


## Shipment Evaluation Procedure

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## 1 Purpose

The purpose of this document is to provide guidance for evaluating specimen shipments received by the ACTG/IMPAACT Repository (BRI, subsequently referred to as the Repository). This information may also be used by other laboratories (e.g. testing laboratories).

## 2 Scope

The Repository and ACTG/IMPAACT Laboratories sending and/or receiving shipments for specimen storage or testing. This SOP is part of the ACTG/IMPAACT Laboratory Manual : (<https://www.hanc.info/labs/labresources/procedures/Pages/actgImpaactLabManual.aspx>).

## 3 Background

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

## 4 Authority and Responsibility

- 4.1 The Network Laboratory Directors (or his/her designee) have the authority to establish, review and update this procedure.
  - 4.1.1 Include, without procedural modification, the portions of the current version of the LTC SOP that are used within the network site-affiliated laboratory
  - 4.1.2 Reference the current version of the LTC SOP
- 4.2 The 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:
  - 4.2.1 Include, without procedural modification, the portions of the current version of the LTC SOP that are used within the network site-affiliated laboratory
  - 4.2.2 Reference the current version of the LTC SOP
- 4.3 All laboratory technologists are responsible for reading and understanding this SOP prior to performing the procedures described.

## 5 Forms

- 5.1 Appendix A: Shipment Evaluation Form
- 5.2 Appendix B: Problem Shipment Reference Sheet

## 5.3 Appendix C: Problem shipment Scoring Table

## 6 Procedure Overview

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

Laboratories will be notified of a problem shipment via the Shipment Evaluation Form (Appendix A). Laboratories will be allowed to dispute problems and document corrective actions to the receiving laboratory via the response section. The Data Management Center (DMC) currently tracks all shipments to the Repository and determines laboratory shipment performance scores for these shipments. The results of each laboratory's shipping performance (to the Repository) are included in monthly ACTG site evaluation reports. Problem shipments may also be reported to the Repository Advisory Group.

ACTG/IMPAACT testing laboratories that receive shipments from ACTG or IMPAACT sites may also utilize this process. At this time, shipments to laboratories are not tracked by the DMC. Problem shipments may be reported to the appropriate protocol team.

## 7 Scoring

- 7.1 A 90% standard was adopted by the ACTG/IMPAACT networks, and has been implemented in this procedure. A laboratory must achieve a score of >90% (fewer than 10% problematic shipments) for all shipments sent to the Repository (other shipments may be evaluated using this procedure, but those results may not be tracked by the DMC).
- 7.2 The problem shipment scoring system was designed to not unduly penalize sites for minor errors, yet still compel laboratories to follow the shipping guidelines and quickly resolve problems, by allowing for significant or complete eradication of penalty points, based on the timely response of the shipping laboratories. Since some shipping errors are more serious in nature, some problems cannot be resolved and will be assigned the maximum predefined penalty.

## 8 Evaluation of Shipment

- 8.1 Shipments sent to the Repository will be monitored for shipment quality. The Repository 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. Some issues are resolvable, while others cannot be resolved (see Appendices B and C for additional information).

- 8.2 Prompt response (within one week of receipt of a Problem Shipment FAX/EMAIL Form) to resolve problems may reduce or nullify penalties. Non-resolvable problems may not reduce penalties, but should be reviewed by the shipping laboratory to prevent the same problems from occurring on future shipments.

## **9 Documentation Procedure for Shipments received by the Repository**

Documentation of the quality of shipments received by the Repository will occur in the following order. The Repository will complete the Shipment Evaluation form and FAX or email it to the shipping laboratory upon receipt of a package:

- 9.1 If the shipment is successful, a completed form citing no problems will be sent to the shipping laboratory and to the DMC.

- 9.2 If a problem is noted, then a completed form citing the problems will be sent to the shipping laboratory.

9.2.1 The shipping laboratory will be allowed one (1) week (five site working days ≈ one week) to respond to the problem.

9.2.2 The shipping laboratory must send a response to the Repository by FAX or Email (to dispute or resolve the problem).

9.2.2.1 The response must document how the issue(s) will be/were resolved; and the date the response was sent.

- 9.3 After one (1) week, the Repository will FAX or email the completed problem shipment form, which may or may not include a response from the shipping laboratory to the DMC for scoring (see scoring table).

## **10 Shipment Scoring**

- 10.1 Each shipment will be assigned a point score; the minimum and maximum score potentials are zero (0) and four (4) points, respectively.
- 10.2 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 scoring table (see Appendix C).
- 10.3 Shipments containing multiple problems will be scored as the sum of the problems, but will not exceed the maximum score potential (4 points). The DMC will track penalty scores for

shipments received at the Repository. The laboratory's total penalty score will be divided by the maximum shipment score to determine the fraction of shipments with penalties.

- 10.4 The metrics that are reported to the ACTG Performance Evaluation Committee (PEC) are the percent of expected specimens shipped to the ACTG Repository, the percent of evaluated specimen shipments with no problems, and the specimen shipment scores for shipments from the last 12 months. Shipping metrics for IMPAACT specimens will be reported to the Leadership Operation Center.

- 10.5 The algorithm used to calculate the shipment score is as follows:

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

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/sites shipment score.

- 10.6 The shipping score for a laboratory is expected to be >90%.

