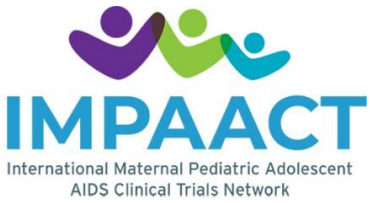


ACTG/IMPAACT LABORATORY STANDARD OPERATING PROCEDURE			
Title:	Shipment Evaluation Procedure		
SOP number:	LTC-SOP-073	Effective:	12May2022
Version:	8.0	Last reviewed:	03Mar2022
Originator:	ACTG/IMPAACT Lab Technologist Committee	Pages:	Page 1 of 11



Shipment Evaluation Procedure

TABLE OF CONTENTS

- 1. PURPOSE 2
- 2. BACKGROUND (IF APPLICABLE)..... 2
- 3. SCOPE..... 2
- 4. DEFINITIONS..... 2
- 5. RESPONSIBILITIES..... 2
- 6. SHIPMENT EVALUATION PROCEDURE 2
- 7. REFERENCES 5
- 8. INQUIRIES..... 5
- 9. NETWORK LAB CENTER SOP APPROVAL 6
- 10. REVISION HISTORY OR RECORD RETIREMENT 7
- 11. APPENDICES 8
- 12. LABORATORY SOP REVIEW 11

ACTG/IMPAACT LABORATORY STANDARD OPERATING PROCEDURE			
Title:	Shipment Evaluation Procedure		
SOP number:	LTC-SOP-073	Effective:	12May2022
Version:	8.0	Last reviewed:	03Mar2022
Originator:	ACTG/IMPAACT Lab Technologist Committee	Pages:	Page 2 of 11

1. PURPOSE

The purpose of this document is to provide guidance for evaluating specimen shipments received by the NIAID Repository, Biomedical Research Institute (BRI).

Note: ACTG/IMPAACT testing laboratories that receive shipments from ACTG or IMPAACT sites may also utilize the Shipment Evaluation Form for internal tracking and reporting to the clinical trial specialist and lab data manager.

2. BACKGROUND

Establishing standards for shipping specimens from the Clinical Research Site (subsequently referred to as the site) strengthens BRI's ability to guarantee the integrity of specimens stored therein and eventually be forwarded for protocol testing. This process actively evaluates and monitors every shipment to BRI and has been shown to dramatically improve overall site performance since its inception in 2011.

3. SCOPE

ACTG/IMPAACT Laboratories who send shipments to BRI that are intended for specimen storage. This SOP is part of the [ACTG/IMPAACT Laboratory Manual](#).

4. DEFINITIONS

- 4.1. BRI – Biomedical Research Institute
- 4.2. NIAID – National Institute of Allergy and Infectious Diseases
- 4.3. DMC – data management center at Frontier Science
- 4.4. LTC – ACTG/IMPAACT Laboratory Technologist Committee
- 4.5. SOP – standard operating procedure
- 4.6. ACTG PEC – the ACTG Performance Evaluation Committee

5. RESPONSIBILITIES

- 5.1. The DAIDS Network Laboratory Principal Investigators (or their designee) have the authority to establish, review and update this process.
- 5.2. Each site laboratory director is responsible for the implementation of this ACTG/IMPAACT Laboratory Manual SOP or laboratory-specific SOP and for ensuring that all appropriate personnel are trained. A laboratory-specific SOP must:
 - 5.2.1. Include, without procedural modification, the portions of the current version of the LTC SOP that are used within the network site-affiliated laboratory;
 - 5.2.2. Reference the current version of the LTC SOP.
- 5.3. All site laboratory technologists are responsible for reading and understanding this SOP prior to shipping specimens to BRI.

6. SHIPMENT EVALUATION PROCEDURE

Staff at BRI will review all materials and specimens received and initiate the Shipment Evaluation Procedure.

ACTG/IMPAACT LABORATORY STANDARD OPERATING PROCEDURE			
Title:	Shipment Evaluation Procedure		
SOP number:	LTC-SOP-073	Effective:	12May2022
Version:	8.0	Last reviewed:	03Mar2022
Originator:	ACTG/IMPAACT Lab Technologist Committee	Pages:	Page 3 of 11

Laboratories will be notified of a problem shipment via the Shipment Evaluation Form (Appendix 1). Laboratories will be allowed to dispute problems and document corrective actions within one week after receiving the shipment evaluation form. The Data Management Center (DMC) tracks all shipments to BRI and determines laboratory shipment performance scores. The results of laboratory's shipping performance (to BRI) are included in monthly ACTG/IMPAACT site evaluation reports. Problem shipments may also be reported to the Repository Advisory Group and appropriate protocol teams.

