



REFERENCE LABORATORY & REPOSITORY

GLOBALTRACESM SYSTEM USER'S GUIDE

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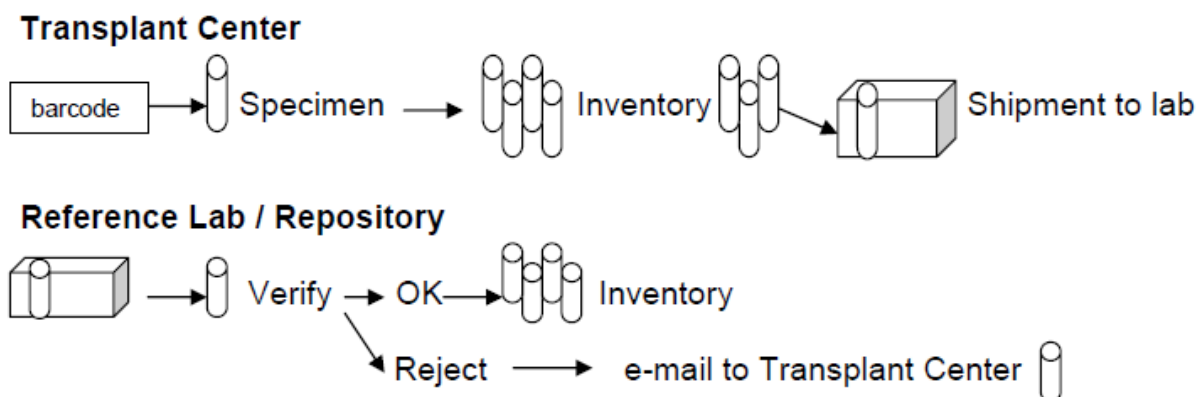
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1.0 OVERVIEW OF THE GLOBALTRACESM SYSTEM

Tracking specimens from the time of collection at a Transplant Center to the arrival at a Reference Laboratory or Repository is essential in a multi-center environment. The GlobalTraceSM System (GTS) is designed to protect a patient's confidentiality while tracking individual specimens at any location within the network of participating institutions. As with all utilities in AdvantageEDC, access to GTS is password protected.

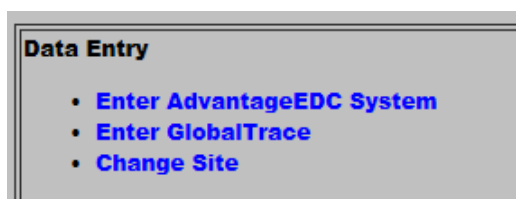
The GTS can be accessed only by the Transplant Centers where the specimens are collected and at the Reference Laboratories or Repositories where the specimens may be processed, stored, and analyzed.

Transplant Centers and Reference Laboratories/Repositories authorized to use GTS have the ability to document information regarding collection of specimens, inventory of specimens, and shipment of specimens in the GTS. Each specimen is identified with a unique barcode number. The Transplant Center creates an electronic shipment corresponding to an actual physical shipment by selecting the desired specimens from its electronic inventory. The Transplant Center sends the electronic shipment to the Reference Lab or the Repository in the GTS. The Reference Lab or Repository compares the electronic shipment with the physical shipment once it arrives. The inventory record for each specimen is updated automatically at both the Transplant Center and the Reference Lab or Repository to reflect the shipment. If there is a problem with the shipment, the GTS shipment documentation is rejected electronically and returned to the originating Transplant Center. The originating Transplant Center corrects the shipment and returns it electronically to the receiving lab. The electronic inventory of specimens should always be an accurate reflection of the status of the physical specimens.



2.0 ACCESS TO THE GLOBALTRACE SYSTEM

Access to the Global Trace System is available in the Data Entry section of the AdvantageEDC Main Menu. Choose the **Enter GlobalTrace** link located under Data Entry to open the GTS main menu.



The GTS menu and the functionality of selected menu items within the menu are the same for Transplant Centers and the Reference Laboratory/Repository, except that the Reference Laboratory and Repository cannot “Add” new specimens.

