

# **REPRIEVE (A5332) Topics for Laboratories**

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# 2 Lab Processing Charts (LPCs): one for Non-ACTG Sites & one for ACTG Sites

The screenshot shows a web browser window displaying the ACTG website. The page title is "Protocol A5332: Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE)". The breadcrumb navigation is "Home >> Studies >> A5332: Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE)". The page has several tabs: "General", "Sites", "Site Protocol Activation Checklist", "Affiliations", and "PSWP". Under the "PSWP" tab, there is a section for "Lab Resources (Protocol Version 3.0)". A table lists various resources:

Type	Name	Dated
	ACTG Sites - A5332 V3 Revised Lab Processing Chart	01/04/2017
	ACTG Sites - A5332 V3 Revised Lab Processing Chart	01/04/2017
	Non-ACTG Sites - A5332 V3 Revised Lab Processing Chart	01/04/2017
	Non-ACTG Sites - A5332 V3 Revised Lab Processing Chart	01/04/2017
	Non-ACTG Sites - LPC Processing Worksheet	
	Lab Details from WebLDMS Training (nonACTG sites only)	08/25/2016
	Non-ACTG Site-Specific Shipping Schedule to BRI	12/15/2016
	Step by Step Guide for LDMS Entries using the REPRIEVE Processing Worksheets	06/30/2015
	Guide for sites when processing lab does NOT have LDMS access.	
	WebLDMS Reference Guide - Shipping	
	WebLDMS Reference Guide - Specimen Management	
	WebLDMS Reference Guide - Storage	

A green arrow points to the "Non-ACTG Sites - A5332 V3 Revised Lab Processing Chart" entry. The footer of the page includes "CONTACT US", "Funded by the US Department of Health & Human Services, the National Institutes of Health, the National Institute of Allergy and Infectious Diseases, and the Division of AIDS.", and "© 2017 Social & Scientific Systems, Inc. MIS 6.20.0".

Located in the ACTG website. In Studies type A5332, select PSWP, Lab Resources

# LPC Organization Review

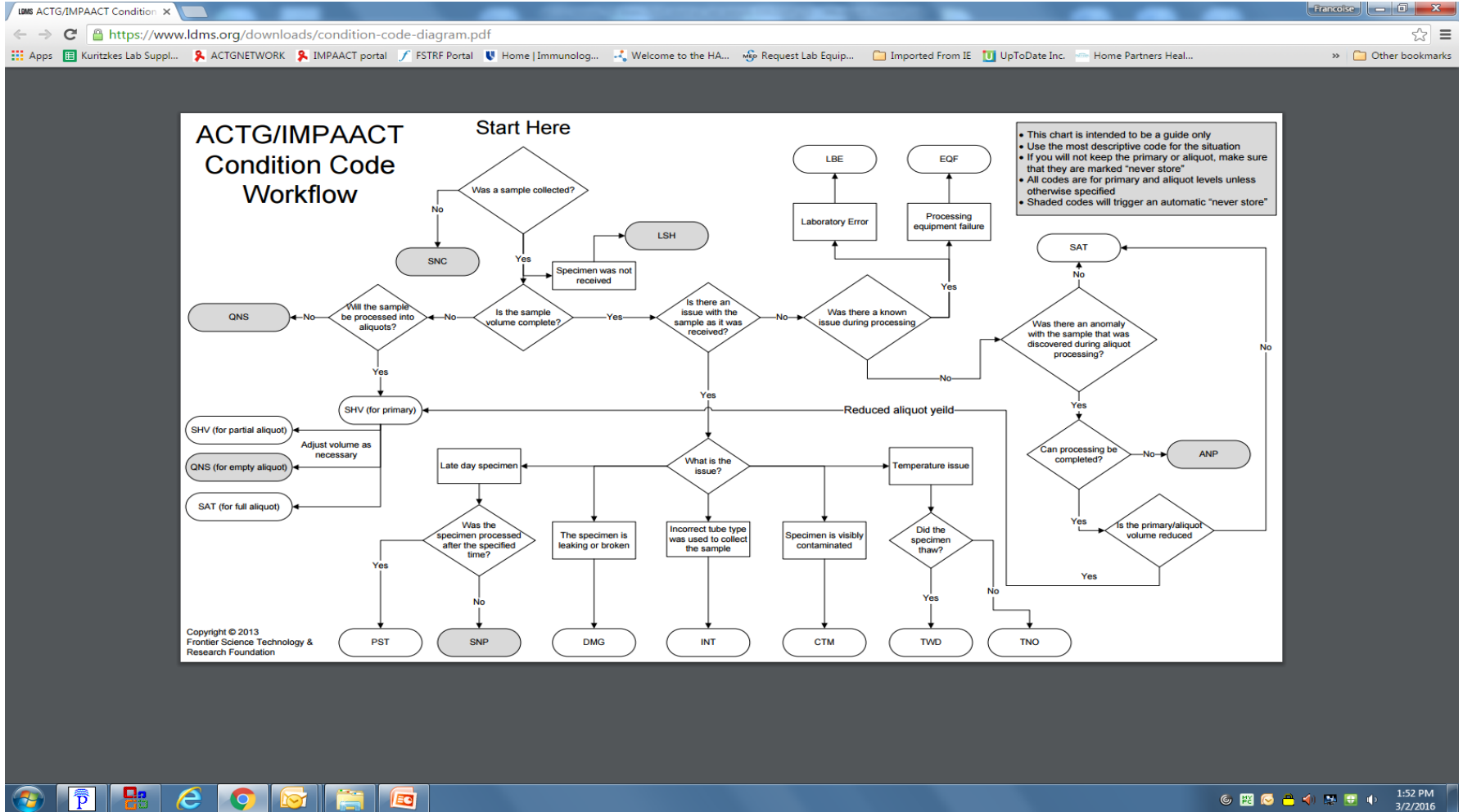
Section 1	Laboratory components of the protocol Schedule of Events
Section 2	Information for tests that are typically “safety labs” and do not require processing for protocol storage
Section 3	Instruction for specimen processing for protocol storage
Section 4	Detailed information for each visit. Includes specimen types & volumes, derivative and aliquoting expectation, LDMS codes
Section 5	Shipping information
Section 6	Revision/update history. Note that updated text is bolded throughout the document.

