	Result Type	Unit	Sex	Age	Range	Activation Date
						Negative	
Urine Protein	TPROT	String		Both	ALL	Normal = Negative to Trace	08/02/2006
Urine Microscopic							
Ammonium Biurate	AMMB	String		Both	ALL	Normal Reference Range = None Seen/Few	11/18/2007
Amorphous Urates or Phosphates	AMURPH	String		Both	ALL	Normal Reference Range = None Seen/Few	11/18/2007
Bacteria	BACUA	String		Both	ALL	Normal Reference Range = None Seen/Few	11/18/2007
Calcium Oxalate	CALC	String		Both	ALL	Normal Reference Range = None Seen/Few	11/18/2007
Fiber	FIBER	String		Both	ALL	Normal Reference Range = None Seen	12/05/2002
Hyaline Cast	HYLC	String		Both	ALL	Normal Reference Range = None Seen	11/18/2007
Mucus	MUCUS	String		Both	ALL	Normal Reference Range = None Seen	12/05/2002
Pollen	POLLEN	String		Both	ALL	Normal Reference Range = None Seen	12/05/2002
RBC Cast	RBCC	String		Both	ALL	Normal Reference Range = None Seen	12/05/2002
RBC Urine	RBCUA	String		Both	ALL	Normal	11/18/2007

Note: All age ranges are inclusive on the low end and exclusive on the high (i.e. an age range of 18y - 50y includes patients from their 18th birthday up to their 50th birthday). All tests in the protocol are displayed, even if no reference range is defined.

Protocol Reference Range Definitions

For ESN: 100545 Duke University, DCRI, CALERIE

Test Name	Test Code	Result Type	Unit	Sex	Age	Range	Activation Date
						Reference Range = 0-3 cells/hpf	
Sperm	SPERM	String		Both	ALL	Normal Reference Range = None Seen	12/05/2002
Squamous Epithelial Cells	SEP	String		Both	ALL	Normal Reference Range = 0-8 cells/hpf	11/18/2007
Starch	STARCH	String		Both	ALL	Normal Reference Range = None Seen	12/05/2002
Transitional Epithelial Cells	TEP	String		Both	ALL	Normal Reference Range = 0-8 cells/hpf	11/18/2007
Trichomonas	TRICH	String		Both	ALL	Normal Reference Range = None Seen	12/05/2002
Triple Phosphate	AMMTPH	String		Both	ALL	Normal Reference Range = None Seen/Few	11/18/2007
UA Comments	UACOM	String		Both	ALL	Not Applicable	12/06/2002
Uric Acid Crystal	UACRY	String		Both	ALL	Normal Reference Range = None Seen/Few	11/18/2007
WBC Cast	WBCC	String		Both	ALL	Normal Reference Range = None Seen	05/18/2004
WBC Urine	WBCUA	String		Both	ALL	Normal Reference Range = 0-5 cells/hpf	11/18/2007

Note: All age ranges are inclusive on the low end and exclusive on the high (i.e. an age range of 18y - 50y includes patients from their 18th birthday up to their 50th birthday). All tests in the protocol are displayed, even if no reference range is defined.

Protocol Reference Range Definitions

For ESN: 100545 Duke University, DCRI, CALERIE

Test Name	Test Code	Result Type	Unit	Sex	Age	Range	Activation Date
Yeast	YSTUA	String		Both	ALL	Normal Reference Range = None Seen/Few	11/18/2007

Note: All age ranges are inclusive on the low end and exclusive on the high (i.e. an age range of 18y - 50y includes patients from their 18th birthday up to their 50th birthday). All tests in the protocol are displayed, even if no reference range is defined.

