Colchester Research Facility Laboratory for Clinical Biochemistry Research (LCBR) University of Vermont Department of Pathology and Laboratory Medicine



Lab Director: Russell P. Tracy, Ph.D. Coordinator: Elaine Cornell MESA 7 Project Manager: Jessica Rooney, MPH MESA Repository Manager: Rebekah Boyle, MS

LCBR

- Russell P. Tracy, Ph.D has directed the LCBR since its inception in 1986; ABCC Boardcertified Clinical Chemist
- Current Personnel includes 8 faculty members, 25 technical and administrative staff, plus students, post-doctoral fellows, and visiting scientists
- Focus on epidemiological & clinical trials research in the areas of coagulation, fibrinolysis, fibrosis, and innate and adaptive immunity
- Frequently serve as a central analysis laboratory and sample repository





Role of the LCBR in MESA 7

We are the MESA 7 Central Blood Analysis Lab (CBAL) and Repository What we do:

- Assist with planning and development of MOPs for blood collection, handling, storage, sample utilization, etc.
- Receive shipments of participant samples from study sites
- Provide quality assurance feedback
- Perform some biomarker testing along with the University of Minnesota
- Inventory and provide repository storage for study samples

Blood Collection



Set Up – Venipuncture Supplies





Draw Tubes

	MESA 7 Draw	v	
(All	Study Sites Except No	orthweste	ern)
Quantity	Туре	Volume	Total Volume
4	EDTA	10 mL	40 mL
1	Serum	10 mL	10 mL
1	Serum	5 mL	5 mL
1	EDTA	2 mL	2 mL
1	EDTA	10 mL	10 mL
1	PaxGene RNA	2.5 mL	2.5 mL
	Total Draw		69.5 mL

MESA 7 Draw



Draw Tubes Continued

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	MESA 7 +	Epi Draw	
	(Northw	estern)	
Quantity	Туре	Volume	Total Volume
4	EDTA	10 mL	40 mL
1	Serum	10 mL	10 mL
1	EDTA	2 mL	2 mL
1	EDTA	6 mL	6 mL
1	СРТ	8 mL	8 mL
1	PaxGene RNA	2.5 mL	2.5 mL
	Total	Draw	68.5 mL



Aliquot Tube Preparation

Label Orientation

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Safety Issues and Precautions for Handling Blood Specimens

In accordance with the OSHA regulations on bloodborne pathogens, the LCBR recommends the following lab safety protocol for the field center laboratories:

- ✓ Use of non-permeable lab coats, latex gloves, and face shields when handling any blood in any situation where splashes, spray, spatter, or droplets of blood may be generated and eye, nose, or mouth contamination can be reasonably anticipated.
- ✓ Use of aerosol containers in all centrifuges.
- ✓ Follow 'Standard Precautions' when handling any blood products.
- ✓ Contaminated needles and sharps shall be immediately placed in a puncture-resistant, leak-proof container. Never recap or break needles.
- ✓ Hepatitis B vaccine should be offered to all unvaccinated technicians handling blood, and documentation of vaccination, or technician's declining to be vaccinated, should be kept on file at the Clinical Center.
- ✓ Limit distractions Noise, radios, phones, etc for your safety and the safety of those around you

Sources of safety information:

http://www.cdc.gov/niosh/topics/bbp/ http://www.osha.gov/SLTC/bloodbornepathogens/index.html http://www.cdc.gov/elcosh/docs/d0300/d000378/d000378.pdf

Preparation of Venipuncture Site

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Venipuncture procedure

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Venipuncture procedure continued



Venipuncture continued



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Remove needle and apply pressure w/ gauze pad

Apply bandage



MESA 7 Classic Samples after Draw



- EDTA After filling, these tubes are mixed for ~30 seconds on the tube rocker then placed on wet ice.
 EDTA tubes for plasma preparation are centrifuged within 30 minutes of the draw. EDTA for whole blood can remain on ice until it can be stored in -80 C freezer.
- Serum After filling, gently invert tube 5 times to ensure proper mixing of the activator with the blood. Tubes remain upright at room temperature for a minimum of 60 minutes, but not longer than 90 minutes, to allow the blood to clot.
- Paxgene After filling, gently invert tube 8-10 times to mix blood with RNA stabilization additive. The tube can remain at room temperature until it is placed in a 80 C freezer for storage.

