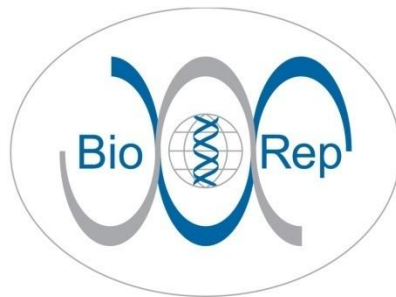




PARKINSON'S
PROGRESSION
MARKERS
INITIATIVE

Play a Part in Parkinson's Research

PPMI Biologics Training Webinar



facilitating research worldwide



Presented by: Alison Ansbach, MS and
Mark Frasier, PhD

v. Nov 2010



Overview

- Equipment
- Supplies (Coriell and Covance)
- Collection and Processing
- Labelling
- Entering Data in eClinical Database
- Shipping
- Quality Control
- Contact Information

Equipment

Phlebotomy Equipment

- You must supply
 - Gloves
 - Alcohol wipes
 - Butterfly needles
 - Tourniquet
 - Gauze Pad
 - Bandage
 - Microcentrifuge tube rack
 - Sharps bin and lid
 - Crushed Ice
 - Dry ice
 - Pipets and pipet tips
- So stock up now!

Required Equipment

- 4 °C and Room Temperature Centrifuge
- -80 °C Freezer

Supplies

(Covance and Coriell)

Initial Supply

Covance: 6 screening visits

Coriell:

- 6 Screening kits
- 4 V01 kits
- 4 V02 kits
- 4 LP Trays
- 1 Supplemental Supplies Kit

General Clinical Labs: Covance Blood Work

- At Screening and annual visits thereafter
- Covance will provide initial supply to kits
 - 3 tubes:
 - Hematology and Differential panel
 - Chemistry Panel
 - Coagulation Group (Only at screening)
- Automatic Resupply

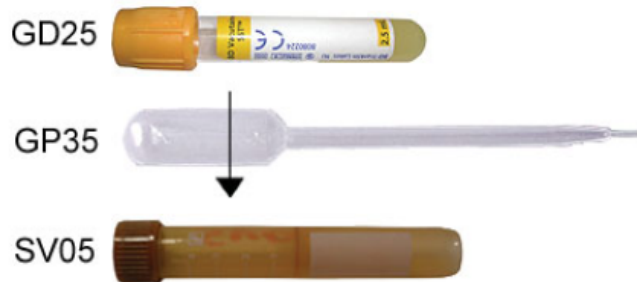
VISIT	Screening	V04/Month 12	V06/Month 24	V08/Month 36	V10/Month 48	V12/Month 60	Premature Withdrawal	Unscheduled
OCCURRENCE	-1 month	Month 12 +/- 30 days	Month 24 +/- 30 days	Month 36 +/- 30 days	Month 48 +/- 30 days	Month 60 +/- 30 days		
TEST GROUPS								
Hematology & Differential Panel	X	X	X	X	X	X	X	0
Chemistry Panel	X	X	X	X	X	X	X	0
Coagulation Group	X							0

Covance Kits

SERUM

Chemistry Panel

One 2.5 mL gold top serum separation tube. Fill tube completely. It is important to thoroughly mix the blood with the clotting activation agent by inverting the tube not less than five times. Allow blood to clot for 30 minutes (tube standing upright). Centrifuge at 1500 to 2000 x g for 15 minutes until clot and serum are separated by a well-formed polymer barrier. Use pipette provided to transfer all the serum into the 5 mL plastic vial labeled CHEMISTRY.



Ambient

Day of
collection

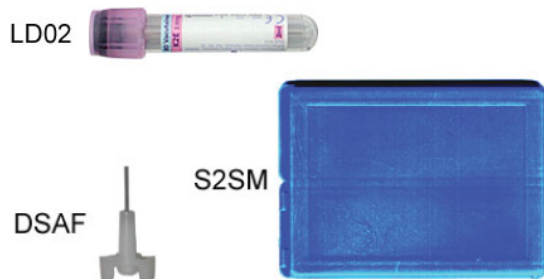
WHOLE BLOOD

Hematology & Differential Panel

Draw whole blood samples last except when collecting coagulation group at the same visit.

One 2 mL lavender top tube. Fill tube completely. Mix immediately by gently inverting the tube at least 8 to 10 times. Make blood smears with blood from the lavender top tube using the Diff-Safe dispenser. Make two slides. Allow to air dry and place in blue slide mailer. **Remove the Diff-Safe from the tube!** Do not forget to ship the tube after using it for the hematology slides.

NOTE: The best source of information in confirmation of hematology results is the blood smear slide prepared by you at the time of draw. Your diligence in slide preparation increases the opportunity to provide hematology results.



Ambient

Day of
collection

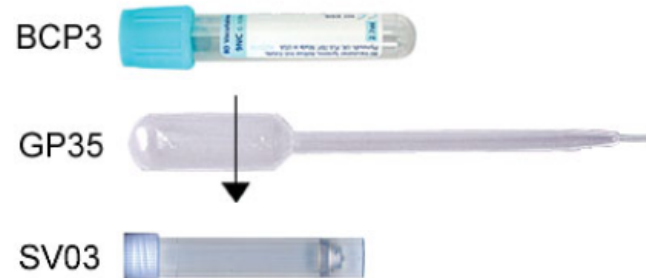
Covance Kits

PLASMA

Coagulation Group

Draw this tube last.

One 2.7 mL blue top sodium citrate tube. Fill tube completely. Mix immediately by gently inverting the tube at least 8 to 10 times. Centrifuge at 1500 to 2000 x g for 15 minutes until cells and plasma are well separated. Use pipette provided to transfer all the plasma into the 3 mL plastic vial labeled COAGULATION GROUP FROZEN. Freeze immediately at -20°C or -70°C until shipment.