Specimens	Shipments
• Update • Update Off Site • Make Not Available • Undo Not Available • Aliquot	• Create a New Shipment • View All Shipments
Reports	Utilities
• Local Inventory • Associated Items	• QC Scan

To return to the AdvantageEDC Main Menu, click **Main Menu** in the top left corner, or **Logout** to exit the system. Session Preferences is a utility for the AdvantageEDC System and does not function in the GlobalTrace System.

[Main Menu](#)

▪ [Extend Session](#) ▪ [Session Preferences](#) ▪ [Logout](#)

Extend Session will extend the time remaining to 20 minutes. A timer is displayed in the bottom corner of the browser that counts down from 20 minutes, resetting each time the user performs an action that accesses the server.



If no action is taken in 20 minutes, the user is logged out of the system automatically. Two warnings will alert the user prior to this occurring.

3.0 GLOBALTRACE SHIPMENT NOTIFICATION EMAIL

When a Transplant Center enters/send a shipment of samples into Global Trace, a notification email is generated and sent to the Reference Laboratory/Repository set to receive the physical shipment the following day. This notification allows the Reference Laboratory/Repository to know in advance the samples that will be arriving at their lab. The email will come from noreply@emmes.com.

SUBJECT LINE: GT:0000012345 From Transplant Center X to Reference Lab Y

The body of the email will include the following: To: (Reference lab contacts and address), From: (Transplant Center contacts and address) as well as the Date Shipped, Carrier, Package Tracking number, and GlobalTrace shipment number.

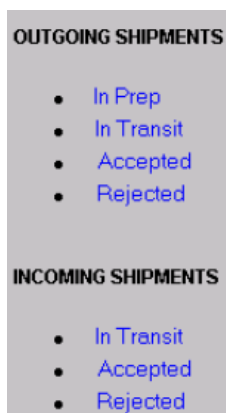
The attachment on the email is an electronic manifest containing sample information the Reference Laboratory/Repository will need for processing/testing. An example manifest:

Specimen Listing for Shipment # 0000012345										
Patient	Protocol	Visit	Specimen #	Specimen Type	Purpose	Amount	Unit	Date Collected	Time Collected	Center Name
009999	1401	0000	140100009999	Whole Blood	Research Sample - Serum	10.0	mL	05/11/2016	1012	Transplant Center X
009999	1401	0000	140100009998	Whole Blood	Research Sample - PBMC	6.0	mL	05/11/2016	1012	Transplant Center X
009999	1401	0000	140100009997	Whole Blood	Research Sample - PBMC	6.0	mL	05/11/2016	1012	Transplant Center X
009999	1401	0000	140100009996	Whole Blood	Research Sample - PBMC	6.0	mL	05/11/2016	1012	Transplant Center X
009999	1401	0000	140100009995	Whole Blood	Research Sample - PBMC	6.0	mL	05/11/2016	1012	Transplant Center X
009999	1401	0000	140100009994	Whole Blood	Research Sample - Plasma	6.0	mL	05/11/2016	1012	Transplant Center X

4.0 VIEWING SHIPMENTS IN GLOBALTRACE



Selecting **View All Shipments** from the Shipments menu displays a summary of the status of all shipments and allows access to the details of shipments:



A Reference Lab or Repository may select from Outgoing or Incoming Shipments as appropriate, but when dealing with samples being shipped to the Reference Lab or Repository, they will mainly select from the Incoming Shipments section. **In Transit** shipments are shipments that have not yet arrived or have not yet been evaluated by the Reference Lab/Repository. **Accepted** shipments are past shipments received at the Reference Lab/Repository that were accepted upon receipt because everything in the physical shipment matched the electronic data entered into GlobalTrace by the Transplant Center. **Rejected** shipments are received shipments that were rejected by the Reference Lab/Repository because the information entered into GlobalTrace by the Transplant Center did not match what was received in the physical shipment. Rejecting a shipment in Global Trace allows the Transplant

Center to make the necessary corrections to the electronic data and resend so that it matches the physical shipment that was received. Click on **In Transit** to view the expected packages.