6.1. Scoring

- 6.1.1. The ACTG/IMPAACT networks have adopted a 90% compliance standard. A laboratory must achieve a score of >90% (fewer than 10% problematic shipments) for all shipments sent to BRI (other shipments may be evaluated using this procedure, but those results are not currently tracked by the DMC).
- 6.1.2. The problem shipment scoring system was designed to avoid unduly penalizing sites for minor errors, yet still compel laboratories to follow the shipping guidelines and quickly resolve problems. The process allows for significant or complete eradication of penalty points based on the timely response from the shipping laboratories. Shipping errors that are more serious or cannot be resolved will be assigned the maximum predefined penalty.

6.2. Evaluation of Shipment

- 6.2.1. Shipments sent to BRI will be monitored for shipment quality. BRI will evaluate each package upon receipt and document the condition of the shipment using the ACTG/IMPAACT Shipment Evaluation Form. Problem shipments will be assessed and scored based on whether or not the problem was resolved.
- 6.2.2. Resolving problems within one week of receiving a Shipment Evaluation Form may reduce or nullify penalties. A response to non-resolvable problems may not reduce penalties. All problems should be reviewed or investigated by the shipping laboratory to prevent the same problems from occurring on future shipments. Failure to respond within one week will incur a penalty.

6.3. Documentation Procedure for Shipments Received by BRI

Documentation of the quality of shipments received by BRI will occur in the following order. BRI will complete the Shipment Evaluation Form and email it to the shipping laboratory:

ACTG/IMPAACT LABORATORY STANDARD OPERATING PROCEDURE			
Title:	Shipment Evaluation Procedure		
SOP number:	LTC-SOP-073	Effective:	12May2022
Version:	8.0	Last reviewed:	03Mar2022
Originator:	ACTG/IMPAACT Lab Technologist Committee	Pages:	Page 4 of 11

- 6.3.1. If the shipment is successful, a completed Shipment Evaluation Form citing no problems will be sent to the shipping laboratory and to the DMC.
- 6.3.2. A completed Shipment Evaluation Form citing any problems will be sent to the shipping laboratory.
 - 6.3.2.1. The shipping laboratory is allowed five working days (excluding holidays) to respond to the Shipment Evaluation Form.
 - 6.3.2.2. The shipping laboratory must complete the Shipment Evaluation form and send the response to BRI by email to dispute or resolve the problem.
 - 6.3.2.2.1. For Error Code 801 (Carrier Issues) and 301 (Packaging Issues) shipping laboratory must email each protocol team a list of the specimens affected by the thawed shipment and copy BRI on the email. Refer to email template in Appendix 3.
 - 6.3.2.2.2. Protocol teams must confirm if the specimens should be stored or destroyed.
 - 6.3.2.3. The response must document how the issues(s) will be/or were resolved.
 - 6.3.2.4. BRI will update specimen condition codes as appropriate. BRI may also apply new labels to specimens, update LDMS data, or add specimen comments according to instructions from the shipping laboratory
- 6.3.3. BRI will send the completed shipment evaluation form, which may or may not include a response from the shipping laboratory to the DMC for scoring (see Appendix 2: Problem Shipment Reference/Scoring Sheet).

6.4. Shipment Scoring

- 6.4.1. Each shipment will be assigned a point score; the minimum and maximum score potentials are zero (0) and four (4) points, respectively.
- 6.4.2. Shipments containing no problems will receive a score of zero (0); shipments containing problems will be assigned a score based on the penalties outlined in the Problem Shipment Reference/Scoring Sheet (Appendix 2).
- 6.4.3. Shipments containing multiple problems will be scored as the sum of the problems but will not exceed the maximum score potential (4 points). The DMS will track penalty scores for the shipments received at BRI. The laboratory's total penalty score will be divided by the maximum shipment score to determine the fraction of the shipments with penalties.
- 6.4.4. The metrics that are reported to the ACTG PEC are the percent of expected shipments shipped to the ACTG repository, the percent of the evaluated specimen shipments with no problems, and the specimen shipments scores for shipments from the last 12 months.
- 6.4.5. The algorithm used to calculate the shipment score is as follows:

$$[100-(100*(\text{total problem penalty} / \{4 * \text{total number of shipments}\}))].$$

ACTG/IMPAACT LABORATORY STANDARD OPERATING PROCEDURE			
Title:	Shipment Evaluation Procedure		
SOP number:	LTC-SOP-073	Effective:	12May2022
Version:	8.0	Last reviewed:	03Mar2022
Originator:	ACTG/IMPAACT Lab Technologist Committee	Pages:	Page 5 of 11

Note: This algorithm looks at the total # of penalty points divided by the maximum # of penalty points based on the number of shipments, multiplies by 100 to achieve a percent (%) of problems, and subtracts from 100% to determine the laboratory's shipment score.