Blood Processing



MESA Exam 7 Processing Guide



Prepare for Centrifugation

Balance tubes to be centrifuged



Use sealed cups to minimize aerosol hazard



Run at 4°C for 30,000 G/min



Pool and Gently Mix

- Have labeled 15 mL (serum)
 50 mL (plasma) pooling tubes ready
- Draw plasma or serum off using a pipette
- Use care to avoid disturbing the cell layer at the bottom of the tube
- Cap and gently rock tube to mix





Pour Over Packed Red Blood Cells

- Have labeled transfer tubes ready for 5 EDTA draw tubes
- Carefully pour any remaining plasma and all packed cells into transfer tube
- Use one transfer tube per draw tube
- Cap and freeze upright in labeled 5x5x3 inch box



Aliquot and Cap



Example rack from Exam 6



Completed blood and urine set

- Place rack with pre-labeled cryovials on ice or cold pack
- Aliquot 0.5 mL plasma into first 10 cryos ('01-'10)
- Aliquot 0.25 mL plasma into next 12 cryos('11-'22)
- Aliquot 0.5 mL plasma into remaining 32 cryos('23-'54)
- Aliquot 0.5 mL serum into first 14 cryos ('55-'68)
- Cap full cryos with colored cap (EDTAblue, serum-red, urine-yellow)
- Change pipette tips between sample types and participants

Processing Notes

- Serum sample processing follows the same steps as EDTA plasma
- Serum must sit for a minimum of 60 minutes before centrifugation to allow for blood to clot
- Fill tubes in **numerical** order
- Do not attempt to make all aliquots if only a partial volume was collected, fill cryos in order with specified volume leaving the last with partial volume
- Mark partial volume samples on the label with a "P" and record on the processing form
- Record all aliquots made and any deviations from protocol on processing form



Processing Form

Participant ID: Processor ID:_ Date: /___/ Processing Form EDTA Processing Start Time: Processing Start Time: Serum Sample Check Sample Check if Cryo Cryo Color Type Comment* Type Color Comment* Vol if Done ÷. Vol Done EDTA B 0.5 mL EDTA B 0.5 mL 1 43 2 EDTA B 0.5 mL 44 EDTA B 0.5 mL 3 EDTA B 0.5 mL 45 EDTA B 0.5 mL 4 EDTA B 0.5 mL 46 EDTA B 0.5 mL 5 EDTA B 0.5 mL 47 EDTA B 0.5 mL 6 EDTA B 0.5 mL 48 EDTA B 0.5 mL 7 EDTA B 0.5 mL 49 EDTA B 0.5 mL 8 EDTA B 0.5 mL 50 EDTA B 0.5 mL 9 EDTA B 0.5 mL 51 EDTA B 0.5 mL 10 EDTA B 0.5 mL 52 EDTA B 0.5 mL 11 EDTA B 0.25 mL 53 EDTA B 0.5 mL 12 EDTA B 0.25 mL 54 EDTA B 0.5 mL 13 EDTA B 0.25 mL R 0.5 mL 55 Serum 14 EDTA B 0.25 mL 56 Serum R 0.5 mL 15 EDTA B 0.25 mL 57 R 0.5 mL Serum 16 EDTA B 0.25 mL 58 Serum R 0.5 mL 17 EDTA B 0.25 mL 59 Serum R 0.5 mL 18 EDTA B 0.25 mL 60 Serum R 0.5 mL R 0.5 mL 19 EDTA B 0.25 mL 61 Serum 20 EDTA B 0.25 mL R 0.5 mL 62 Serum 21 EDTA B 0.25 mL R 0.5 mL 63 Serum Serum 22 EDTA B 0.25 mL 64 R 0.5 mL 23 EDTA B 0.5 mL 65 Serum R 0.5 mL 24 EDTA B 0.5 mL 66 Serum R 0.5 mL 25 EDTA B 0.5 mL R 0.5 mL 67 Serum 26 EDTA B 0.5 mL 68 Serum R 0.5 mL 27 EDTA B 0.5 mL 69 Urine Y 1.5 mL 28 EDTA B 0.5 mL Y 1.5 mL 70 Urine Y 1.5 mL 29 EDTA B 0.5 mL 71 Urine 30 EDTA B 0.5 mL 72 Y 1.5 mL Urine 31 EDTA B 0.5 mL 73 Urine Y 1.5 mL 32 EDTA B 0.5 mL 74 Y 1.5 mL Urine 33 EDTA B 0.5 mL 75 pRBC W ~5 34 EDTA B 0.5 mL 76 pRBC W ~5 35 EDTA B 0.5 mL 77 pRBC W ~5 36 EDTA B 0.5 mL 78 pRBC W ~5 37 EDTA B 0.5 mL 79 pRBC W ~5 38 EDTA B 0.5 mL 80 EDTA WB DT 2 mL 39 EDTA B 0.5 mL 81 PAXgene RNA DT ~9 nL 40 EDTA B 0.5 mL 82 Hair Folicles G N/A 41 EDTA B 0.5 mL 83 Hair Shafts N/A N/A 42 EDTA B 0.5 mL * P = partial volume B=Blue, R=Red, Y=yellow, W=White, G=Green, DT=Draw Tube Comments: LCBR: Frozen: Y N

Draft 1/12/2022

Urine Collection and Processing



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'spot' urine collection ~11 mLs required for processing 1.5 mL x 6 cryos