Shipment Summary																			
OUTGOING SHIPMENTS		OUTGOING SHIPMENTS: In Preparation																	
- In Prep - In Transit - Accepted - Rejected		Display results in sets of Rows / Page: 10 Display Click on a column header to sort the grid																	
INCOMING SHIPMENTS		<table border="1"> <thead> <tr> <th>Shipment ID</th><th>Date Created</th><th>Destination</th><th>Tracking #</th><th>Carrier</th></tr> </thead> <tbody> <tr> <td>0000000040</td><td>05/06/2004</td><td>Emory University Laboratory</td><td>98769846</td><td>Federal Express Priority Overnight</td></tr> <tr> <td>0000000041</td><td>05/06/2004</td><td>NHLBI Repository</td><td></td><td>Federal Express Priority Overnight</td></tr> </tbody> </table>			Shipment ID	Date Created	Destination	Tracking #	Carrier	0000000040	05/06/2004	Emory University Laboratory	98769846	Federal Express Priority Overnight	0000000041	05/06/2004	NHLBI Repository		Federal Express Priority Overnight
Shipment ID	Date Created	Destination	Tracking #	Carrier															
0000000040	05/06/2004	Emory University Laboratory	98769846	Federal Express Priority Overnight															
0000000041	05/06/2004	NHLBI Repository		Federal Express Priority Overnight															
- In Transit - Accepted - Rejected		Page 1 of 1 [1] 2 records found Download displayed results to Excel																	

The listing of shipments may be downloaded to Excel by clicking on the option below the listing.

5.0 RECEIVING THE PHYSICAL SHIPMENT

The physical shipment received at the Reference Lab/Repository should contain a printed copy of the GlobalTrace electronic manifest. The printed manifest is another representation of the data sent electronically in the GlobalTrace shipment notification email. The Reference Laboratory or Repository is responsible for certifying that the physical specimens received from a Transplant Center match the electronic shipment in the GlobalTrace System. Please verify the following:

- Specimen Barcode IDs entered in GTS match the labels physically applied to the specimens in the shipment.
- Correct tubes types were used for each individual specimen
- There are no extra tubes in the shipment not entered into GlobalTrace
- There are no extra tubes entered into GlobalTrace that were not received in the physical shipment.
- Sample arrives in a condition that is testable.

You should receive an electronic notification/GlobalTrace manifest for every shipment of samples delivered to your lab. If you do not, please contact BMT CTN DCC staff.

6.0 ACCEPTING OR REJECTING A SHIPMENT

Accepting a Shipment

When it has been determined that the physical shipment matches the data entered into Global Trace, the shipment can then be accepted in GlobalTrace. Under the list of In Transit shipments, click on the **Shipment ID** (blue) corresponding to the shipment you would like to accept in Global Trace.

Shipment ID	Date Created	Destination
0000000040	05/06/2004	Emory University Laboratory
0000000041	05/06/2004	NHLBI Repository

Main Menu > GlobalTrace > Shipment Summary • Extend Session • Session Preferences • Log

Shipment Receive

SHIPMENT ID: 0000022243	DATE SHIPPED: 05/11/2016
SHIPPED FROM: Mount Sinai Medical Center	CREATED BY: Sonia Rai
CARRIER: Federal Express	TRACKING #: 804355268254 Check Status
SHIPMENT RECEIVED: 05/12/2016 (mm/dd/yyyy)	SHIPMENT REJECTION EXPLANATION:
Comment: N/A	

[Accept All Items](#) [Reject All Items](#) [Accept Shipment](#) [Reject Shipment](#) [View Shipment Manifest](#)

Click on a column header to sort the grid

Specimen	Patient	PROTOCOL	Visit Number	Specimen Type	Action	Rejection Reason	Comments
120200087121	008390	1202	0056	Whole blood	Not Evaluated ▼		
120200087122	008390	1202	0056	Whole blood	Not Evaluated ▼		

The Shipment Receive screen will display the details of the shipment, a field to enter the date the shipment was received and a field to explain a rejection, if necessary. The tool bar directly below these fields includes the following options:

[Accept All Items](#) [Reject All Items](#) [Accept Shipment](#) [Reject Shipment](#) [View Shipment Manifest](#)

Accept All Items: Clicking on **Accept All Items** indicates that all specimens are acceptable. Particularly for large shipments, this option may be preferred over designating each individual item as accepted. Once all are accepted, the user may then select one or a few items to change to rejected if necessary.

Reject All Items: Clicking **Reject All Items** indicates that all specimens in the shipment are rejected.