Appendix B

Shipment Alert Form (Copy & Complete)



A LabCorp Company

SHIPMENT ALERT FORM

On the DAY OF SHIPMENT, please complete and fax this form to:

ESOTERIX Clinical Trials Services

FAX: 512-225-1273

ATTENTION: Marina Rivera

(Phone: 908-709-5809)

Sponsor/ Protocol: **DCRI/ CALERIE Amendment 1.4**

Investigator Last Name: _____

Site Number: _____

Contact Person at Site: _____

Phone Number: _____

Date of Shipment: _____ / _____ / _____
DD / MMM / YYYY

**Number of Boxes Shipped
to Cranford, NJ :** _____

FedEx Airbill Number(s): _____

ESN: 100545

Esoterix Monitor: Marina Rivera, Phone # 877-788-8861 x5809
Esoterix Project Manager: Linda Evanello, Phone # 877-788-8861 x5879

Appendix C

Example Test Request Forms

(May be copied & completed: Contact Esoterix)

3966210883



A LabCorp Company

Esoterix Clinical Trials Services
A LabCorp Company
750 Walnut Ave
Cranford, NJ 07016
877-788-8861

Requisition Number:



LABORATORY TEST REQUEST FORM
Duke Clinical Research Institute
Protocol CALERIE, Amendment 1.4
Screen Visit 2 or Screen: REPEAT

Investigator:

Site #:

ESN #:

Instructions:

- SUBJECT MUST BE FASTING!
- Complete all information with ball-point pen.
- Be sure sample tube labels match the requisition.

Ship AMBIENT on day of collection.

Note: If you miss the courier, store all samples in refrigerator EXCEPT Lavender tube. Hold Lavender at Room Temperature until ready to ship.

Refer to the Esoterix Investigator's Laboratory Manual for further instruction.

Testing Required:

- CBC/Diff - ambient
- Urinalysis - ambient
- Chemistry - ambient
- Lipids Panel - ambient
- Serum Pregnancy (on Females) - ambient

Subject ID:	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date of Birth:	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	-	<input type="text"/>
	Day		Month			YYYY
Gender:	<input type="checkbox"/>	Male	<input type="checkbox"/>	Female		
Fasting Status:	<input type="checkbox"/>	Fasting	<input type="checkbox"/>	Non-Fasting		
	(12+ Hours Fasting is REQUIRED!)					
Collection Date:	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Day		Month			YYYY
Collection Time:	<input type="text"/>	:	<input type="text"/>			
	(24 hr clock)					
			HH			MM
Visit	<input type="checkbox"/>	Screen Visit 2				
(Select One)	<input type="checkbox"/>	Screen: REPEAT				

For Esoterix Use Only

Expected Container Type	# Containers Expected Back	# Containers Received	Condition Received			
			Amb	Frz	Refrig	Thaw
4.0 mL EDTA-Whole Blood	1					
Blood Smears, dried (Slide Holder)	1					
Serum in Transfer Tube	1					
8.0 mL Urine Tube with preservative	1					

Accessioner's Initials/Date: _____

General Comments:

DISTRIBUTION:

SUBMIT TWO COPIES WITH AMBIENT SPECIMENS. RETAIN BOTTOM COPY FOR YOUR FILES.
RETAIN A COPY OF YOUR AIRBILL FOR EACH SHIPMENT.



A LabCorp Company

Esoterix Clinical Trials Services
 A LabCorp Company
 750 Walnut Ave
 Cranford, NJ 07016
 877-788-8861

Requisition Number:



LABORATORY TEST REQUEST FORM
Duke Clinical Research Institute
 Protocol CALERIE, Amendment 1.4
Baseline, Months 12 & 24

Investigator:

Site #:

ESN #:

Instructions:

-SUBJECT MUST BE FASTING!

-FREEZE Gel Packs 24-48 hours before use.

-Ship using Combo-Shipper

-Complete all information with ball-point pen.

-Be sure sample tube labels match the requisition.

Ship specimens on day of collection.

Note: If you miss the courier, store all samples in refrigerator EXCEPT Lavender tube. Hold Lavender at Room Temperature until ready to ship.

Refer to the Esoterix Investigator's Laboratory Manual for further instruction.

