Laboratory Queries for Clinical Studies at Frontier Science Foundation





Lab Queries

What is a Lab Query?

Formal, tracked, inquiry sent to your laboratory from Frontier Science

Why are Lab Queries Important?

Queries resolve data discrepancies between LDMS and other sources, such as CRFs

Who is Responsible for the Query?

Frontier Science issues the Query.
Clinical, Processing, and Assay Labs
work together to resolve and
respond to the Query

Who can View the Query System?

Lab & Site Users with Frontier
Science Portal Accounts can view
the Query System

Who can Respond to Queries?

Designated "Query Contact" can respond to Queries. They also receive Query Notification Emails containing a URL Frontier Science Portal utility

Who can be a Query Contact?

Each lab should have at least two users designated as Query Contacts.

Lab specific SOPs determine who is designated.





Query Resolution and Response



View the new Query in the FS Query System.

Respond to the Query ONLY if there are questions about the Query, there are barriers to data resolution, or the Query has been resolved.

Do NOT Respond to the Query with, "We Are Working On It", etc.

Investigate the issue. Work with the clinic and/or assay labs as

needed.

Identify the data discrepancy in LDMS and/or CRF: Participant, Specimen, Assay, etc.

Identify

Correct

Correct the data in the eCRF or LDMS as needed.

Use the Comment field to note the original data that was changed, who made the change, and when the change was made.

Notify

If applicable, notify all relevant groups, in writing, who have handled the specimen of the data correction in LDMS, including receiving and testing laboratories.

Respond

Respond to the Query in the FS Query System with what was changed and who was notified of the changes.

Respond within 2 weeks of the new Query.





Query Resolution and Response

Common Query Types

These Do Not Represent All Possible Query Types

- Date/Time Discrepancies
- Duplicate Results
- Overdue Shipping
- Visit Errors
- Unexpected Specimen Code

- Missing Or Unexpected Inventory
- Missing Or Unexpected Assay Results
- Specimens Not In Storage
- PBMC Tracking Fields Are Empty

Preventing Future Queries

- Track Query patterns over time
- Implement appropriate corrective/preventative measures for process improvement
- Perform careful data entry QA/QC
- Create a clinic-lab pathway for communicating data corrections
- Review query system often:
 - Bookmark the portal url on your web-browser





Network Evaluation & Other Mandates

Key staff at ACTG/IMPAACT and REPRIEVE laboratories (and their corresponding sites) receive reports to assist them with monitoring their performance. Metrics include:

Query Responsiveness: Percentage of queries responded within 14 days

- ACTG/IMPAACT target is 90%
- REPRIEVE target is 80%

PBMC Shipping Storage Compliance: Percentage of PBMCs shipped within 5 weeks of collection or stored locally in liquid nitrogen

- ACTG/IMPAACT target is 95%
- N/A for REPRIEVE

Percent shipped to the Repository: Percentage of available specimens shipped to the Repository

- ACTG/REPRIEVE target is 95%
- N/A for IMPAACT

Shipment Evaluation Score: Composite score measuring quality of shipments to the BRI repository (applies to NIAID site labs only)

ACTG/IMPAACT/REPRIEVE target is 90

Each network has their own process for formally evaluating sites and labs



Required Use of the LDMS Storage Module

If a Lab's storage score of less than 100%, a Query will issued.

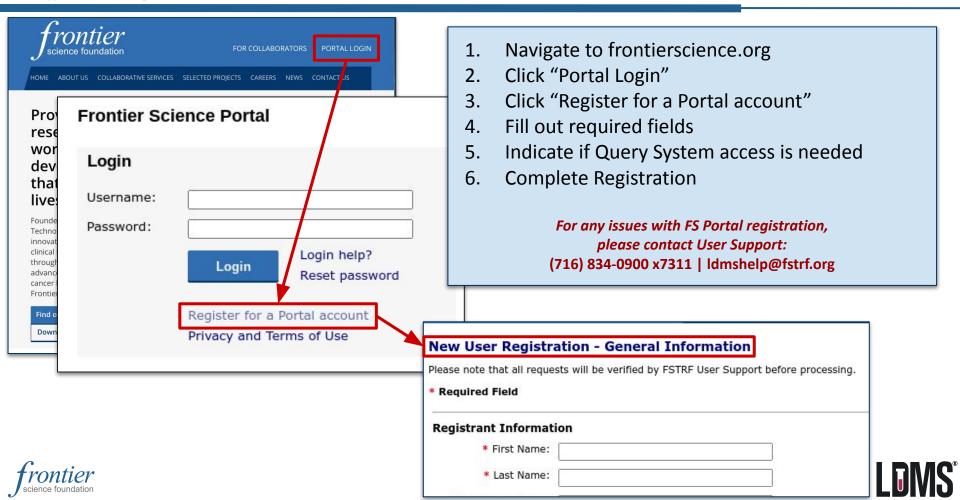
The Specimens Not in Storage Report can be used to identify potential gaps in LDMS storage data and can be accessed in the Reports module in LDMS. The report lists specimens that are available in a laboratory's database but have not had a storage location assigned in the Storage Module.

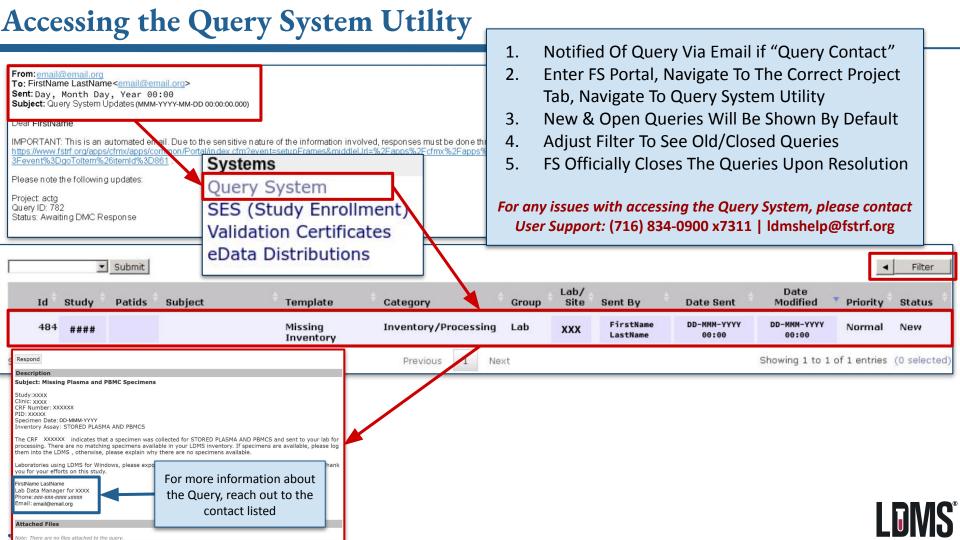
Required Entry of LDMS PBMC Processing Tracking Fields

Labs are required to complete the PBMC specimen processing fields. The Specimen Processing Report can be accessed in the Reports modules in LDMS. Results can be filtered to display only viable PBMCs (Derivative=CEL), and can be filtered further by date. Labs can use this report to review logged specimens and verify that all required fields are completed.

- Processing Date
- Processing Time
- Processed By [Tech Initials]
- Total Cell Count
- Frozen Date
- Frozen Time

Requesting FS Portal Access





Updating Lab Contacts & Query Contact