Labeled urine aliquots

•Cryovials 69-74, 2 mL size vial

•1.5 mL urine added to each tube

•Place all tubes on ice until the can be frozen @ -80 C

(preferably within 10 mins)

Prepare for Freezer







- Place all cryovials in 5x5x2 inch fiberboard box with 100 cell grid
- Label box with "Freezer Box" label
- Place Paxgene RNA draw tube, EDTA 2 mL whole blood draw tube, and 5 pRBC transfer tubes in 5 x 5 x 3 inch fiberboard box with 49 cell grid
- All samples should be frozen upright in a -80°C freezer until ready to ship

Blind Duplicates for QC

- A blind duplicate sample for quality • control will be reserved from $\sim 10\%$ of participants (5% each for EDTA and serum.).
- Participants selected for EDTA QC activity will automatically be selected for urine QC.
- Participants will be selected for QC • purposes based on the last two digits of their ID numbers.
- EDTA & urine QC activity last 2 digits ٠ of their 7 digit MESA ID are 06, 16, 26, 36, and 46.
- Serum QC activity last 2 digits of their 7 digit MESA ID are 56, 66, 76, 86, and 96.





MESA EXAM 6: - BLIND DUPLICATE SHIPPING FORM

Date of shipm
Center:

Prepared by:

FedEx Air Bill#:

nclude in shipment AND e-n Blind Dupe /QC ID#	Sample Type	Color code (red, purple, yello
Blind Dupe /QC ID#	Sample Type	Color code (led, purple, yeno
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Packing and Shipping



Participant Blood Cryovial Sample Shipment



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Cryovial Box 1 Participant



Tall Tubes Box 1 Participant (4 participant sets fit per box)



Date of shipment: _____ Center:

Prepared by:

FedEx Air Bill#:

(Include in shipment AND e-mail: Jessica.lanzer@med.uvm.edu, <u>Elaine.Cornell@uvm.edu</u>, and Rebekah.Boyle@uvm.edu)

MESA ID#	VISIT DATE	BOX #

MESA_Exam7_ ShippingForm

Packing Frozen Blood Samples

The following shipping instructions comply with the International Air Transport Association's Goods Regulation-Packaging Instructions 650 and 954

- Line Styrofoam mailer with cushioning/absorbent material (lab mat)
- Place 5-10 lbs of dry ice in bottom of mailer
- Place another layer of absorbent material on top of dry ice to act as a barrier between the dry ice and freezer boxes
- Ensure cryovials are packed in 5x5x2 inch cardboard freezer boxes with either 81 or 100 cell grids
- Secure cryovial boxes with rubber bands and place in a zip top bag with absorbent material sufficient for the volume of sample being sent
- Ensure tall tubes are packaged according to instructions and placed in zip top bag with absorbent material sufficient for the volume of sample being sent
- Place bagged samples into Styrofoam mailer
- Place another layer of absorbent material over freezer boxes
- Place remaining dry ice (~5-10 lbs) on top of absorbent material and put the top of the Styrofoam in place
- Insert the shipping form and participant processing forms on top of the Styrofoam mailer before sealing the outer cardboard flaps







Shipping Schedule

- Frozen samples should be shipped Monday or Tuesday of every other week
- We would like to develop a shipping schedule so every site ships the same week, but are divided between the two days
- Please let us know if you have any limitation at your site that are related to schedule (Dry Ice availability, etc)



Shipping Frozen Blood Samples



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Use Fed-Ex Priority Overnight Delivery

Shipment information should be e-mailed to Jessica Rooney, Elaine Cornell, and Rebekah Boyle (<u>Jessica.lanzer@med.uvm.edu</u> elaine.cornell@med.uvm.edu & Rebekah.boyle@med.uvm.edu)

- All packages must be marked with
 - A UN3373 Biological Substance Category B label
 - A dangerous goods Category 9 UN1845 Dry Ice label (with dry ice weight)
 - A completed Fed-Ex air bill
 - The shipper and recipient's name, address, and phone number
- All packages should be shipped to:

Rebekah Boyle University of Vermont Laboratory for Clinical Biochemistry Research 360 South Park Drive Colchester, VT 05446 p:(802)656-8938

Certification



Certification Process

Obtaining Certification

- Read and understand the appropriate chapters in the MESA 7 Manual of Operations.
- Attend Central Training Zoom session
- Successfully complete the written exam
- Successfully complete blood draw/processing while be observed
 Maintaining Certification
- Perform phlebotomy/processing on a minimum of one person every month for the first three month and every other month after that

Certifying Other Technicians

- Ensure new technician has read MESA's Laboratory MOP and section of the Exam 7 MOP.
- Perform phlebotomy/processing with new technician observing
- Supervise as new technician drawing/processing blood samples from one volunteer as described in the protocol and in accordance with the certification checklist
- Administer written examination prepared by LCBR.
- Send exams and checklists to LCBR and CC