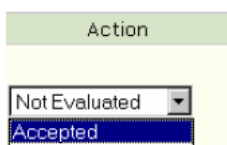
Accept Shipment: Clicking **Accept Shipment** accepts the entire shipment in GlobalTrace and transfers all specimens to the receiving lab's inventory.

Reject Shipment: Will be discussed further in the "Rejecting a Shipment" section of this guide.

View Shipment Manifest: The shipment manifest is available for viewing with the option to print and/or download.

Below the tool bar, each individual specimen in the shipment is listed. The order of the display may be sorted by clicking on any of the column headers. The details of a particular specimen may be viewed by clicking on the **Specimen number** (blue). To return to the shipment after viewing a particular specimen in GlobalTrace, click on **Shipment Receive** in the tool bar.

If it has been confirmed that the electronic and physical shipment match, click the **Accept All Items** button. This action changes all specimens from “Not Evaluated” to “Accepted”. Alternatively, you can change each individual specimen to “Accepted”:



The image shows a screenshot of a web interface. At the top, there is a green header bar with the word 'Action' in white. Below this, there is a yellow rectangular area containing a dropdown menu. The dropdown menu is currently open, showing two options: 'Not Evaluated' (in a grey box) and 'Accepted' (in a blue box with white text). The 'Accepted' option is highlighted.

Enter the Date Received in the box provided. Click on Accept Shipment to transfer all specimens in the electronic shipment to the Reference Lab/Repository inventory. The shipment appears as accepted to the sending Transplant Center and the specimens are removed from their GlobalTrace inventory. To be able to accept a shipment, all specimens must be designated as either “Accepted” or “Ruined in Transit”. A specimen indicated as “Ruined in Transit” is automatically made Not Available in the GlobalTrace inventory.

Rejecting a Shipment

If the Reference Lab or Repository rejects a shipment, the physical specimens do not need to be shipped back to the originating Transplant Center. The documentation can be corrected and resubmitted by the Transplant Center through the GlobalTrace System.

If the shipment is rejected, the Transplant Center automatically receives an email indicating that the shipment has been rejected. This email is generated by GTS and is distributed to designated recipients. The Transplant Center must correct the electronic shipment and re-send to the Reference Lab/Repository. Once the electronic inventory matches the physical specimens sent, the Reference Lab or Repository accepts the shipment.

When it has been determined that the physical shipment DOES NOT match the data entered into Global Trace, the shipment can be Rejected in GlobalTrace. Under the list of In Transit shipments, click on the **Shipment ID** (blue) corresponding to the shipment you would like to reject in Global Trace.

<u>Shipment ID</u>	<u>Date Created</u>	<u>Destination</u>
0000000040	05/06/2004	Emory University Laboratory
0000000041	05/06/2004	NHLBI Repository

Main Menu > GlobalTrace > Shipment Summary • Extend Session • Session Preferences • Log

Shipment Receive

SHIPMENT ID: 0000022243		DATE SHIPPED: 05/11/2016	
SHIPPED FROM: Mount Sinai Medical Center		CREATED BY: Sonia Rai	
CARRIER: Federal Express		TRACKING #: 804355268254 Check Status	
SHIPMENT RECEIVED: 05/12/2016 (mm/dd/yyyy)		SHIPMENT REJECTION EXPLANATION:	
Comment: N/A			

[Accept All Items](#) [Reject All Items](#) [Accept Shipment](#) [Reject Shipment](#) [View Shipment Manifest](#)

Click on a column header to sort the grid

Specimen	Patient	PROTOCOL	Visit Number	Specimen Type	Action	Rejection Reason	Comments
120200087121	008390	1202	0056	Whole blood	Not Evaluated ▼		
120200087122	008390	1202	0056	Whole blood	Not Evaluated ▼		

There are two locations in the detailed shipment window for describing the discrepancy. The first is the Shipment Rejection Explanation. This field is used to explain the problem to the Transplant Center as in the example below.

SHIPMENT REJECTION EXPLANATION:

Alternatively, in the listing for each specimen, a field for Specimen Rejection Reason is provided. In addition, there is a place for Comments next to each Specimen Rejection Reason field. These fields are displayed in the Transplant Center's shipment display in GTS after the shipment is rejected.