Frozen

Day of
collection

Ordering Kits

- Coriell provides materials to collect and ship samples
- Each site will place kit orders through Coriell's online database
- Please allow turnaround time of at least one week

The current date is: 5-20-2010

Welcome **Alison Ansbach**
Visits: 2632 (Last Login: 05/19/2010)
[Logout](#)
@ Coriell Institute

» [Contracts](#) » [Management](#) » [Q-Depot](#) » [Resources](#) » [SNP Data](#)

Current Location: » [Home](#) » [Contracts](#) » [PPMI Project Management](#) » [Kit Request](#) [Q Memory\(2\)](#)

PPMI Project Management
[Kit Request](#)

Coriell Institute PPMI New Kit Order Request Page

Important Information:

- Please allow one week lead time when requesting kit supplies
- If this is the first time you will be receiving kits, please indicate this when entering your request
- Verify shipping information by clicking on the 'Verify Contact' button. If your current shipping address is different than what is on file, please contact the PPMI Project Manager to update.

Kit Request Required Data:

Kit Type:

Contact Name: Alison Ansbach

Select where supplies need to be shipped:

Request:

Coriell Institute for Medical Research
© 2004-2009 | [Q-Master](#) | [Q-Map](#) | [Home](#)

Collection and Processing (Research Samples)

Submitting samples to Coriell/BioRep:

3 types of visits, 3 types of kits

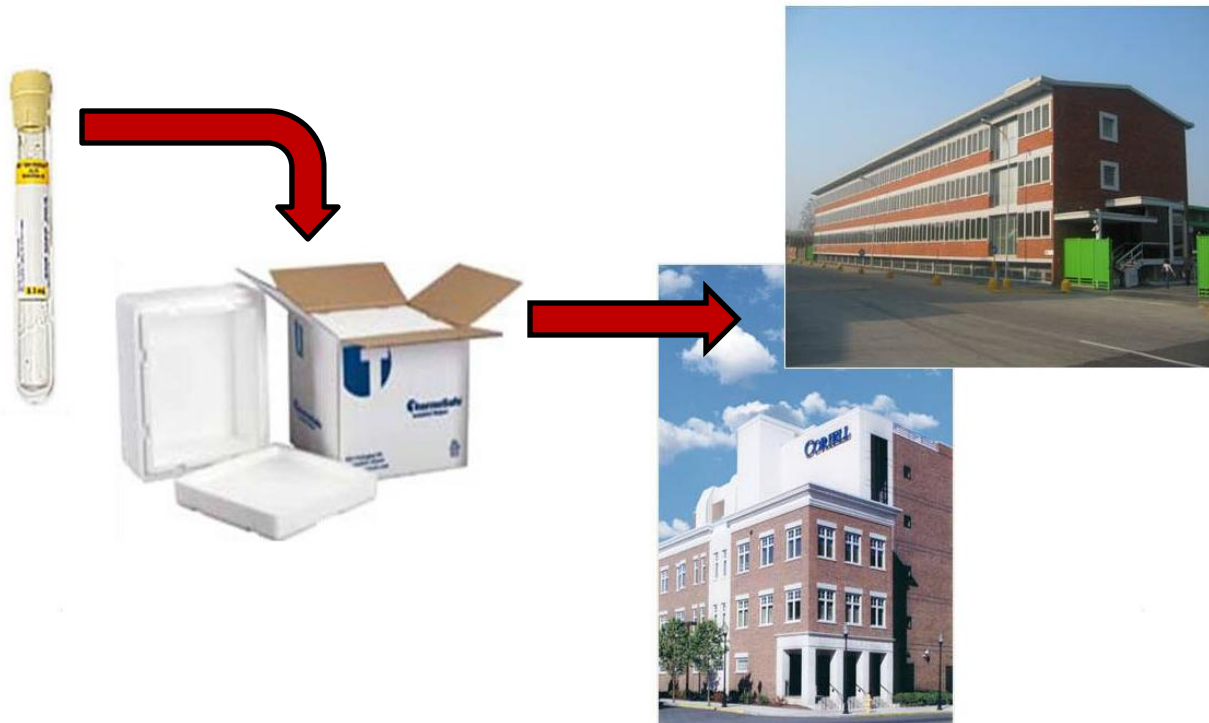
Sample	SCREENING VISIT	Baseline/V02/ V04/V06/V08/ V10/V12	V01/V03/V05/ V07/ V09/V11
Blood for DNA extraction	x		
Blood for Plasma		x	x
Blood for Serum		x	x
Whole Blood		x	x
Blood for RNA extraction		x	x
Urine		x	
CSF		x	

Standardization and Quality are Key!!

Be sure to carefully review the biologics manual prior to the first subject visit and reference during visits as needed.

Screening Visit: Blood for DNA Extraction

- Fill one 8.5ml yellow-top tube with blood
- Keep blood at room temp - DO NOT refrigerate or freeze
- Ship to Coriell/BioRep same day as blood is drawn

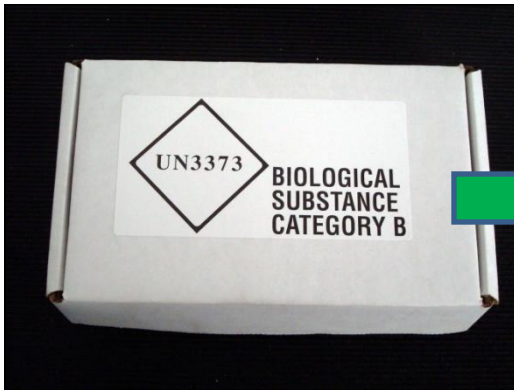


Screening Kit Contents



Type of specimen to be collected:
1 **yellow** top tube of blood

Packaging & Shipping the Screening Kit



Baseline, 6 month, and Annual Visits: Plasma, Serum, Whole Blood, RNA, Urine & CSF

- Fill one each of the following blood tubes:

