



**Duke** Human Vaccine Institute

# **IQA Cryopreservation Web-Based System User Guide**

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## I. Overview of System

This user guide provides instructions for using the Immunology Quality Assessment Cryopreservation Web-Based System (IQA Cryo WBS) for the IQA Cryopreservation Proficiency Testing (PT) Program located at the Duke Human Vaccine Institute (DHVI). The leadership of the AIDS Clinical Trials Group (ACTG) and the International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT) requires that Clinical Trial Units participate in a quarterly proficiency testing program to evaluate the ability to reliably cryopreserve viable PBMCs (Peripheral Blood Mononuclear Cells). The IQA Cryopreservation PT Program measures the viability and viable recovery of PBMC samples processed at laboratories on a quarterly basis to ensure PBMC sample integrity in support of NIAID-DAIDS studies.

The IQA Cryo WBS will be used by participating sites for the following:

- Access the current reminder notices and additional resources
- Enter the Site data and PT sample information
- Retrieve IQA Cryopreservation PT Reports
- Enter IQA Investigation Report (IR) information
- Directly communicate and/or provide feedback to the IQA

Each IQA Cryopreservation PT quarter will be named based on the active quarter number, year, and External Proficiency (EP) number. The EP number determines if the site is submitting samples to the regularly occurring quarter or as a resubmission of the most recent quarter. For example, sites participating in Proficiency Test Q2 2025-1 are submitting samples to the June 2025 quarter, while sites participating in Proficiency Test Q2 2025-2 are resubmitting samples for the June 2025 quarter. PBMC processing technicians from each site must be participating in quarterly PT rounds and maintain a satisfactory score in each participating PT to be able to collect and store PBMCs for protocols. Any technician who receives an Unsatisfactory score must resubmit samples for evaluation and receive a satisfactory score prior to proceeding with processing PBMCs for network protocols. It is the laboratory's responsibility to maintain and monitor the certification and participation status of each processor.

The IQA Cryo WBS requires an initial registration process for actively participating IQA Cryo sites. Users will be associated with the applicable registered site and can only view relevant information. At the beginning of each PT quarter, primary users will receive an email notification. The email notification will include the dates that the IQA will be accepting shipments for the given PT quarter. Prior to shipping, a site will enter the required contact and PT sample information. The primary user will be notified upon generation of the IQA Cryopreservation PT Report. Following IQA review, the primary user will receive an email notification regarding the status of the IQA Investigation Report (IR) Form. If the IQA management team determines the IQA IR Form to be incomplete, the site will be notified to provide additional feedback. The IQA Cryo WBS enables a site to communicate directly with the IQA Cryopreservation team during an active PT quarter. The IQA Cryopreservation team can be contacted outside of active PT quarters by emailing Raul Louzao ([raul.louzao@duke.edu](mailto:raul.louzao@duke.edu)) or Carmela Archual ([carmela.archual@duke.edu](mailto:carmela.archual@duke.edu)).

The browsers currently supported by IQA Cryo WBS:

- Edge 83.0.478.37 and up
  - Firefox 59.0.2 and up
  - Chrome 65.0 and up (Recommended browser)
- Note:** Internet Explorer is not supported by this application



## I. Site and User Registration

### Sites

Prior to user registration a site must complete the IQA Cryopreservation PT Program Contact Information Form.

- IQA Cryopreservation management team will provide the form to the site.
- A registering site is required to select the PBMC processor as the primary user.
  - A maximum of 2 processors are allowed to submit quarterly for each site. Each submission will consist of 2 aliquots from a single donor.
  - Laboratories with only 1 staff member capable of PBMC processing will submit 2 aliquots from a single donor quarterly.
  - Laboratories with more than 2 staff members capable of PBMC processing are expected to maintain a regular rotation of up to 4 processors, with 2 sets of 2 technicians submitting samples in alternating quarters.
- A site may request IQA Cryo WBS access for additional site users.
- The completed form should be returned to [carmela.archual@duke.edu](mailto:carmela.archual@duke.edu).

### Users

The IQA Cryopreservation management team will grant access to the IQA Cryo WBS for each user, refer to Table 1.0 for the types of user access.