Laboratory users should select a reason for the rejection of a particular specimen from the Rejection Reason field.

- Missing: Use when specimen is missing from the physical shipment.
- Wrong Type: Use when specimen received is the wrong type of specimen (i.e. whole blood received when assay performed on serum)
- Insufficient Volume: Use when specimen contains insufficient volume to run the designated assay and thus cannot be used.

Rejection Reason

Missing
Wrong Type
Insufficient Volume

Laboratory users should provide additional detail, when appropriate, in the Comments field.

Rejecting a shipment does not require that all specimens be rejected. If the receiving Reference Lab or Repository accepts all acceptable specimens and rejects only those specimens that require rejection, the resolution of a rejected shipment will be much easier for

the Transplant Center to identify and resolve discrepant items. It also makes it easier for the Reference Lab or Repository to recognize if the necessary modifications have been made and the shipment is now acceptable. This method also transfers all acceptable specimens to the Reference Lab or Repository inventory in a timely manner.

In the example below, a shipment of four specimens contains a missing specimen. Accept all of the specimens, then go back and indicate that the missing specimen is rejected by selecting "Rejected" for that specimen.

* Specimen	Patient	Visit Number	Specimen Type	Action
* AB030001090	IUB_NA-000395	0090	Plasma (cryovial)	Rejected
AB030001091	IUB_NA-000395	0090	Plasma (cryovial)	Accepted
AB030001092	IUB_NA-000395	0090	Plasma (cryovial)	Accepted
AB030001093	IUB_NA-000395	0090	Plasma (cryovial)	Accepted

Then, enter the rejection reason.

* Specimen	Patient	Visit Number	Specimen Type	Action	Rejection Reason
* AB030001090	IUB_NA-000395	0090	Plasma (cryovial)	Rejected	Missing
AB030001091	IUB_NA-000395	0090	Plasma (cryovial)	Accepted	

When the status of all specimens is marked correctly, click **Reject Shipment** to complete the process. The reason for rejecting the shipment must be provided in either the Shipment Rejection Explanation field or the Specimen Rejection Reason or the shipment cannot be rejected.

Accepting a Previously Rejected Shipment

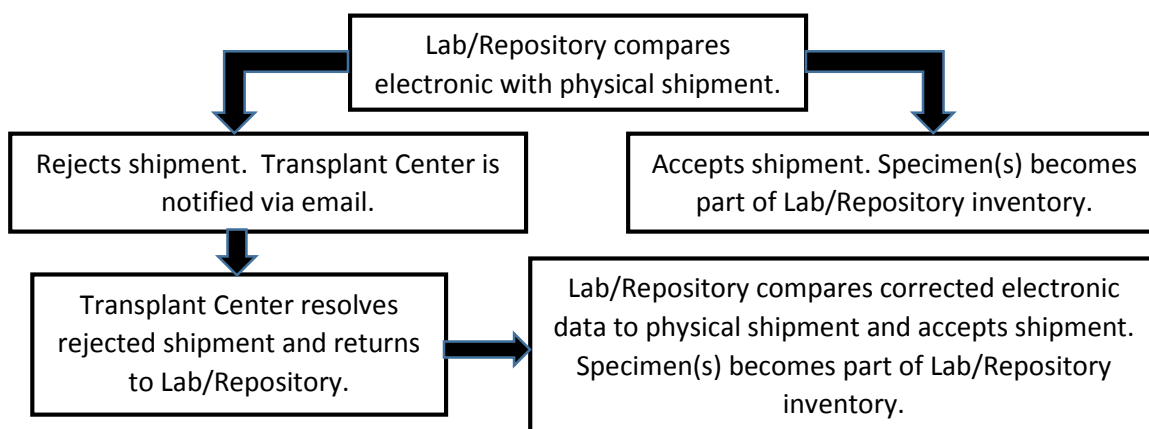
The originating Transplant Center makes the necessary adjustments to the electronic shipment and re-sends the shipment electronically to the Reference Lab or Repository. The Reference Lab or Repository may then accept the shipment, after confirming that corrections made by the Transplant Center result in a comparison of the electronic and physical shipments without discrepancies. Using the example from above, the shipment was rejected because a specimen

was missing from the physical shipment. The site resolved the discrepancy by removing the specimen from the electronic shipment and resending the shipment.