***On Page 1 of your LPC, you will find a list of suggested supplies that your site will need to purchase prior to processing Reprieve samples. Their cost is included in the package received for enrolling participants in the study.***

# LDMS Using LDMS for REPRIEVE

- Non-Network sites & labs use **Web LDMS**.
- Log samples and generate labels, document specimen condition, freeze/storage conditions, generate reports and shipping manifests.
- Document aliquot freeze date & time.
- Web LDMS trainings via webinar
  - Sites/labs will be contacted directly by the DMC to register for upcoming trainings as they are approved to use WebLDMS.

# WebLDMS Codes



[https://www.ldms.org/resources/ldms/web/#topics/specimen\\_management/topics/c\\_specimen\\_conditions.html](https://www.ldms.org/resources/ldms/web/#topics/specimen_management/topics/c_specimen_conditions.html)

# Example of Reprieve Processing Form

<b>A5332 Processing</b>					
Per posted V3 A5332-Non Network LPC					
	PID:	PID:	PID:	PID:	PID:
Collection date					
Collection Time					
Visit number					
Received date					
Received time					
Technician's Initials					
ADDITIVE:	EDT or DPE / SST / SPO (or SFE for brazil) / NON(**)	EDT or DPE / SST / SPO (or SFE for brazil) / NON(**)	EDT or DPE / SST / SPO (or SFE for brazil) / NON(**)	EDT or DPE / SST / SPO (or SFE for brazil) / NON(**)	EDT or DPE / SST / SPO (or SFE for brazil) / NON(**)
BLOOD VOLUME:	mL	mL	mL	mL	mL
<b>PROCESSING</b>					
START TIME (*):	:	:	:	:	:
FREEZING TIME:	:	:	:	:	:
Freezing temperature					
Nb of aliquots @ volume					
<b>Comments:</b>					
(*) Starting time is when centrifugation starts		(**) NON is the additive entered in LDMS for the urine collection			
<b>Expected storage per visit:</b>	<b>Blood Volumes</b>	<b>Number of Aliquots x Volume-LDMS code</b>	<b>Other Option</b>	<b>Special Notes</b>	
<b>Entry</b>	5mL SST	1x1.8mL-BLD/SST/SER		separate within 1-2 hours after collection	
	20mL SST	4x1.8mL-BLD/SST/SER		separate within 1-2 hours after collection	
	20mL EDT	4x1.8mL-BLD/EDT/PL1	<b>4x1.8mL BLD/DPE/PL1</b>	process within 1-2 hours after collection	
	5mL SPO (optional for brazilian sites: use SFE tube)	1x1.8mL-BLD/SPO/PL1	<b>1X1.8mL BLD/SFE/PL1</b>	process within 1-2 hours after collection	
	Urine	1x1.0mL-URN/NON/URN		separate within 1-2 hours after collection	
<b>Mo 12</b>	5mL SST	1x1.8mL-BLD/SST/SER		separate within 1-2 hours after collection	
	5mL SPO (optional for brazilian sites: use SFE tube)	1x1.8mL-BLD/SPO/PL1	<b>1X1.8mL BLD/SFE/PL1</b>	process within 1-2 hours after collection	
	10mL SST	2x1.8mL-BLD/SST/SER		separate within 1-2 hours after collection	
	10mL EDT	2x1.8mL-BLD/EDT/PL1	<b>2x1.8mL BLD/DPE/PL1</b>	process within 1-2 hours after collection	
<b>Mo 24, 36, 48, 60</b>	5mL SST	1x1.8mL-BLD/SST/SER		separate within 1-2 hours after collection	
	5mL SPO (optional for brazilian sites: use SFE tube)	1x1.8mL-BLD/SPO/PL1	<b>1X1.8mL BLD/SFE/PL1</b>	process within 1-2 hours after collection	
<b>Mo 72/Discontinuation</b>	5mL SST	1x1.8mL-BLD/SST/SER		separate within 1-2 hours after collection	
	10mL SST	2x1.8mL-BLD/SST/SER		separate within 1-2 hours after collection	
	10mL EDT	2x1.8mL-BLD/EDT/PL1	<b>2x1.8mL BLD/DPE/PL1</b>	process within 1-2 hours after collection	
	5mL SPO (optional for brazilian sites: use SFE tube)	1x1.8mL-BLD/SPO/PL1	<b>1X1.8mL BLD/SFE/PL1</b>	process within 1-2 hours after collection	