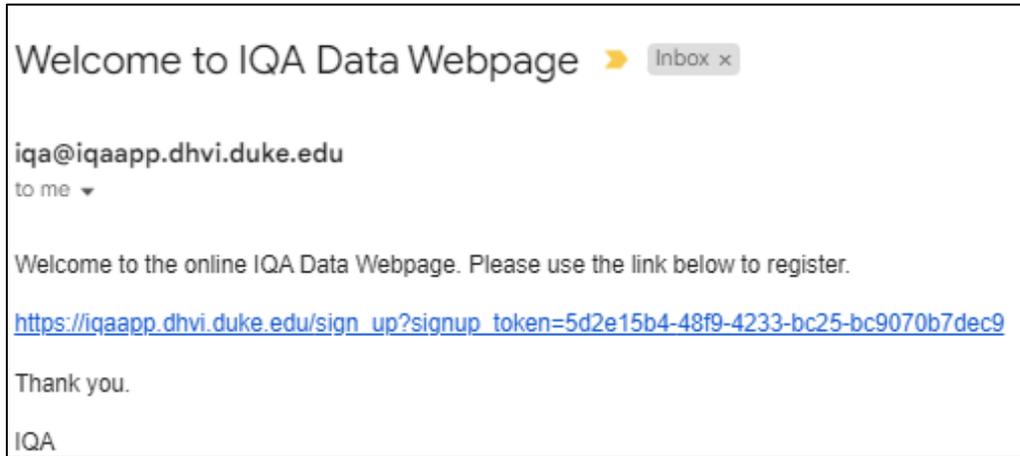
Table 1.0: IQA WBS User Access

Primary User	Additional User	IQA Cryo WBS Access
YES	NO	Receive IQA Cryo WBS email communications.
YES	YES	Access the current reminder notices and additional resources.
YES	YES	Enter the Site data and PT sample information.
YES	YES	Retrieve IQA Cryopreservation PT Reports.
YES	YES	Enter IQA Investigation Report (IR) information.
YES	YES	Directly communicate and/or provide feedback to the IQA.

- The primary and additional site users will receive a user registration email.
  - The email link is active for 24 hours, after the email link has expired users will need to request a new registration email from the IQA.
  - To request a new registration email, contact: [carmela.archual@duke.edu](mailto:carmela.archual@duke.edu).
- The IQA Cryo WBS Registration Page is accessed by the link included in the registration email, refer to Figure 1.0.



Figure 1.0: IQA Cryo WBS: New User Email



- All site user's will be required to complete the user registration page, refer to Figure 2.0.
  - The **Email** field will be pre-populated with the user email address.
  - Enter the **Primary Phone Number**.
  - Enter confidential **Password** and the **Password Confirmation**.
    - Password requirements: length at least 8 characters, at most 40 characters, at least one lowercase, one uppercase, and one digit.
  - Click the **Register** button.

Figure 2.0: IQA Cryo WBS: User Registration Page

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An NIH, NIAID, DAIDS Program

**Duke Human Vaccine Institute**

### Register

Email

First Name

Last Name

Primary Phone Number

Password

Password confirmation

Contact Us powered by SCIMED SOLUTIONS IQA Prod1 - 4.2.0



- The user will be redirected to the site registration page, refer to Figure 3.0.
- All site user's will be required to complete the site registration page:
  - Contact information – most current telephone number.
  - Enter the site address.
  - Click the **Update Site** button.

Figure 3.0: IQA Cryo WBS: Site Registration Page

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Programs | [iqatestuser0@gmail.com](#) | [Site Info](#) | [Log Out](#)

## Register Your Site

Please take some time to register your site. Thank you.

### Site Information

**Name**  
IQA Cryo Test User\_Tech A

**Primary email**  
iqatestuser0@gmail.com

**Primary investigator**  
--

**Institution**  
--

### Contact Information

[Add Phone Number](#)

### Address

**City**

**State**

**Zip Code**

**Country**

### Site Personnel

<b>Name</b>	Sarah Keinonen	<span style="color: red;">✘</span>
<b>Email</b>	iqatestuser0@gmail.com	
<b>Phone</b>	000000000000	

[Add User](#)

Contact Us | powered by **SCIMED SOLUTIONS** | IQA Test - 4.4.0.rc-9



## II. Logging into the IQA Cryo WBS

A registered user can access the IQA Cryo WBS log-in page from the following link: <https://igaapp.dhvi.duke.edu/users/login>, refer to Figure 4.0.