Testing Required:

CBC/Diff - ambient

Urinalysis - ambient

Chemistry - CHILLED

Lipid Panel - CHILLED

CRP-hs - CHILLED

Insulin - CHILLED

Subject ID:	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date of Birth:	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Day		Month		YYYY	
Gender:	<input type="checkbox"/>	Male	<input type="checkbox"/>	Female		
Fasting Status:	<input type="checkbox"/>	Fasting	<input type="checkbox"/>	Non-Fasting		
	(12+ Hours Fasting is REQUIRED!)					
Collection Date:	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Day		Month		YYYY	
Collection Time:	<input type="text"/>	:	<input type="text"/>			
	(24 hr clock)		HH	MM		
Visit (Select One)	<input type="checkbox"/>	Baseline				
	<input type="checkbox"/>	Month 12				
	<input type="checkbox"/>	Month 24				

For Esoterix Use Only

Expected Container Type	# Containers Expected Back	# Containers Received	Condition Received			
			Amb	Frz	Refrig	Thaw
4.0 mL EDTA-Whole Blood	1					
Blood Smears, dried (Slide Holder)	1					
Serum in Transfer Tube - CHILLED	2					
8.0 mL Urine Tube with preservative	1					

Accessioner's Initials/Date: _____

General Comments:

DISTRIBUTION:

SUBMIT TWO COPIES WITH SPECIMENS. RETAIN BOTTOM COPY FOR YOUR FILES.
 RETAIN A COPY OF YOUR AIRBILL FOR EACH SHIPMENT.

1214149147



A LabCorp Company

Esoterix Clinical Trials Services
 A LabCorp Company
 750 Walnut Ave
 Cranford, NJ 07016
 877-788-8861

Requisition Number:



LABORATORY TEST REQUEST FORM
Duke Clinical Research Institute
 Protocol CALERIE, Amendment 1.4
Months 1, 3, 6, 9, 18

Investigator:

Site #:

ESN #:

Instructions:

- Complete all information with ball-point pen.
- Be sure sample tube labels match the requisition.

Ship AMBIENT on day of collection.

Note: If you miss the courier, store all samples in refrigerator EXCEPT Lavender tube. Hold Lavender at Room Temperature until ready to ship.

Refer to the Esoterix Investigator's Laboratory Manual for further instruction.

Testing Required:

- CBC/Diff - ambient
- Chemistry (no lipids) - ambient
- Urinalysis - ambient

Subject ID:	-	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	-	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
Date of Birth:	-	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	-	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
	Day		Month	YYYY
Gender:	<input type="checkbox"/> Male		<input type="checkbox"/> Female	
Fasting Status: (8+ Hours)	<input type="checkbox"/> Fasting		<input type="checkbox"/> Non-Fasting	
Collection Date:	-	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	-	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
	Day		Month	YYYY
Collection Time: (24 hr clock)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	:	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	
	HH		MM	
Visit (Select One)	<input type="checkbox"/> Month 1		<input type="checkbox"/> Month 9	
	<input type="checkbox"/> Month 3		<input type="checkbox"/> Month 18	
	<input type="checkbox"/> Month 6			

For Esoterix Use Only

Expected Container Type	# Containers Expected Back	# Containers Received	Condition Received			
			Amb	Frz	Refrig	Thaw
4.0 mL EDTA-Whole Blood	1					
Blood Smears, dried (Slide Holder)	1					
Serum in Transfer Tube	1					
8.0 mL Urine Tube with preservative	1					

Accessioner's Initials/Date: _____

General Comments:

DISTRIBUTION:

SUBMIT TWO COPIES WITH AMBIENT SPECIMENS. RETAIN BOTTOM COPY FOR YOUR FILES.
 RETAIN A COPY OF YOUR AIRBILL FOR EACH SHIPMENT.

8111603257



A LabCorp Company

Esoterix Clinical Trials Services
A LabCorp Company
750 Walnut Ave
Cranford, NJ 07016
877-788-8861

Requisition Number:



LABORATORY TEST REQUEST FORM
Duke Clinical Research Institute
Protocol CALERIE, Amendment 1.4
Off Schedule Testing

Investigator:

Site #:

ESN #:

Instructions:

- Complete all information with ball-point pen.
-Be sure sample tube labels match the requisition.