# REPRIEVE aliquot storage & shipment to the Repository (BRI)

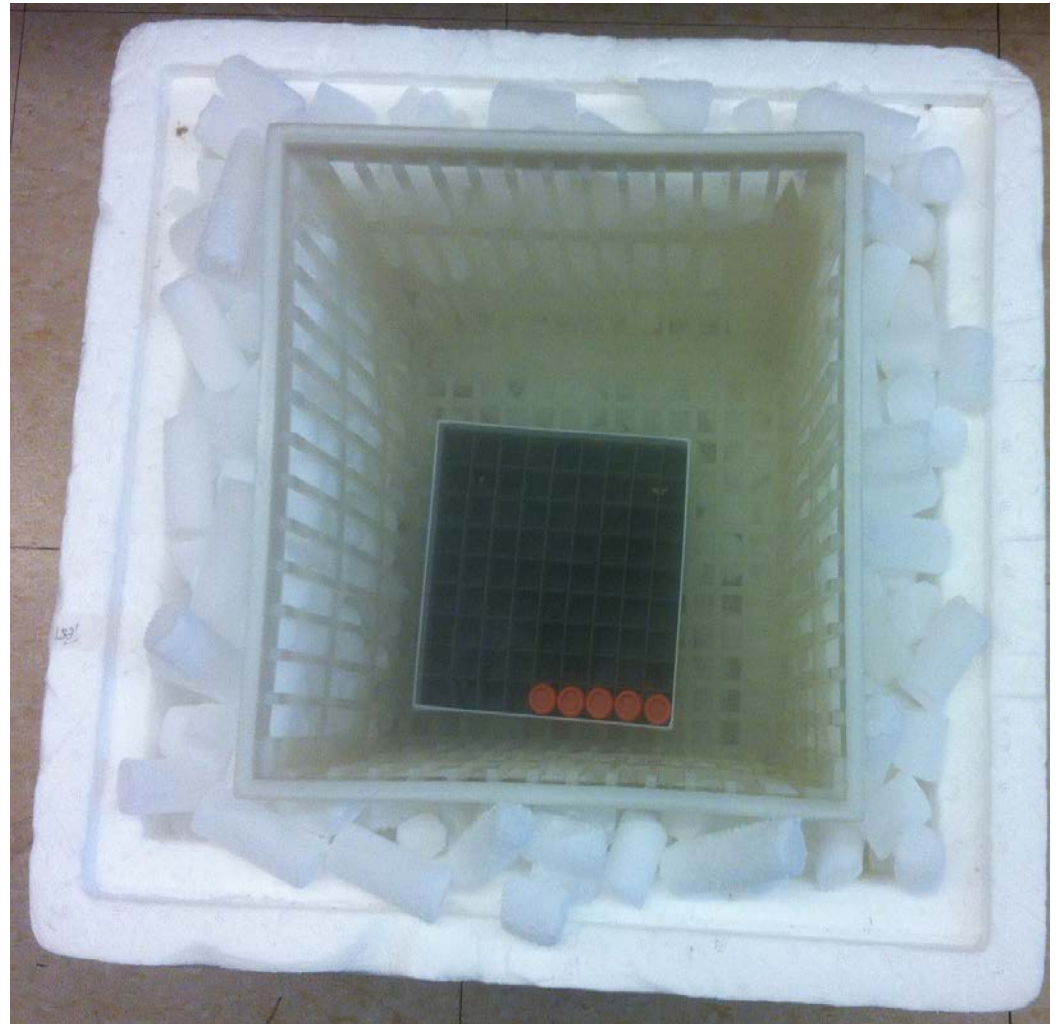


- Store in **REPRIEVE A5332 freezer boxes**.
- Do NOT mix with samples from any other protocols.
- Ship to BRI, per assigned schedule (in PSWP)

<https://member.actgnetwork.org/cms/dl/26914>

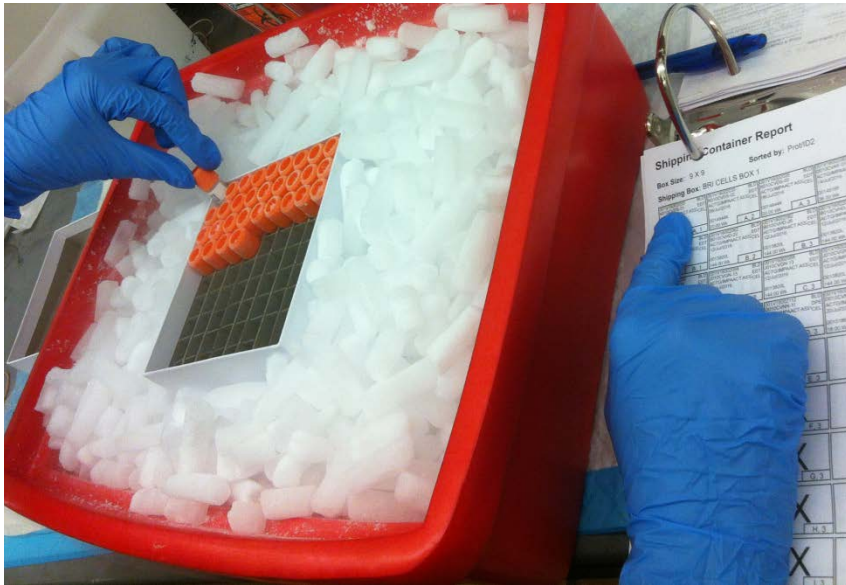
# REPRIEVE Aliquot Storage, QA/QC, Shipment

Be creative to keep your frozen samples from being exposed to temperature fluctuations while out of the freezer





# Keep the Chain of Cold at All Time

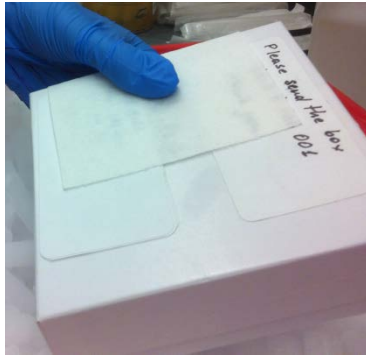


During QA/QC

While preparing your shipment to BRI



# Steps to prepare a shipment to BRI



Wrap the labelled freezer box with absorbent strip (i.e. STP-152)



Insert freezer box in leak proof bag and Tyvek envelope (i.e. STP-730)



STP320 System



Record on Tyvek envelope: the LDMS batch number, From: [your lab number], To: BRI, and the shipping date.