Figure 4.0: IQA Cryo WBS Log-in page



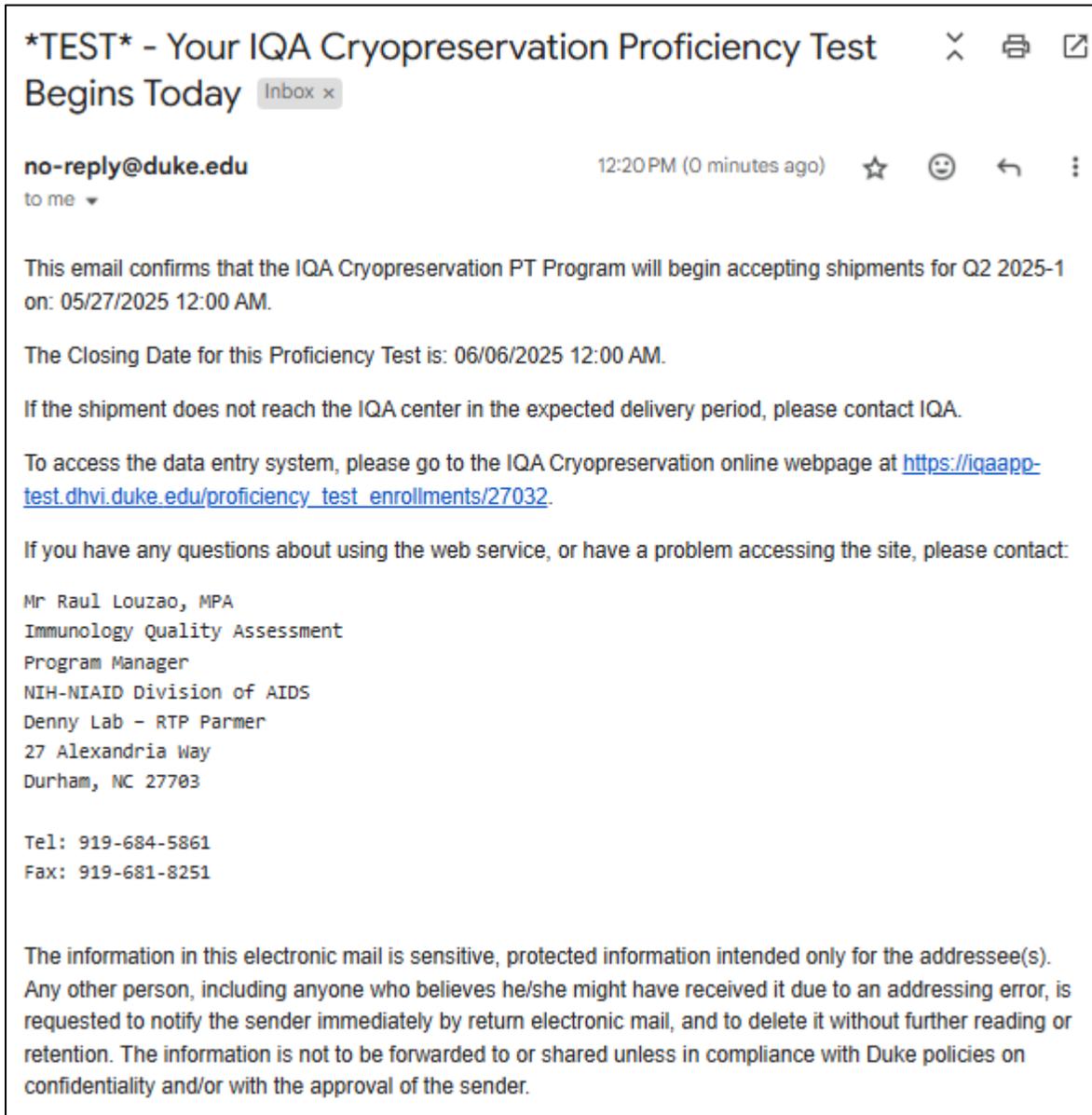
- Enter **Email** address and **Password**.
  - Ensure that the **Sign in with Email** is selected, sign in with DHE Credentials is only for IQA/Duke-based users.
- Click the **Sign In** button.
  - If a user fails to enter the correct password after four consecutive attempts, the account will be locked for 15 minutes. The user account will automatically unlock after 15 minutes.
  - For forgotten passwords, select **Forgot/Reset your password**. A reset link for the user's password will be sent via email.