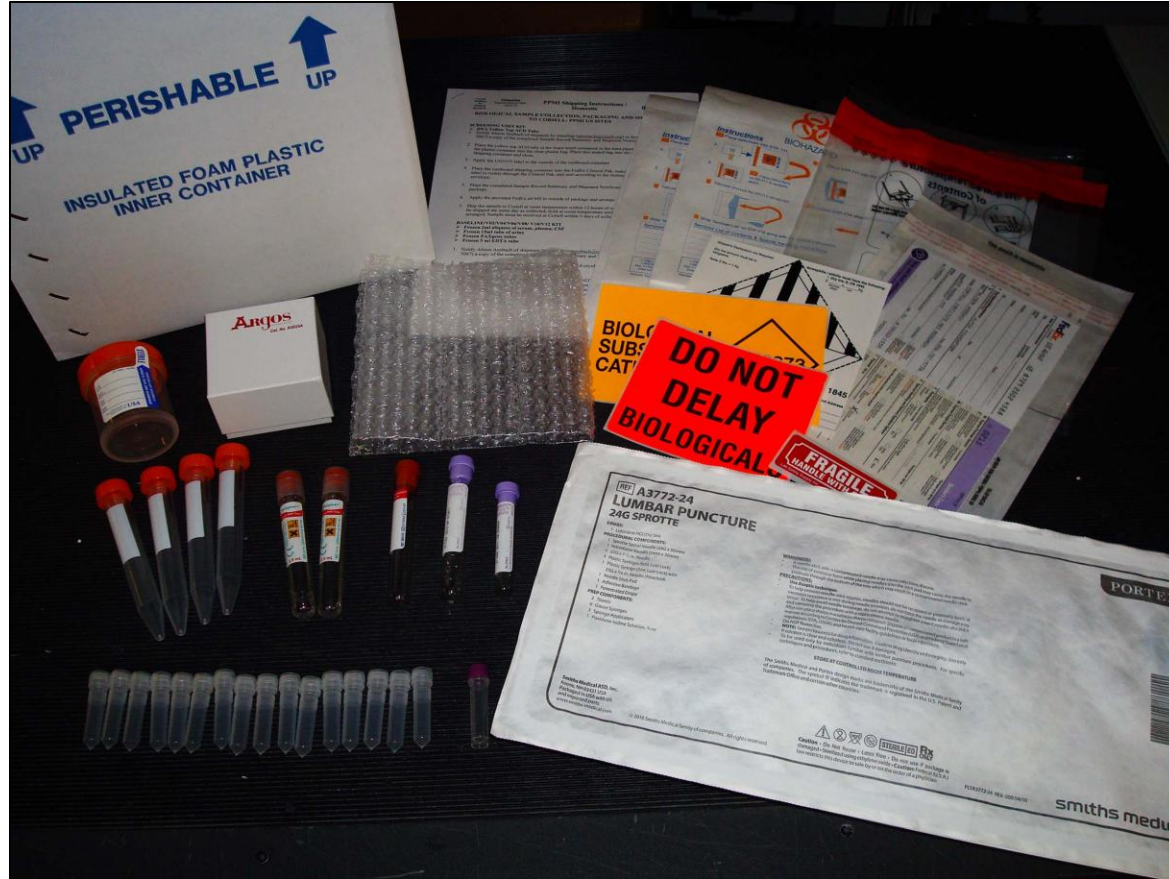
- PAXgene (RNA)
- Large (10ml) **Purple** top (plasma)
- Small (5ml) **Purple** top (whole blood)
- **Red** top (serum)



- Collect urine and CSF
- Process each specimen per protocol
- Ship to Coriell/BioRep on dry ice

Baseline/V02/V04/V06/V08/V10/V12

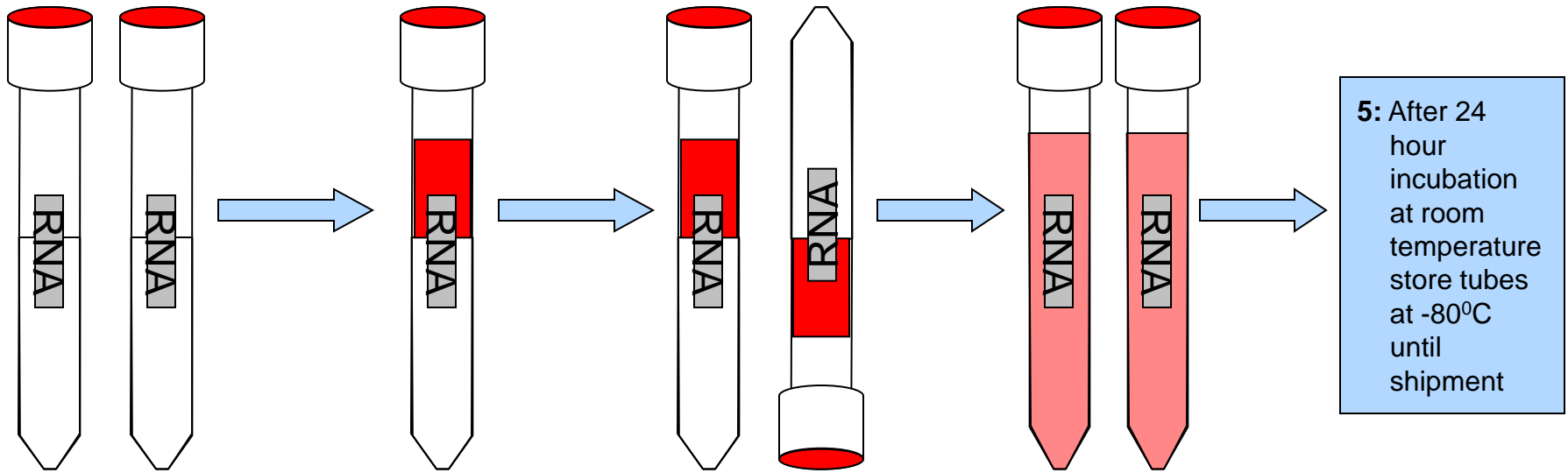
Kit Contents



Types of specimen to be collected:

- | | |
|-----------------------------------------------------------|---------------------------|
| 1 red top tube of blood (for serum) | 2 PAXgene blood RNA tubes |
| 1 [10ml] purple top tube of blood (for plasma) | Urine sample |
| 1 [5ml] purple top tube of blood (for whole blood) | Cerebrospinal fluid |

PaxGene Tube Preparation



1: Store tubes at room temperature, label with pre-printed "RNA" labels prior to blood draw.