If submitting Insulin/CRP, FREEZE Gel Packs
24-48 hours before use.

Ship specimens on day of collection.

Note: If you miss the courier, store all samples in
refrigerator EXCEPT Lavender tube. Hold Lavender at
Room Temperature until ready to ship.

Refer to the Esoterix Lab Manual for further
instruction.

Submit only the specimens required for
your selected test:

- Anemia Surveillance (Iron and CBC)
CBC/Diff (Repeat)
Chemistry (Repeat)
Urinalysis (Repeat)
Serum Pregnancy, Qual. (Repeat)
Lipid Panel (Repeat)
CRP-hs (Repeat) CHILLED
Insulin (Repeat) CHILLED

<<< Select Test !

Off Schedule Visit

Subject ID: [] [] - [] [] [] []
Date of Birth: [] [] - [] [] [] - [] [] [] []
Gender: [] Male [] Female
Fasting Status: [] Fasting [] Non-Fasting
Collection Date: [] [] - [] [] [] - [] [] [] []
Collection Time: [] [] : [] []

Accessioning Notes:

- Anemia Surveillance: Order : "IRON" (surveillance) PLUS
"WBC/RBC/HGB/HCT/MCV/MCH/MCHC/Platelet Count (surv.)"
-REPEAT tests: Order as marked.

For Esoterix Use Only

Table with 4 columns: Expected Container Type, # Containers Expected Back, # Containers Received, Condition Received (Amb, Frz, Refrig, Thaw)

Accessioner's Initials/Date:
General Comments:

DISTRIBUTION:

SUBMIT TWO COPIES WITH SPECIMENS. RETAIN BOTTOM COPY FOR YOUR FILES.
RETAIN A COPY OF YOUR AIRBILL FOR EACH SHIPMENT.

Appendix D

Supply Re-order Form (Copy & Complete)

Supply Reorder Form

Duke Clinical Research Institute

CALERIE, Amendment 1.4

FAX to Marina Rivera (512) 225-1273

(e-mail: riveram@labcorp.com)

ORDER
COMBO
SHIPPERS
BELOW

QTY	VISIT KIT	QTY	VISIT KIT
	Screen / Screen-RPT		Months 1, 3, 6, 9, 18
	*Baseline / Month 12 / Month 24		Off-Schedule

QTY	BULK ITEM	
	8.5 mL SST tube, each	TT8.5
	6.0 mL SST tube, each	TT6
	10 mL Transfer tube, each	TVG10
	Transfer Pipette, each	PIPST
	4.0 mL EDTA tube, each	LAV4
	Double Slide Holder with Slides, each	SLPAK
	Diff-Safe Dispenser, each	DIFF5
	8.0 mL Urine preservative tube & collection cup	UTSTB
	21 gauge Eclipse Needles, each	21G1N
	23 gauge "Butterfly" Safety-Lock Needles, each	BFN23
	Adult Vacutainer Holder - Single Use, each	AVAC
	Alcohol Swabs, box of 200	AC200
	Band Aids, box of 100	BANDB

**SHIPPING
MATERIAL**

QTY	ITEM	
	Absorbent pad	ABSPD
	Small Biohazard Bags	SPBAG
	FedEx Airbills to Cranford-NJ	FATCJ
	Airbill Pouch	POUCH
	FedEx Diagnostic Pak	FEDEX
	Saturday Delivery Labels	SADEL

***NOTE: order this COMBO for EACH INSULIN VISIT**

QTY	ITEM	
	Foil Pouch, each	FOILB
	Combo-Shipper, each	STYRO
	Gel Packs, each	COLDP x2

Other Comments or Requests:



SECTION TO BE COMPLETED BY THE SITE

Site Number:	
PI Last Name:	
Person placing order:	
Telephone Number :	
Date Supplies Needed*:	

For Esoterix use only:

Date fax received:
Date ordered in CTx:
Workorder #:
Expected delivery date:

***ALLOW 5-7 BUSINESS DAYS FOR KIT ASSEMBLY AND DELIVERY**

Appendix E

Site Instructions for Safety Shielding
Blood Collection Needles

OSHA's best practice guideline regarding needle holders states that the needle and holder must be disposed of into the Sharps container as one unit. The needle should not be removed from the blood collection device.