### III. Data Reporting

The primary user(s) will be notified of an active PT quarter by an IQA Cryo WBS email notification, refer to Figure 5.0.

Figure 5.0: IQA Cryo WBS Email Notification of Active PT Quarter

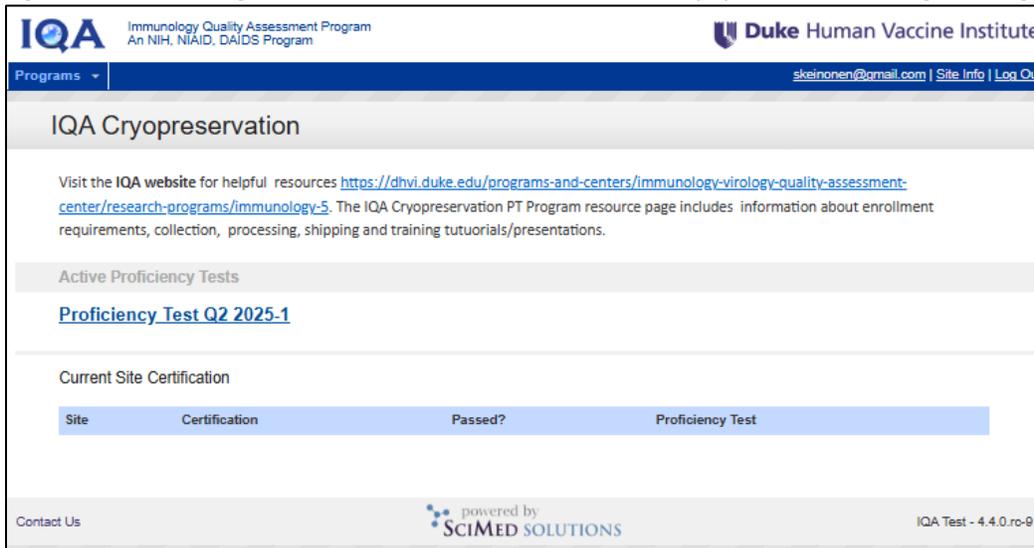


- The email will include the start and end date that the IQA will be accepting PT shipments for the active PT quarter.
  - A primary user can access the IQA Cryo WBS by clicking the link provided in the email notification.
  - Additional site users can log in to the IQA Cryo WBS by the following link:  
<https://iqaapp.dhvi.duke.edu/users/login>.



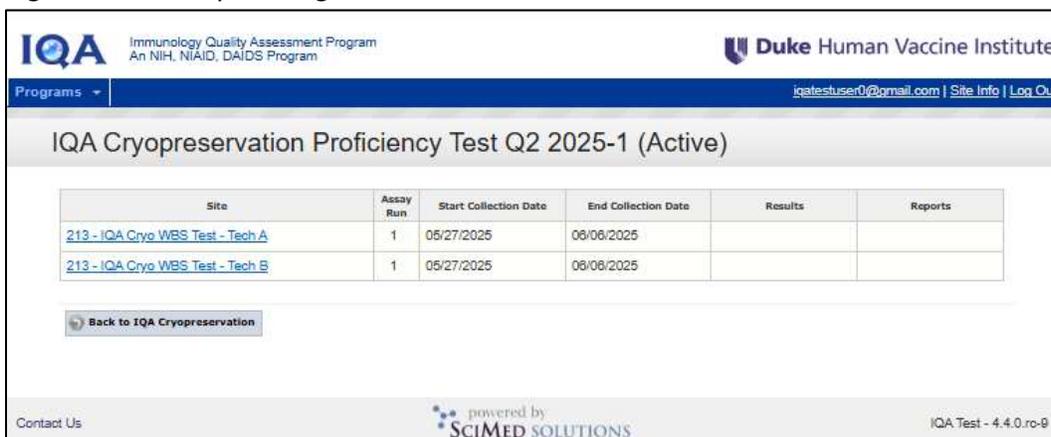
- After successful login, Click **Select Programs > IQA Cryopreservation >Active Proficiency Test.**
- The IQA Cryopreservation Program Page will include a list of all active and completed PT quarters.
  - Regular PT quarter’s will be indicated by a **-1** and a resubmission PT quarter will be indicated by **-2.** Only sites that are required to resubmit PT samples for a given quarter will be able to access or view the resubmission quarters.
- Click on the PT name under the Active Proficiency Tests, e.g., Proficiency Test Q2 2025-1.0, refer to Figure 6.0.