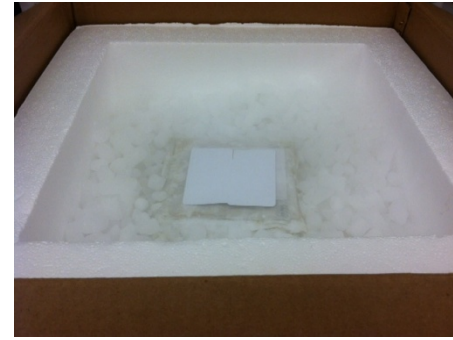
# Steps to prepare a shipment to BRI



Place dry ice in Styrofoam box to cool down the inner box (i.e. STP-111)



Insert the storage box into the inner box



Close the inner box and fill shipper with dry ice



In the pouch:

- 1) LDMS Shipping Manifest
- 2) LDMS Storage Container Report
- 3) EMPTY sign
- 4) Airbill for the return of your shipper.



**Do Not include CDs, Thumb drives with stored LDMS files.**

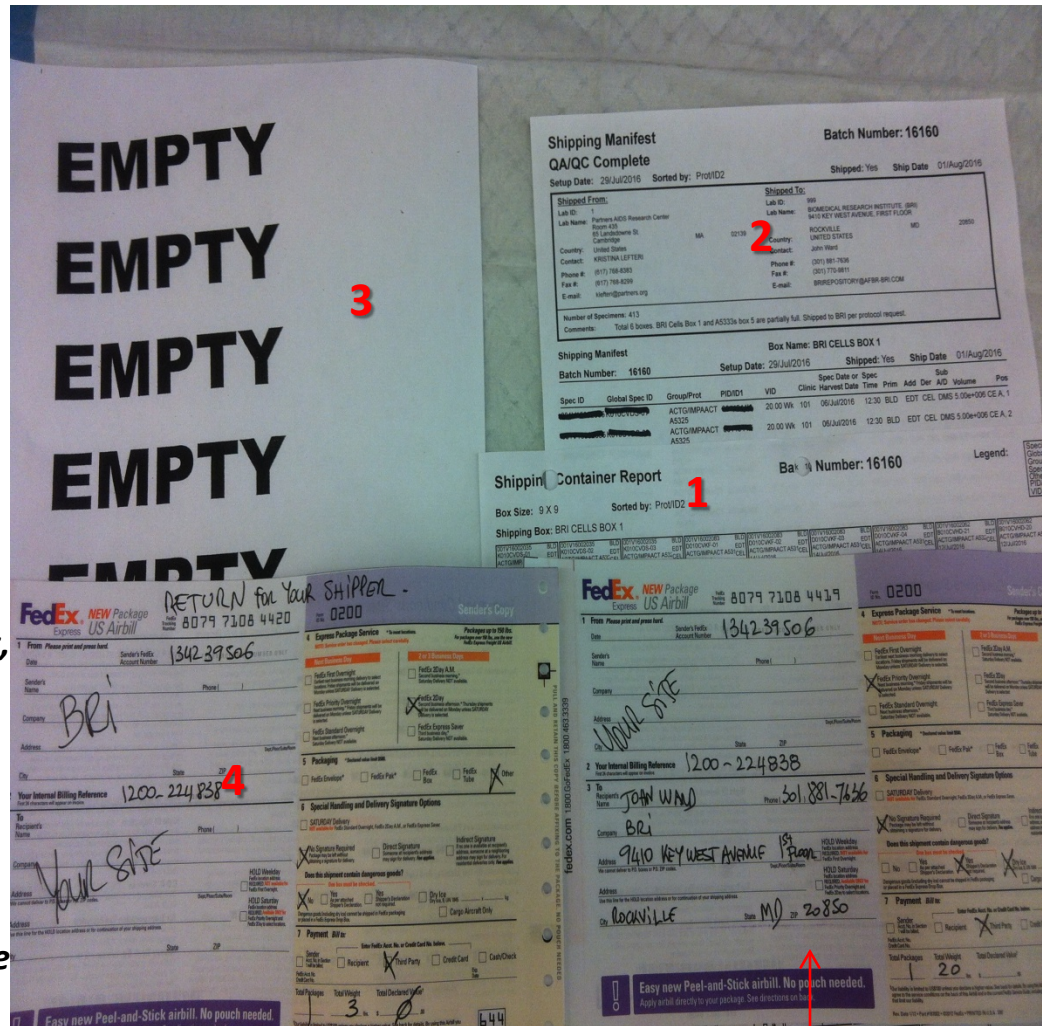
# Before closing the Shipper!