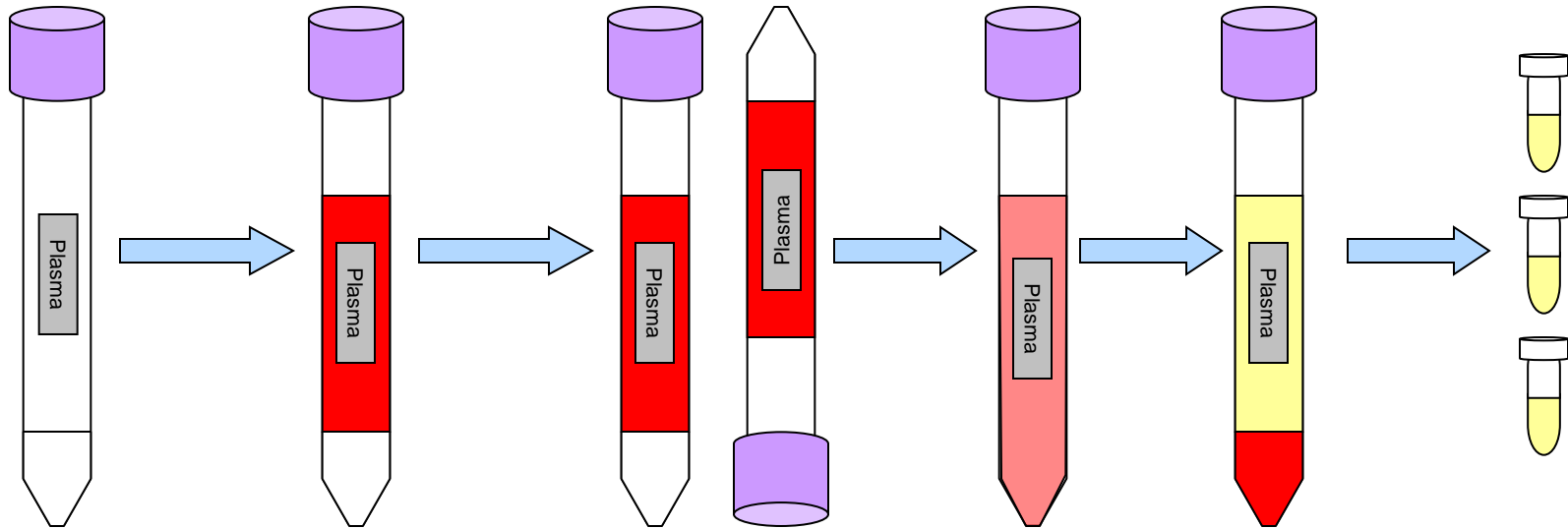
2: Collect blood into one PAXgene tube, allowing blood to flow 10 seconds and ensuring blood has stopped flowing each time.

3: Immediately after blood draw, invert tube gently 8-10 times to mix samples. Repeat Step 2 and 3 for second tube.

4: Incubate tubes upright at room temperature for 24 hours before freezing samples.

5: After 24 hour incubation at room temperature store tubes at -80°C until shipment

Plasma Preparation



1: Store tubes at room temperature, label with pre-printed "Plasma" labels prior to blood draw.

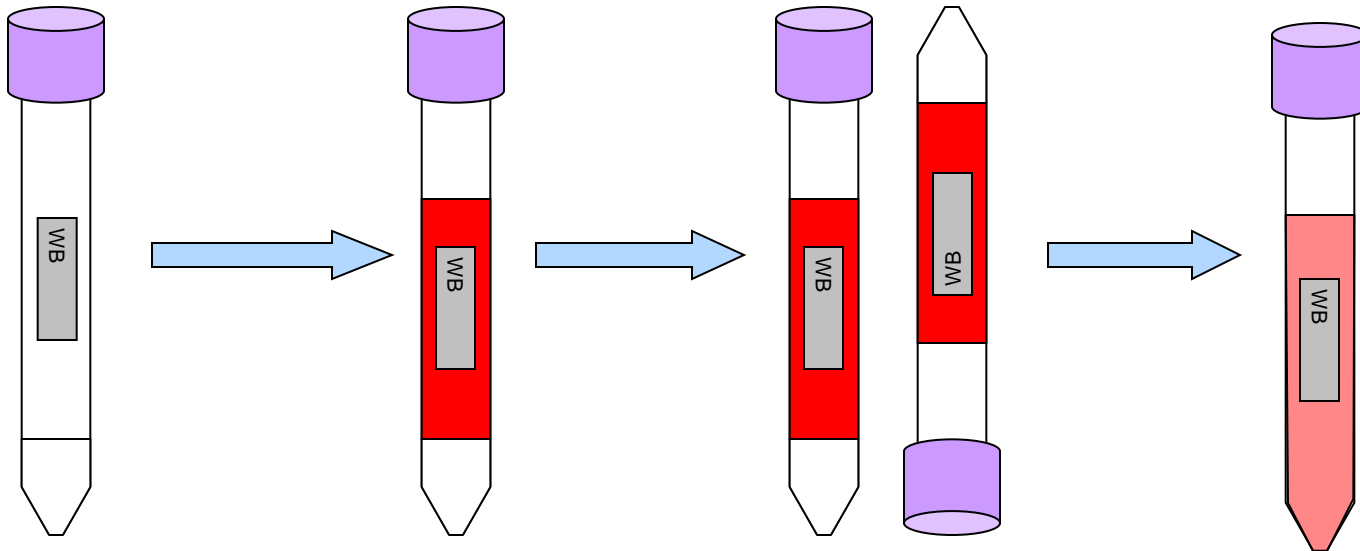
2: Collect blood in Plasma Tube, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

3: Immediately after blood draw, invert tubes 8-10 times to mix samples.

4: Within 30 minutes of blood draw, centrifuge samples at 4°C, 1500 x g for 15 minutes.

5: Label micro centrifuge tubes with preprinted "Plasma" labels. Use transfer pipette to aliquot 1.5 ml samples of plasma. Store plasma aliquots at -80°C until shipment.