Needle-Based Safety

Needle is always bevel up toward the pink safety shield

Some BD PrecisionGlide™ needle quality and sharpness

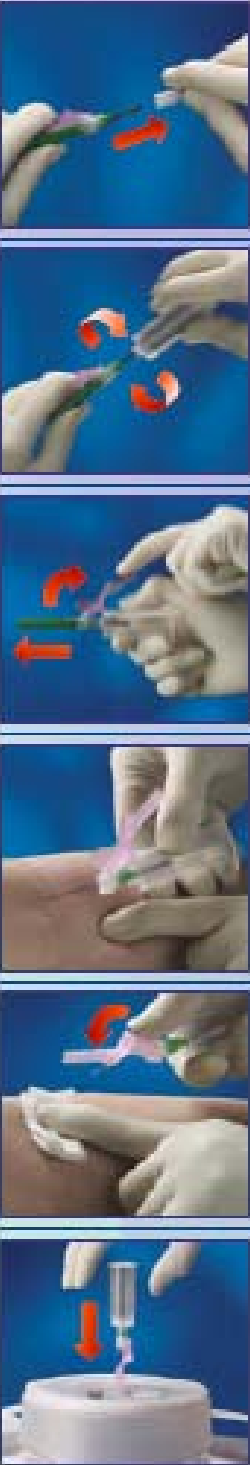
Safety shield is an "integral" part of the needle

Thumb pad for easy one-handed activation

Pre-load line

Engraved text to help drive compliance

Instructions for Use



Holding both pink shield and green cap, twist and remove white cap.

While holding the needle firmly, screw holder onto needle until it fits securely.

(a) Rotate pink safety shield back toward the holder.
(b) Twist and pull green needle cap straight off.

Perform venipuncture according to your facility's established procedures.

Immediately after removing needle from vein, cover needle by pushing pink safety shield forward with thumb. An audible click may be heard. Lock into place and inspect. **DO NOT** attempt to engage shield by pressing against hard surface.

DO NOT remove needle from holder. Dispose of the needle and holder as one unit into nearest sharps container. **DO NOT REUSE.**

BD Vacutainer™ One Use Holders

Compatible with the entire BD Vacutainer® Venous Blood Collection System



BD Vacutainer® Eclipse™ Blood Collection Needle BD Vacutainer® Safety-Lok™ Blood Collection Set BD Vacutainer® Multiple Sample Luer Adapter

BD Vacutainer®

Safety-Lok™ Blood Collection Set with Pre-Attached Holder

Instructions for Use



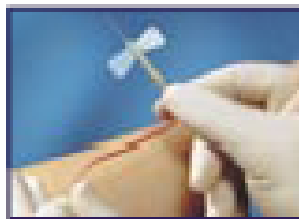
- 1 Open package at arrow. Product is ready to use right out of the package.



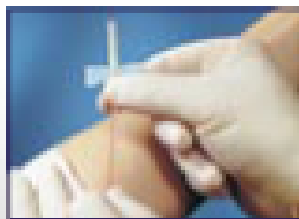
- 2 Apply light pressure to site using three fingers, as shown.



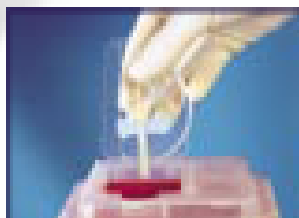
- 3 Withdraw blood collection set by grasping the translucent yellow safety shield grip area with the thumb and index finger.