For example: If a laboratory shipped a total of 16 packages over 12 months, the laboratory's 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:

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

## 11 References

- 11.1 ACTG: SOP-126 ACTG Performance Measures and Standards <https://actgnetwork.org/node/430>
- 11.2 ACTG: SOP-144 Shipment of Clinical Specimens to the ACTG Specimen Repository at <https://actgnetwork.org/node/430>
- 11.3 IMPAACT: Specimen Storage Policy at <http://impaactnetwork.org/about-us/LabCenter/SpecRepository.htm>

### 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.**

**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):**

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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):**

**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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## Appendix B: Problem Shipment Reference Sheet for Recipient/ Data Center Use

### Shipping Problems Reportable to the DMC

#### I. Documentation Problems:

##### A. Missing Paperwork/Shipping File

- ☐ CRF-protocol specific, for testing labs only (code 101)
- ☐ Manifest –paper (code 102)
- ☐ Boxmap-paper (code 103)
- ☐ Shipping File-electronic (code 105)
- ☐ FAX or e-mail notification missing (code 106)

#### Resolved?

- |                              |                             |
|------------------------------|-----------------------------|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |

##### B. Paperwork/Shipping File Errors

- ☐ File doesn't work, FAX/Email contains incorrect information (code 201)
- ☐ Incomplete shipping notification or missing files (code 207)
- ☐ Shipping File/Manifest/Specimen mismatch (code 208)
- ☐ Other manifest problems, e.g. not legible (code 209)

- |                              |                             |
|------------------------------|-----------------------------|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |

#### II. Packaging Issues

##### A. Shipping containers

- ☐ Insufficient dry ice- package received on time, but thawed (code 301)
- ☐ Improper packaging used (code 302)
- ☐ Improper labeling (code 303)
- ☐ Unacceptable container/packaging, e.g. CEL shipped on Dry Ice (code 304)

Not resolvable- (see scoring table)  
 Not resolvable- (see scoring table)  
 Not resolvable- (see scoring table)  
 Not resolvable- (see scoring table)

##### B. Specimen/Container Problems

- ☐ Wrong/misabeled container, e.g. no plastic freezer boxes (code 402)

Not resolvable- (see scoring table)

#### III. Specimen/ACTG-IMPAACT Issues

##### A. Organizational problems

- ☐ Boxes mixed ACTG/IMPAACT/Other (code 501)
- ☐ Vials out of order in box / CEL not in separate box (code 502)
- ☐ Partial boxes lack explanation (code 504)

Not resolvable- (see scoring table)  
 Not resolvable- (see scoring table)  
☐ Yes ☐ No

##### B. Labeling/Derivative problems

- ☐ Label/Manifest mismatch, e.g. date discrepancy (code 601)
- ☐ Wrong specimen type (code 602)
- ☐ Identifier mismatch/NO or WRONG specimen sent (code 604)
- ☐ Improper use of identifiers, e.g. participant's names (code 605)
- ☐ Other labeling problems/missing codes (code 606)
- ☐ No LDMS barcode label on tube(s), unless appropriate (code 608)

<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Yes	<input type="checkbox"/> No
Not resolvable- (see scoring table)	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Yes	<input type="checkbox"/> No

##### C. Miscellaneous problems

- ☐ Shipment sent after deadline (code 701)
- ☐ Sent against recipient's schedule (code 702)
- ☐ >10% errors in a given shipment/box (code 703)

Not resolvable- (see scoring table)  
 Not resolvable- (see scoring table)  
 Not resolvable- (see scoring table)

#### IV. Carrier Issues

- ☐ Shipment Delayed by carrier- package thawed (code 801)

Not resolvable- (see scoring table)

#### V. Other: (code 901)

☐ Yes ☐ No



### Appendix C: Problem Shipment Scoring Table

Problem ID	Resolvable?	How to resolve?	Maximum Penalty (Not Resolved)	Minimum Penalty (Resolved)
Missing Paperwork/File (section I.A)	Y	Submit missing paperwork- in the case of missing fax or email, must provide proof of missing communication	4	0
Paperwork/File Errors (section I.B)	Y	Correct incorrect data.	4	0
<i>Shipping containers (section II.A)</i>	N	Cannot resolve- but must send new samples if applicable (i.e. for testing labs).	4	2 for new samples w/in 1 week
<i>Specimen Problems (section II.B)</i>	N	Cannot resolve	1	1
Organizational problems (section III.A)	N	Cannot resolve except for partial box explanation (i.e. must be valid reason)	1	1 (code 504 - 0 points if resolved)
Labeling/Derivative problems (section III.B)	Y	Correct incomplete data. In case of inappropriate use of identifiers, there is no resolution and maximum penalty is applied.	4	0
LDMS Barcode Label problems (section III.B)	Y	If a required LDMS barcode label is missing, the resolution is determined by the recipient.	1	1
<b>Miscellaneous problems (section III.C)</b>	N	Cannot resolve	2 (Exception: code 703 = 4 points)	2 (Exception: code 703 = 4 points)
<i>Carrier Issues (section IV.)</i>	N	Cannot resolve error, but must send new samples to testing lab, if possible.	1	0
<i>OTHER (section V.)</i>	?	Will need to determine on an individual basis	4	0

**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.