Whole Blood Preparation



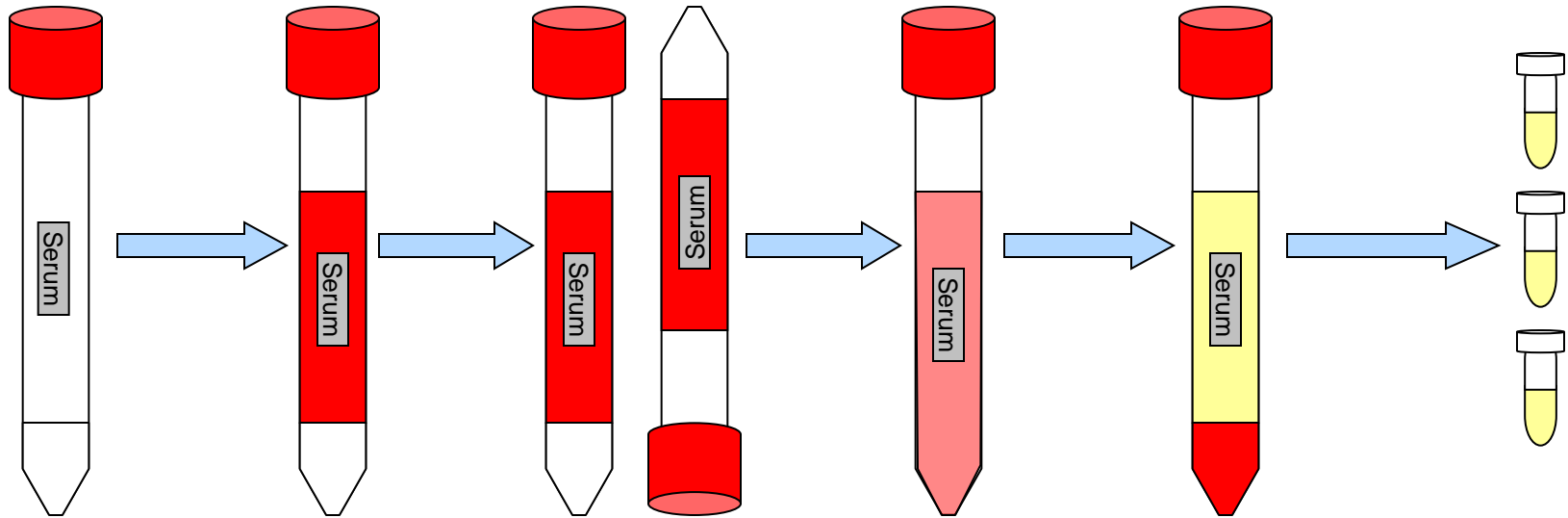
1: Store tube at room temperature, label with pre-printed "WB" label prior to blood draw.

2: Collect blood, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

3: Immediately after blood draw, invert tube 3 times to mix sample.

4: Immediately after inversion, freeze the sample in a -80 freezer until ready to ship.

Serum Preparation



1: Store tubes at room temperature, label with pre-printed "Serum" labels prior to blood draw.

2: Collect blood in Plasma Tube, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

3: Immediately after blood draw, invert tubes 8-10 times to mix samples.

4: Allow blood to clot at room temperature for 15 minutes.

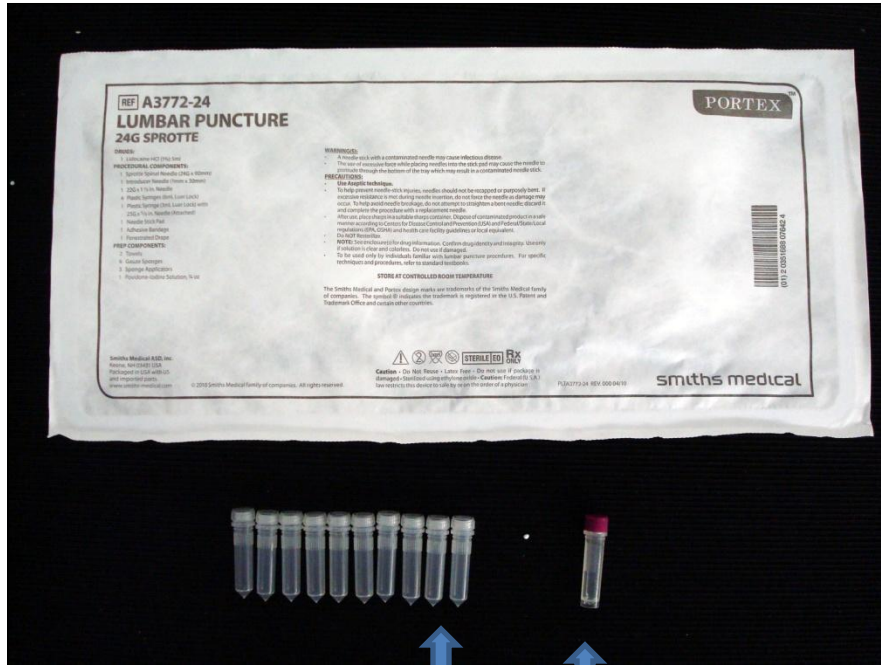
5: Within 60 minutes of collection, centrifuge samples at 4°C, 1500 x g for 15 minutes.

6: Label micro centrifuge tubes with preprinted "Serum" labels. Use transfer pipette to aliquot 1.5 ml samples of plasma. Store plasma aliquots at -80°C until shipment.