Insert the following 4 documents in a plastic pouch to be taped to the Styrofoam cover:

1. LDMS Shipping Container Report
2. LDMS Shipping Manifest
3. An “Empty” sign for the return of your shipper
4. A return FedEx Air bill with your address

**Note: a CD is no longer mailed with the shipment, please see next slide regarding emailing a digital file**

**Note for Non Network sites only: The FedEx Account number and the Internal Billing Reference for both the shipment to BRI and the return of your shipper shown here can be found in Section 5 of your LPC .**



Also shown here: the Shipping Air bill

# The Final Touches!



Make sure that all labels are in place.

Add relevant shipper and consignee info as indicated on the air bill. Add dry ice weight in kg.

**Notify BRI of your incoming shipment: Email or FAX a completed page 2 of the ACTG/IMPAACT Ambient/Refrigerated/Frozen Shipment Notice form.**

<https://www.hanc.info/labs/labresources/procedures/Pages/actgImpaactLabManual.aspx>



# Shipment Evaluation Documentation

- BRI performs 100% QC for all shipments received.
- BRI will report condition of shipment to both the site lab and the performance evaluation committee.
- **If problem noted, site/labs must respond to BRI within 1 week;**

**Contact the REPRIEVE Lab**

**Committee asap:**

[reprise.labcom@FSTRF.org](mailto:reprise.labcom@FSTRF.org)



**Shipment Evaluation Procedure**

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**Appendix A: ACTG/IMPAACT Shipment Evaluation Form**

ACTG/IMPAACT SHIPMENT EVALUATION FORM  
NOTE: SHIPPING LABS ARE RESPONSIBLE FOR TRACKING ALL PACKAGES  
Shipper: ACTG  IMPAACT  Other  Specify: \_\_\_\_\_

Receiving Lab # \_\_\_\_\_ Shipping Lab # \_\_\_\_\_ CTU # \_\_\_\_\_  
Date Received (dd-mm-yyyy) \_\_\_\_\_ # of Specimens \_\_\_\_\_  
Shipping Lab Name \_\_\_\_\_ Shipping Lab Fax # \_\_\_\_\_  
Shipment Tracking # \_\_\_\_\_ LDMS Batch # \_\_\_\_\_

Was This Shipment Received With Any Problems? (circle/check one)  YES  NO  
If yes, proceed with Form. If no, stop.

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Shipping Problem (please refer to Shipping Problems Reportable to the DMC): This form is intended to provide documentation of problem shipments and their resolution.

Provide Shipping Problem Code and Description of the Problem (completed by recipient):

The shipping lab must respond to the problem shipment within 1 week of receipt. Please FAX or Email all responses/resolutions to: FAX: Email:	By (date):
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Response (completed by the shipping lab and faxed or emailed to the recipient by the date listed above):

Shipping Lab Tech completing the Response: \_\_\_\_\_  
Recipient contact for Response: \_\_\_\_\_

Resolution (completed by the recipient): *All Resolutions must be documented prior to faxing to the DMC.*

WAS THIS SHIPMENT RESOLVED WITHIN 1 WEEK OF RECEIVING THIS FORM? (Completed by recipient):  YES  NO

Comments:

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