Figure 6.0: Accessing an Active PT Quarter from the IQA Cryopreservation Program Page



- The user will be directed to the IQA Cryopreservation Proficiency Test (IQA Cryo PT) Page.
  - The IQA will assign each site’s PBMC processing technician as Tech A or Tech B or Tech C or Tech D.
    - For example, if LDMS 213 has 2 PBMC processing technicians the WBS will display an entry for Tech A and Tech B, refer to Figure 7.0. NOTE: A PBMC processing technician submitting data will only see their assigned Tech letter to submit data.

Figure 7.0: IQA Cryo PT Page





- The IQA Cryo PT Page will display a table, refer to Table 2.0.

Table 2.0: IQA Cryo PT Page Table

<b>Site</b>	LDMS number and Site Name and PBMC processing technician alphabetical designation (A or B or C or D).
<b>Start Collection Date</b>	First date of the active PT quarter that the IQA will start accepting PT shipments.
<b>End Collection Date</b>	Last date of the active PT quarter that the IQA will be accepting PT shipments and the date that the site completed the PT data entry.
<b>Results</b>	The date the IQA enters results for the site.
<b>Reports</b>	A link directing the user to the available IQA Cryo Result Report.

- Click the Site, under the **Site** column.
  - The user will be directed to the IQA Cryo PT Menu, refer to Figure 8.0.

Figure 8.0: Active IQA Cryo PT Menu



- The IQA Cryo PT Menu Page includes the PT quarter information, refer to Table 3.0.

Table 3.0: IQA Cryo PT Menu Page

<b>Instructions</b>	Includes detailed instructions for the PT quarter.
<b>Site Data</b>	The user will enter contact and PT sample data information.
<b>Reports</b>	Includes the available IQA Cryopreservation PT Report and/or IQA IR Form.
<b>Communication/Feedback</b>	Allows the user to document comments or feedback for each active PT quarter. The comments will only be viewable by the submitting site and IQA management.
<b>Back to Proficiency Test</b>	Direct the user to the IQA Cryo PT Page.
<b>Back to IQA Cryopreservation</b>	Direct the user to the IQA Cryo Program Page.



- Select the **Site Data** tab.
- The Site Data tab includes the Contact and Donor tabs, refer to Figure 9.0 and Table 4.0.

Figure 9.0: IQA Cryo PT Menu - Site Data Tab – Contact Information

The screenshot shows a web-based form titled "IQA Cryopreservation Proficiency Test Q2 2025-1 - 213 - IQA Cryo WBS Assay Run 1 Test - Tech A". The form is divided into two main sections: "Contact Information" and "Donors". The "Contact Information" section contains the following fields:

- Site Name: IQA Cryo WBS Test - Tech A
- Test Cycle: Quarter: 3 - September EP in Quarter: 1
- LDM5 Site Number: 213
- Lab Director:
  - Title:
  - First Name:
  - Last Name:
  - Phone Number:
  - Email:
- Contact:
  - First Name:
  - Last Name:
  - Phone Number:
  - Email:
  - Network Affiliation:

At the bottom of the form, there are "Save" and "Submit" buttons. Navigation links at the bottom include "Back to Proficiency Test Q2 2025-1" and "Back to IQA Cryopreservation". The footer of the page includes "Contact Us", "powered by SCIMED SOLUTIONS", and "IQA Test - 4.4.0.r-9".

Table 4.0 –Contact Information Tab Requirements

<b>Lab Director</b> (Lab director information will be pre-populated from prior data submissions and will be editable.)	<b>Required or Optional Entry</b>	<b>Contact</b> (Person submitting the IQA Cryopreservation PT sample information.)	<b>Required or Optional Entry</b>
Title	Optional	First Name	Required
First Name	Required	Last Name	Required
Last Name	Required	Phone Number	Required
Phone Number	Required	Email	Required
Email	Required	Network Affiliation	Required



- The Contact and Donor tabs must be completed before the data can be submitted to the IQA.
- If a required field is left blank it will be highlighted in red and a comment will appear, refer to Figure 10.0.