Urine Sample Preparation

- Collect in the cup provided
- Transfer to 15 mL Conical tube
- Spin at 4 °C for 15 minutes at 2500xg
- Label 15 mL transfer tube, pipette supernatant into clean tube
- Freeze on dry ice or at -80 °C immediately

Lumbar Puncture Tray



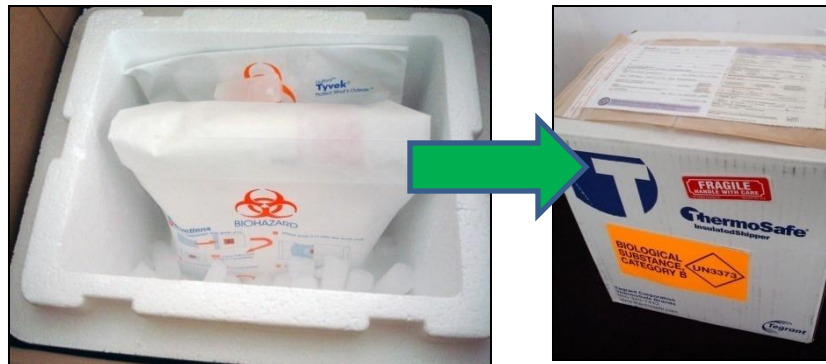
Purple top 2ml vial for clinical lab

Clear 2ml vials for repository

LP Procedure

- 24g Sprotte needle provided in custom kit
- Label and Pre-cool aliquot tubes on ice—tubes NOT in LP tray but in blood kits
- Collect first 1-2 cc's, place in purple top tube
 - Send within 4 hours of collection to local lab for routine analysis (protein, cell count, glucose)
- Collect next 15 cc's CSF and transfer to 15 mL conical tubes
 - Immediately mix in 15 mL conical tubes
 - Spin at 2000x g for 10 minutes at ROOM TEMPERATURE
 - Immediately aliquot approx. 1.5 mL into pre-cooled aliquot tubes
 - Freeze at -80 °C immediately

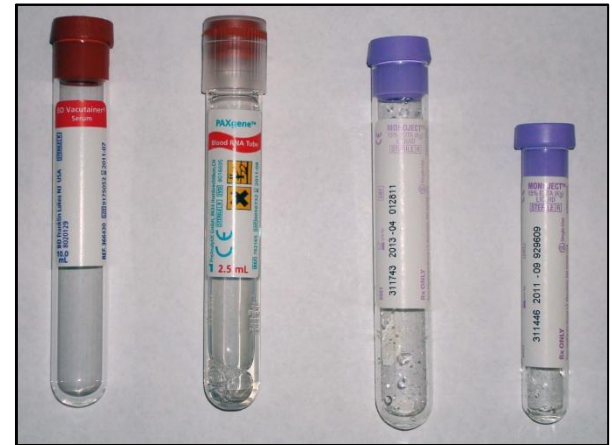
Packaging & Shipping the Baseline Kit



V01/V03/V05/V07/V09/V11: Plasma, Serum, Whole Blood & RNA

- Fill one each of the following blood tubes:

- PAXgene (RNA)
- Large (10ml) **Purple** top (plasma)
- Small (5ml) **Purple** top (whole blood)
- **Red** top (serum)



- Process each specimen per protocol
- Ship to Coriell/BioRep on dry ice

V01/V03/V05/V07/V09/V11

Kit Contents



Type of specimen to be collected:

- 1 **red** top tube of blood (for serum)
- 1 [10ml] **purple** top tube of blood (for plasma)
- 1 [5ml] **purple** top tube of blood (whole blood)
- 2 PAXgene blood RNA tubes

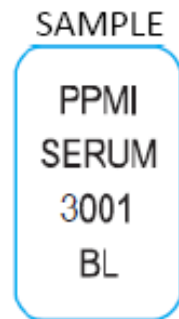
Packaging & Shipping the V01/V03/V05/V07/V09/V11 Kit



Labelling Samples

Labelling Biologic Samples

- Labels provided by the CTCC
- Labels are pre-printed with:
 - Study name (PPMI)
 - Specimen type (Serum, Plasma, CSF, etc.)
 - Subject ID number (based on block assigned to your site)
 - Visit number (BL, V01, V02, etc.)



Labelling Biologic Samples

- ENSURE ALL SAMPLES ARE PROPERLY LABELED!
- You should label each tube during processing so samples do not get mixed
- You must label each aliquot tube to ensure proper identification of each sample upon receipt at Coriell/BioRep

Entering Data into EDC

Timely Data Entry

- At the time samples are collected, ensure all information is recorded accurately on the DNA Sample, Laboratory Procedures and LP data forms
- Data captured in EDC will be used for sample reconciliation
- Information from the CRF source worksheets should be entered on the day of the visit (or within 2 business days per protocol)

DNA Sample CRF

PPMI																		
DNA SAMPLE																		
1	3	2					5	6										
SUBJECT ID							VISIT NO											
INITIALS						SITE NO					VISIT DATE							
											MM		DD		YYYY			
1. Blood sample for DNA: (0 = Not Collected, 1 = Collected)										1.								
1a. Date blood sample for DNA collected:										1a.								
												MM		DD		YYYY		
2. Volume of blood collected: (milliliters)										2.								
3. Date DNA sample shipped:										3.								
												MM		DD		YYYY		

Whole Blood Sample CRF

PPMI													
1 3 2			WHOLE BLOOD SAMPLE						7 8				
SUBJECT ID										VISIT NO			
INITIALS				SITE NO				VISIT DATE					
								MM		DD		YYYY	

1. Whole blood for storage and analysis: (0 = Not collected, 1 = Collected) 1. ☐

1a. Date of whole blood collection:

1a. ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
MM DD YYYY

2. Comments:

Lab Procedures CRF – page 2

Blood Sample Collection

4. Date blood samples collected:

4.

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MM DD YYYY

(RNA – PAXgene RED TOP)

5. Blood for PAXgene/RNA: (0 = Not collected, 1 = Collected)

5.

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5a. Time of PAXgene/RNA sample collection:
(24-hours at room temperature)

5a.

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5b. Date PAXgene/RNA samples placed in freezer:

5b.

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MM DD YYYY

5c. Time PAXgene/RNA samples placed in freezer:

5c.

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 :

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5d. Storage temperature: (Celsius)

5d.

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(PLASMA – EDTA PURPLE TOP)

6. Blood for plasma: (0 = Not collected, 1 = Collected)

6.

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6a. Time of plasma sample collection: (24-hour clock)

6a.

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6b. Time of centrifugation: (24-hour clock)

6b.

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6c. Rate of centrifugation: (xg)

6c.