- 4 With opposite hand, grasp tubing between thumb and index finger.



- 5 Push the yellow shield forward until the safety shield is locked in place.



- 6 Dispose of the BD Vacutainer® Safety-Lok™ Blood Collection Set and holder in the nearest sharps container.

BD Global Technical Services:

1-800-537-0273

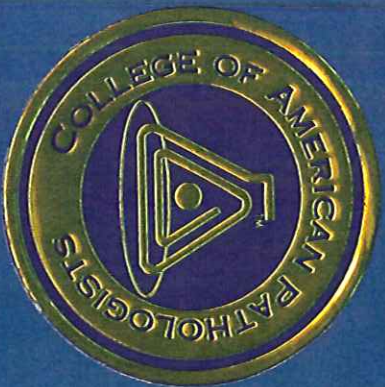
Appendix F

LABORATORY CERTIFICATIONS



Advancing Excellence

**Accredited
Laboratory**



The College of American Pathologists

certifies that the laboratory named below

***Esoterix Clinical Trials Services
Laboratory***

Cranford, New Jersey

Steven M. Diamond, DO

LAP Number: 7179720

AU-ID: 1387682

CLIA Number: 31D1004205

has met all applicable standards for accreditation and is hereby fully accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to April 15, 2011 to maintain accreditation.

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

Chair, Commission on Laboratory Accreditation

President, College of American Pathologists

CENTERS FOR MEDICARE & MEDICAID SERVICES
 CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
 CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
 ESOTERIX CLINICAL TRIALS SERVICES
 750 WALNUT AVENUE
 CRANFORD, NJ 07016

CLIA ID NUMBER
 31D1004205
 EFFECTIVE DATE
 07/01/2009

LABORATORY DIRECTOR
 STEVEN M DIAMOND DO

EXPIRATION DATE
 06/30/2011

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.



Judith A. Yost

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

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:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
PARASITOLOGY (130)	07/01/2003		
VIROLOGY (140)	04/03/2007		
GENERAL IMMUNOLOGY (220)	07/01/2003		
ROUTINE CHEMISTRY (310)	07/01/2003		
URINALYSIS (320)	07/01/2003		
ENDOCRINOLOGY (330)	07/01/2003		
TOXICOLOGY (340)	08/23/2004		
HEMATOLOGY (400)	07/01/2003		

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.

Appendix G

CURRICULUM VITAE

Steven Diamond, DO, Medical Director
Esoterix Clinical Trials Services, Cranford, NJ

CURRICULUM VITAE

Name: Steven Diamond, DO, MBA, FCAP

Education:

<u>High School</u>	<u>Attended</u>		<u>Graduate</u>
<u>Name of High School</u>	<u>From</u>	<u>To</u>	
Long Beach High School	9/57	6/61	

<u>College</u>	<u>Major</u>	<u>Attended</u>		<u>Degree</u>
<u>Name of College or University</u>		<u>From</u>	<u>To</u>	
Queens College	Mathematics	9/61	6/65	B A
Queens College	Chemistry	6/65	9/66	M A
Chicago College of Osteopathic Medicine Midwestern University	Doctor of Osteopathic	9/66	6/70	D O
Wharton School of Business	Business	7/92	6/94	M B A

Job Experience:

<u>Institution</u>	<u>Title</u>	<u>Job Duties</u>	<u>From</u>	<u>To</u>
Hunterdon Medical Center	Medical Director	Anatomic and Clinical Pathology	7/99	Present
Hunterdon County Medical Examiner	Director	Medical Examiner	1/01	Present
Esoterix Clinical Trial Services	Medical Director	Clinical Trials	7/03	Present

Awards, Licenses, Board Certifications:

<u>Award, Certification</u>	<u>Date</u>	<u>Certification Number</u>	<u>Specialization</u>
Anatomic and Clinical Pathology	11/75	American Board	Pathology
Hematopathology	5/77	American Board	Pathology

Signature of Employee:



Date:

8/10/07