6.4.6. The expected shipping score for a laboratory is >90%.

For example: If a laboratory shipped a total of 16 packages over 12 months, the laboratory maximum shipment score would be 64 points. During this time frame, the DMC documented a total penalty score of 6 points for that laboratory. The shipment score for this laboratory is as follows:

$$[100 - (100 * (6 / \{4 * 16\}))] = [100 - 9.375] = 90.625 (91\%).$$

6.4.7. Processing laboratories should review their DMC monthly report.

6.4.7.1. The report covers all shipments received by BRI within the previous 12 months.

6.4.7.2. Contact the DMC (fstrf.labdiv@fstrf.org) for questions regarding this monthly report.

7. REFERENCES

7.1. ACTG: LTC-SOP-22 ACTG/IMPAACT Network Guidelines for Shipping and Receiving Biological Substance, Category B specimens

<https://www.hanc.info/resources/sops-guidelines-resources/laboratory/actg-impaaact-laboratory-resources.html>

7.2. ACTG: SOP-126 ACTG Performance Measures and Standards

<https://member.mis.s-3.net/cms/fpage/6172/1290>

7.3. ACTG: SOP-144 Shipment of Clinical Specimens to the ACTG Specimen Repository

<https://member.mis.s-3.net/cms/fpage/6172/1290>

7.4. IMPAACT: MOP Section 17, Laboratory Considerations

https://www.impactnetwork.org/sites/default/files/2021-01/FINAL_17_LabConsiderations_V3.0_20JAN2021.pdf

7.5. IMPAACT: MOP Section 18, Network Evaluation


https://www.impactnetwork.org/sites/default/files/2021-01/FINAL_18_Evaluation_V3.0_20JAN2021.pdf

8. INQUIRIES

Contact the ACTG/IMPAACT LTC Leadership at actg.ltcleadership@fstrf.org for questions and comments related these procedures.

ACTG/IMPAACT LABORATORY STANDARD OPERATING PROCEDURE			
Title:	Shipment Evaluation Procedure		
SOP number:	LTC-SOP-073	Effective:	12May2022
Version:	8.0	Last reviewed:	03Mar2022
Originator:	ACTG/IMPAACT Lab Technologist Committee	Pages:	Page 6 of 11

9. NETWORK LAB CENTER SOP APPROVAL

NETWORK	NAME and TITLE	SIGNATURE	Date of Approval (ddmmyyyy)
ACTG/IMPAACT	Grace Aldrovandi, MD ACTG/IMPAACT Network Laboratory Principal Investigator		01Apr2022

ACTG/IMPAACT LABORATORY STANDARD OPERATING PROCEDURE			
Title:	Shipment Evaluation Procedure		
SOP number:	LTC-SOP-073	Effective:	12May2022
Version:	8.0	Last reviewed:	03Mar2022
Originator:	ACTG/IMPAACT Lab Technologist Committee	Pages:	Page 7 of 11

10. REVISION HISTORY OR RECORD RETIREMENT

VERSION #	EFFECTIVE DATE (ddMmmyyyy)	REPLACES	DATE OF REVISION (ddMmmyyyy)	RATIONALE FOR [REVISION/RETIREMENT]
8.0	01Jun2022	7.0	03Mar2022	Addressed barcode scanning errors and added guidance for specimens received thawed at BRI.

ACTG/IMPAACT LABORATORY STANDARD OPERATING PROCEDURE			
Title:	Shipment Evaluation Procedure		
SOP number:	LTC-SOP-073	Effective:	12May2022
Version:	8.0	Last reviewed:	03Mar2022
Originator:	ACTG/IMPAACT Lab Technologist Committee	Pages:	Page 8 of 11

11. APPENDICES

11.1. Appendix 1: 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 # _____ CRS # _____

Date Received (ddMmmmyyyy) _____ # of Specimens _____

Shipping Lab Name _____

Shipment Tracking # _____ LDMS Batch # _____

Was This Shipment Received With Any Problems? (circle/check one) YES NO

If yes, proceed with Form. If no, stop.