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6d. Duration of centrifugation: (minutes)

6d.

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6e. Indicate temperature at which tube was spun: (Celsius)

6e.

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6f. Total volume aliquotted after spinning: (milliliters)

6f.

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6g. Total number of aliquot tubes:

6g.

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6h. Time plasma samples placed in freezer: (24-hour clock)

6h.

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6i. Storage temperature: (Celsius)

6i.

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Lab Procedures CRF – page 3

(SERUM – RED TOP)

7. Blood for serum: (0 = Not collected, 1 = Collected) 7. ☐
- 7a. Time of serum sample collection: (24-hour clock) 7a. ☐☐ : ☐☐
- 7b. Time of centrifugation: (24-hour clock) 7b. ☐☐ : ☐☐
- 7c. Rate of centrifugation: (xg) 7c. ☐☐☐☐
- 7d. Duration of centrifugation: (minutes) 7d. ☐☐
- 7e. Indicate temperature at which tube was spun: (Celsius) 7e. ☐☐
- 7f. Total volume aliquotted after spinning: (milliliters) 7f. ☐ . ☐
- 7g. Total number of aliquot tubes: 7g. ☐
- 7h. Time serum samples placed in freezer: (24-hour clock) 7h. ☐☐ : ☐☐
- 7i. Storage temperature: (Celsius) 7i. ☐ - ☐☐

(GENERAL LABS)

8. Blood for clinical labs: (0 = Not collected, 1 = Collected) 8. ☐
- 8a. Date shipped to central lab: 8a. ☐☐ MM ☐☐ DD ☐☐☐☐ YYYY

Lumbar Puncture CRF

PPMI	
LUMBAR PUNCTURE	
<div style="display: flex; justify-content: space-between;"> <div> <div style="border: 1px solid black; padding: 2px;">1</div> <div style="border: 1px solid black; padding: 2px;">3</div> <div style="border: 1px solid black; padding: 2px;">2</div> </div> <div> <div style="border: 1px solid black; padding: 2px;">6</div> <div style="border: 1px solid black; padding: 2px;">4</div> </div> </div>	
SUBJECT ID <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>	VISIT NO <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
INITIALS <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>	SITE NO <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
VISIT DATE <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>	
MM DD YYYY	
A. Date of last intake of food:	A. <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
MM DD YYYY	
B. Time of last intake of food: (24-hour clock)	B. <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> : <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
C. Is subject on medication for PD? (0 = No, 1 = Yes)	C. <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
Ga. Date of most recent PD medication dosing:	Ga. <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
MM DD YYYY	
Gb. Time of most recent PD medication dosing (24-hour clock)	Gb. <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> : <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
1. Lumbar puncture for collection of CSF: (0 = Not collected (comment required), 1 = Collected)	1. <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
2. Date CSF collected:	2. <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
MM DD YYYY	
3. Indicate needle used to collect CSF: 1 = 20g Quincke (sharp bevelled) needle 2 = 22g Quincke (sharp bevelled) needle 3 = 25g Quincke (sharp bevelled) needle 4 = 22g Sprotte (atraumatic) needle 5 = 24g Sprotte (atraumatic) needle (preferred) 6 = 18g	3. <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
4. Indicate method of collecting the CSF: 1 = Gravity 2 = Syringe suction	4. <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
5. Lumbar puncture performed at the: 1 = L3-L4 Interspace 2 = L2-L3 Interspace 3 = Unknown	5. <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
6. Subject position when lumbar puncture performed: 1 = Sitting, leaned over (preferred) 2 = Lying, curled up on side 3 = Unknown	6. <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>
7. Time CSF collected: (24-hour clock)	7. <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div> : <div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>

Note to record time of last meal.

Note to record info about PD meds (if applicable).

Lumbar Puncture CRF – page 2

8.	Volume of CSF collected prior spinning: (milliliters)	8.	<input type="text"/>	<input type="text"/>			
9.	Time CSF was centrifuged: (24-hour clock) (Within 15 minutes from sample collection)	9.	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
10.	Rate of centrifugation for the CSF sample: (xg)	10.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
11.	Temperature at which CSF tube was spun: (Celsius)	11.	<input type="text"/>	<input type="text"/>			
12.	Time CSF sample aliquotted: (24-hour clock)	12.	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
13.	Total volume of CSF aliquotted after spinning: (milliliters)	13.	<input type="text"/>	<input type="text"/>			
14.	Total number of aliquot tubes:	14.	<input type="text"/>	<input type="text"/>			
15.	Was part of sample discarded due to a bloody tap? (0 = No, 1 = Yes)	15.	<input type="text"/>				
16.	Time samples were either placed in freezer or placed on dry ice: (24-hour clock)	16.	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
16a.	Storage temperature if placed in freezer: (Celsius)	16a.	-	<input type="text"/>	<input type="text"/>		
17.	Was part of the sample sent to local lab for analyses? (0 = No, 1 = Yes) If No, specify in Comments	17.	<input type="text"/>				
18.	What is the white blood cell count?	18.	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>
18a.	Indicate units: <input type="checkbox"/> 10 ⁹ mcL <input type="checkbox"/> 10 ⁹ mcL						
19.	What is the red blood cell count?	19.	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>
19a.	Indicate units: <input type="checkbox"/> 10 ⁹ mcL <input type="checkbox"/> 10 ⁹ mcL						
20.	What is the total protein?	20.	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>
20a.	Indicate units: <input type="checkbox"/> mg/dL <input type="checkbox"/> g/dL <input type="checkbox"/> g/L						
21.	What is the total glucose?	21.	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>
21a.	Indicate units: <input type="checkbox"/> mg/dL <input type="checkbox"/> mmol/L						

Record results from
the local lab
analysis of the CSF.

Lumbar Puncture CRF – page 3

22. Was a fluoroscopy performed? (0 = No, 1 = Yes)

22. ☐

22a. Date of fluoroscopy:

22a.

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MM DD YYYY

23. Was a lumbar spine film performed? (0 = No, 1 = Yes)

23. ☐

23a. Date of spine film:

23a.