Figure 10.0: Site Data – Error Message

The screenshot shows the IQA web-based system interface. At the top, there are logos for IQA (Immunology Quality Assessment Program) and Duke Human Vaccine Institute. The page title is "IQA Cryopreservation Proficiency Test Q2 2025-1 - 213 - IQA Cryo WBS Test - Tech A". The main content area has tabs for "INSTRUCTIONS", "SITE DATA", "REPORTS", and "COMMUNICATION/FEEDBACK". The "SITE DATA" tab is active, and within it, the "Contact Information" sub-tab is selected. The form contains the following fields and values:

- Site Name: IQA Cryo WBS Test - Tech A
- LDMS Site Number: 213
- Test Cycle: Quarter: 3 - September EP in Quarter: 1
- Lab Director: Title, First Name, Last Name, Phone Number, Email
- Contact: First Name, Last Name, Phone Number, Email, Network Affiliation

The "Last Name" field for the Lab Director is highlighted in red, and a tooltip message reads: "At least 2 characters are required. This field is required". There are "Save" and "Submit" buttons at the bottom of the form. Navigation links at the bottom include "Back to Proficiency Test Q2 2025-1" and "Back to IQA Cryopreservation". The footer contains "Contact Us", "powered by SCIMED SOLUTIONS", and "IQA Test - 4.4.0.rc-9".

- Click the **Save** button to exit before submitting data.
- Click the **Donors** tab.
  - A regularly scheduled PT quarter will include 1 donor tab.
  - The Donor Tab data entry must be completed before the site data can be submitted, refer to Figure 11.0.



Figure 11.0: Site Data Tab - Donor Data Entry Tab

INSTRUCTIONS | **SITE DATA** | REPORTS | COMMUNICATION/FEEDBACK

Contact Information | Donors

Donor 1

Processing technician:

Sample 1 ID#:

Sample 2 ID#:

Date of Blood Draw:

HIV Status:

Volume of Blood Draw:  mls

Most Current CD4 Absolute #:  mm<sup>3</sup>

Anticoagulant used:

Date of Blood Separation:

Cell Counting Method Used:

Total Viable Cell Yield:  x 10<sup>6</sup>  
(Total # of PBMC)

Viability:  %

Viability Method Used:

Freezing Date:

Volume per Vial:  mls

Number of Vials Frozen:

Total Viable Cell Count per Vial:  x 10<sup>6</sup>  
(Should be volume per vial times 10 million)

Shipping Date:

Number of Vials Shipped:

Save Submit

- Resubmission PT quarters include 2 donors tabs, refer to Figure 12.0.

Figure 12.0: Donor Data Entry Tab – Resubmission PT Quarter

INSTRUCTIONS | **SITE DATA** | IQA RESULTS | IR REPORT | REPORTS | COMMUNICATION/FEEDBACK

Contact Information | Donors

Donor 1 | Donor 2



- Refer to Table 5.0 for the data entry requirements on the Donors Information Tab.

Table 5.0: Data Entry Requirements for the Donor tabs

<b>Donor Field</b>	<b>Date Entry Requirement</b>	<b>Required or Optional</b>
Processing technician	Processing Tech initials	Required
Sample ID#	Enter LDMS GID for Each Sample ID #	Required
Date of Blood Draw	Select date from calendar or enter (mm/dd/yyyy) format	Required
HIV Status	Select status from dropdown	Required
Volume of Blood Draw	Total volume of blood draw (mL)	Required
Most Current CD4 Absolute #	CD4 Absolute #	Optional
Anticoagulant	Select anticoagulant from dropdown	Required
Date of Blood Separation	Select date from calendar or enter (mm/dd/yyyy) format	Required
Cell Counting Method Used	Select 'Manual' or 'Automated' from the dropdown <ul style="list-style-type: none"> <li>• Manual: 'with Trypan Blue' or 'without Trypan Blue' should be selected from the dropdown</li> <li>• Automated: Specify Machine from the dropdown. If the user selects 'Other' for Specify Machine, they will be required to enter text in Field "Please Specify"</li> </ul>	Required
Total Viable Cell Yield	Total viable cells collected from the blood draw	Required
Viability	Percentage viability obtained from the blood draw	Required
Viability Method Used	Select Trypan Blue or Other from the dropdown <ul style="list-style-type: none"> <li>• If Other is selected, the user will be required to enter details</li> </ul>	Required
Freezing Date	Select date from calendar or enter (mm/dd/yyyy) format	Required
Volume per Vial	Volume of PBMC suspension in each vial (mL)	Required
Number of Vials Frozen	Total number of vials frozen per blood draw	Required
Total Viable Cell Count per Vial	Total number of viable cells per vial	Required
Shipping Date	Select date from calendar or enter (mm/dd/yyyy) format	Required
Number of Vials Shipped	Number of vials shipped to the IQA per blood draw	Required