Specimen	Patient	Visit Number	Specimen Type	Action
AB030001090	IUB_NA-000395	0090	Plasma (cryovial)	REMOVED
AB030001091	IUB_NA-000395	0090	Plasma (cryovial)	ACCEPTED
AB030001092	IUB_NA-000395	0090	Plasma (cryovial)	ACCEPTED
AB030001093	IUB_NA-000395	0090	Plasma (cryovial)	ACCEPTED

The electronic shipment now agrees with the physical shipment and the receiving lab should enter the date and accept the shipment.

7.0 PROCESS FLOWCHART FOR RECEIVING LAB

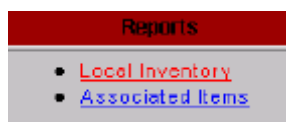


8.0 REPORTS

The **Reports** menu of GTS allows sites to view all or a selected set of specimens in their inventory. The **Local Inventory** allows the user to see whether a specimen is available or not available. The **Associated Specimen** report allows the user to view all specimens associated with a particular subject.

A local inventory is maintained for each site/lab using GlobalTrace. The Reports section allows convenient access to the entire inventory and provides a filtering tool to allow display of specimens with a particular attribute, such as a specimen of one specified type or collected on a particular date. The specimen attributes can also be accessed from the report.

From the GTS Menu, select **Local Inventory** from the Reports menu to display the inventory report.



The local inventory screen is displayed. **A protocol must be selected prior to the display of any specimens.** To display all items in your local inventory for the selected protocol, the fields in the second box may all be left blank and the user need only click **Display**.

The specimens are displayed below the filtering box. The details for each specimen are available by clicking on the specimen number.

Specimen	Specimen Type	Purpose	Collection Date	Arrival Date	Status	Patient	Visit	Barcode	Location & Box Info
AB030001002	blood (vacutainer)	FACS Analysis	05/04/2004		Available	555555-000466	0028		Refrigerator B, Box 102
AB030001003	blood (vacutainer)	FACS Analysis	05/04/2004		Available	555555-000466	0028		Refrigerator B, Box 102
AB030001010	serum (cryovial)	Immunoglobulin and Antibody Titer Serum	04/20/2004		Available	IUB_NA-000171	-008		Freezer #2, Box A101
AB030001011	serum (cryovial)	Immunoglobulin and Antibody Titer Serum	04/20/2004		Available	IUB_NA-000171	-008		Freezer #2, Box A101

Additional specimens can be viewed by using the navigation options at the bottom of the window. The total number of specimens meeting the defined parameters (or all specimens if no parameters are defined) is displayed below the window.

The number of specimens to be displayed on the screen can be defined prior to clicking on **Display**.

9.0 GLOBALTRACE DEFINITIONS

Specimen: The specimen barcode number. Clicking this blue number takes the user to the Specimen page for the specimen

Specimen Type: The attributes of the specimen, i.e. whole blood, bone marrow aspirate, buccal swab, etc.

Purpose: The purpose of the specimen, i.e. Undefined Future Research (serum), Future Research (plasma), etc.

Collection Date: The date the specimen was collected.

Arrival Date: This field is blank for specimens that are in the inventory of the Transplant Center that collected them. After a specimen has been shipped to and received by the Reference Lab or Repository, this field is populated with the date it arrived at the Reference Lab or Repository.

Status: The current status of a specimen. Specimens may be made part of shipment, available, not available, or sent.

- **In Prep:** A shipment has been created and this specimen is included. The shipment has not yet been sent.
- **Available:** The specimen has been added to the local inventory and is available for modification, shipment or testing.
- **Not available:** The specimen has been made not available and cannot be shipped or used.
- **Sent:** The specimen has been shipped to the Reference Lab or Repository and is no longer in the local inventory at the Transplant Center. The Reference Lab or Repository has not received the specimen at this point. Once received by the Reference Lab or Repository, the specimen is removed from the Transplant Center's inventory.

Patient: This is the patient's ID number, which is used to identify their specimens in the GlobalTrace System.

Barcode: Displays the barcode for the specimen. The barcode can be printed and scanned.