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MM DD YYYY

Shipping Samples (Covance and Coriell/BioRep)

Covance Shipping Instructions

- Ambient Day of Collection
 - Hematology and Differential
 - Chemistry Panel
- FROZEN Day of Collection
 - Coagulation Group (Screening Only)
- Packaging and Shipping Instructions
 - Refer to Covance Laboratory Manual

Coriell/BioRep Sample Record Shipping Form

PPMI
Sample Record Summary and Shipment Notification

Site Number:

Principal Investigator:

Coordinator:

Telephone:

Email:

Date Sample(s) Shipped:

Instructions: This form must be completed for shipment of all research samples. Notify Coriell or BioRep (email, fax or phone) in advance of shipment using contact information below. Place a copy in the shipment box and file a copy of the completed form in the study binder. Site will be contacted should there be issues with samples noted upon receipt or shipment did not include this form.

Please be sure to list the **Subject ID** that corresponds to the pre-printed labels. List only one "Specimen Type" per row.

Completed by Submitter/Site						Completed by Repository	
Subject ID Number	Specimen Type (RNA,DNA, WB, Urine, CSF, Plasma, or Serum)	Visit Type (BL, V01, V02, etc.)	# of Tubes	Gender	Date of Draw	Repository ID Number	Notation of problems
Total number of tubes:							

Courier (check one):

1

FedEx

7

DHL

9

Other (specify):

Tracking Number:

Contact Information:

Coriell - U.S. Sites

Alison Ansbach

aansbach@coriell.org

Fax: 856-966-5067

Ph: 856-757-9756

BioRep – European Sites

PPMI@biorep.it

Fax: +39 02 58018471

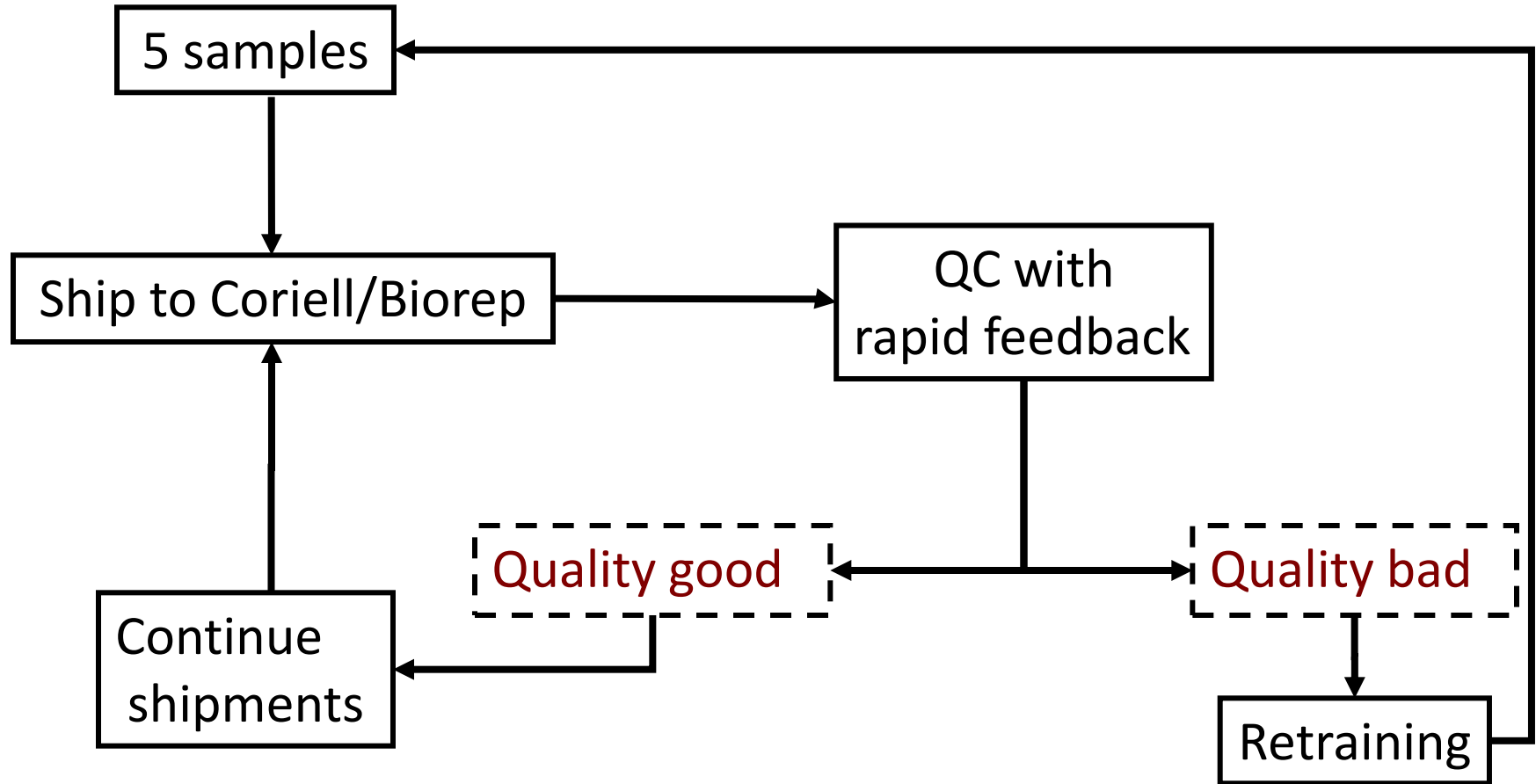
Ph: +39 02 58014369

Quality Control of Research Samples

QC Feedback to Sites

- Purpose: Provide feedback to sites to confirm whether procedures are being followed per the research lab manual
- QC Checklist Form completed for first 2 subject's samples submitted (SC and BL visit)
- Coriell and BioRep completes upon receipt of the SC and BL visit and emails completed form back to site
- Site should file copy in study binder

Quality Control



Summary

- Adhering to protocol and Manual is CRITICAL!
- Do not hesitate to contact CTCC/Coriell/BioRep with any questions or feedback

Coriell Contact Info

Coriell

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BioRep Contact Info

BioRep

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