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 email all responses/resolutions to: Email:	By (date):
--	-------------------

Response (completed by the shipping lab and 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 emailing to the DMC.*

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

Comments:

ACTG/IMPAACT LABORATORY STANDARD OPERATING PROCEDURE			
Title:	Shipment Evaluation Procedure		
SOP number:	LTC-SOP-073	Effective:	12May2022
Version:	8.0	Last reviewed:	03Mar2022
Originator:	ACTG/IMPAACT Lab Technologist Committee	Pages:	Page 9 of 11

11.2. Appendix 2: Problem Shipment Reference/Scoring Sheet

Section		Problem Description	Problem Code	Is Problem Resolvable?	How to resolve?	Maximum Penalty (Not Resolved)	Minimum Penalty (Resolved)
I. Documentation	A. Missing Paperwork/ Shipping file/ Notification	Shipping Manifest - paper	102	Y	Email missing manifest	4	0
		Shipping Container Report (Boxmap) - paper	103	Y	Email missing shipping container report	4	0
		Shipping File - electronic	105	Y	Email missing shipping file (batch file)	4	0
		Shipment Notification	106	Y	Provide evidence of missing notification	4	0
	B. Paperwork/ Shipping File/ Notification Errors	LDMS Shipping File does not import	201	Y	Correct data, email new shipping file	4	0
		Incomplete/Incorrect shipping notification	207	Y	Email corrected form	4	0
		Shipping File/Shipping Manifest/Specimen mismatch	208	Y	Correct data, email new shipping file	4	0
	Other manifest problems, e.g., illegible	209	Y	Email corrected manifest	4	0	
II. Packaging Issues	A. Shipping Containers	Insufficient dry ice - package received on time, but thawed	301	N	Cannot resolve, notify protocol teams	4	4
		Improper packaging used	302	N	Cannot resolve	4	4
		Improper labeling; sent to incorrect lab; pass-thru not labeled	303	N	Cannot resolve	4	4
		Unacceptable coolant, e.g., CEL >5 weeks shipped on dry ice	304	N	Cannot resolve	4	4
	B. Container/ Cryovial	Incorrect/mislabeled container, e.g., plastic box	402	N	Cannot resolve	1	1
		Cracked or bulging cryovial(s)	403	N	Cannot resolve	1	1
III. Specimen/ACTG-IMPAACT Issues	A. Organizational Problems	Multiple networks or specimen types (e.g., CEL+SER) mixed in box	501	N	Cannot resolve	1	1
		Vials out of order/mixed protocols not separated by a space	502	N	Cannot resolve	1	1
		Partial boxes lack explanation/comments missing on manifest	504	Y	Provide explanation	1	0
	B. Labeling/ Derivative Problems	Label/manifest mismatch, e.g., date discrepancy	601	Y	Correct data	4	0
		Incorrect specimen type	602	Y	Correct data	4	0
		Identifier mismatch/missing or incorrect specimen	604	Y	Correct data	4	0
		Improper use of identifiers, e.g., participant's names	605	N	Cannot resolve	4	4
		Other labeling problems/missing information	606	Y	Correct data/ship corrected label(s) if needed	4	0
		No LDMS barcode (without explanation), >10% labels unscannable	608	Y	Provide explanation	1	0
	C. Miscellaneous Problems	Shipment sent after deadline or outside recipient schedule	701	N	Cannot resolve	2	2
		Contaminated specimen vials	702	N	Cannot resolve	4	4
>10% errors in a shipment/box (exclude label scannability)		703	N	Cannot resolve	4	4	
IV. Carrier Issues	Shipment delayed by carrier - package thawed	801	Y	Notify protocol teams of affected specimens	4	0	
V. Other	Penalty/resolvability to be determined on an individual basis	901	Y or N	Will need to determine on an individual basis	4	0	
<p>Note: All errors in a shipment must be resolved for the minimum penalty to be assessed. Scoring is determined for each shipment, not for each penalty. The shipment score will reflect the maximum penalty associated with the worst infringement. The maximum shipment score is 4 points, the minimum shipment score is 0 points.</p>							

ACTG/IMPAACT LABORATORY STANDARD OPERATING PROCEDURE			
Title:	Shipment Evaluation Procedure		
SOP number:	LTC-SOP-073	Effective:	12May2022
Version:	8.0	Last reviewed:	03Mar2022
Originator:	ACTG/IMPAACT Lab Technologist Committee	Pages:	Page 10 of 11

11.3. Appendix 3: Email Template for Notifying Protocol Team of Thawed Specimens (Error Codes 801 and 301)

To: ACTG Protocol Team
CC: BRI Repository
Subject: Notification of Specimens Received Thawed at BRI (<i>insert LDMS shipment #</i>)
Attachments: Shipping Manifest or Shipping Container Report
<p>Dear Protocol Team,</p> <p>Attached is a list of specimens that were received at BRI due to (<i>insert reason</i>). Please confirm if BRI should store or destroy these specimens. Based on this decision the condition code in LDMS will be changed to TWD (thawed) or DST (destroyed) as appropriate.</p>