- Complete all required donor fields.
  - Click **Save**, to save the results and exit the Site Data Tab.
  - Click **Submit**, to submit the entered data to the IQA.
    - If there are required fields with blank values on any of the site data tabs, the user will be required to go back and enter data in the required fields before the data will be submitted successfully.
    - When a user clicks the Submit button, the system will issue a warning message. This warning message is intended to notify the user that the submitted data will no longer be editable.
      - Click **Ok** to submit the data to the IQA.
        - To edit submitted results, the user will be required to contact [carmela.archual@duke.edu](mailto:carmela.archual@duke.edu).
  - A message will appear at the top of the page stating results have been submitted, refer to Figure 13.0.

Figure 13.0: Site Data Submitted Message

The screenshot shows the top navigation bar with the IQA logo and Duke Human Vaccine Institute name. Below the navigation bar, a green message box states "Site Data has been submitted". Below the message box, the page title reads "IQA Cryopreservation Proficiency Test Q2 2025-1 - 213 - IQA Cryo WBS Assay Run 1 Test - Tech A".

- The date of the site data submission will be displayed on the IQA Cryo PT Page in the **End Collection Date** column, refer to Figure 14.0.

Figure 14.0: Data Submission Confirmation - IQA Cryo PT Page

The screenshot shows the IQA Cryo PT Page with the title "IQA Cryopreservation Proficiency Test Q2 2025-1 (Active)". Below the title, there is a link for "IQA Cryo Reminder Notice Q2 2025". A table displays the submission data for two sites:

Site	Assay Run	Start Collection Date	End Collection Date	Results	Reports
<a href="#">213 - IQA Cryo WBS Test - Tech A</a>	1	05/27/2025	06/06/2025 <a href="#">Submitted 04/25/2025</a>		
<a href="#">213 - IQA Cryo WBS Test - Tech B</a>	1	05/27/2025	06/06/2025 <a href="#">Submitted 04/25/2025</a>		

Below the table, there is a button labeled "Back to IQA Cryopreservation". At the bottom of the page, there is a footer with "Contact Us", "powered by SCIMED SOLUTIONS", and "IQA Test - 4.4.0.rc-9".



- The date of the IQA result data submission will be displayed on the IQA Cryo PT Page in the **Results** column, refer to Figure 15.0.

Figure 15.0: IQA Data Entry Complete- IQA Cryo PT Page

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Programs | [iqatestuser0@gmail.com](#) | [Site Info](#) | [Log Out](#)

### IQA Cryopreservation Proficiency Test Q2 2025-1 (Active)

[IQA Cryo Reminder Notice Q2 2025](#)

Site	Assay Run	Start Collection Date	End Collection Date	Results	Reports
<a href="#">213 - IQA Cryo WBS Test - Tech A</a>	1	05/27/2025	06/06/2025 <a href="#">Submitted</a> 04/25/2025	Completed 04/25/2025	
<a href="#">213 - IQA Cryo WBS Test - Tech B</a>	1	05/27/2025	06/06/2025 <a href="#">Submitted</a> 04/25/2025	Completed 04/25/2025	

[Back to IQA Cryopreservation](#)

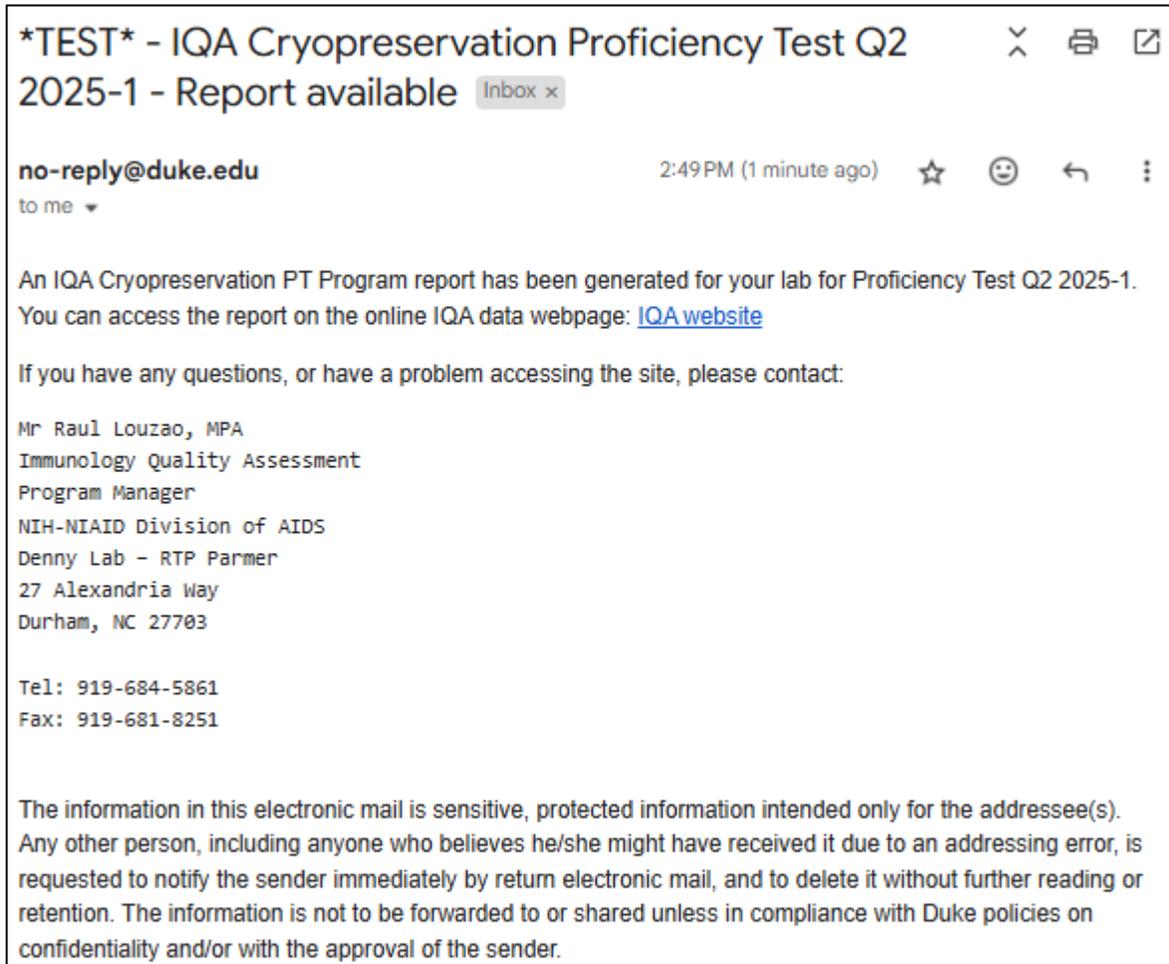
Contact Us | powered by **SCIMED SOLUTIONS** | IQA Test - 4.4.0.rc-9



#### IV. Retrieving Site Specific Report

- The primary site user(s) will receive an IQA Cryo WBS email notification upon the site specific IQA Cryo PT Report generation, refer to Figure 16.0.

Figure 16.0: IQA Cryopreservation PT Result Report Notification Email



- The IQA Cryo PT Menu can be accessed by primary and additional site users.
  - Primary User - Clicking the link included in the IQA Cryopreservation PT Report notification email.
  - Additional User - The report availability is indicated in the **Reports** column on the IQA Cryo PT Page.
- The **Report Available** link will direct the user to the IQA Cryo PT Menu, refer to Figure 17.0.



Figure 17.0: IQA Cryo PT Report Available- IQA Cryo PT Page

Site	Assay Run	Start Collection Date	End Collection Date	Results	Reports
<a href="#">213 - IQA Cryo WBS Test - Tech A</a>	1	05/27/2025	06/06/2025 <a href="#">Submitted 04/25/2025</a>	Completed 04/25/2025	<a href="#">Report Available</a>
<a href="#">213 - IQA Cryo WBS Test - Tech B</a>	1	05/27/2025	06/06/2025 <a href="#">Submitted 04/25/2025</a>	Completed 04/25/2025	<a href="#">Report Available</a>

- An IQA Cryopreservation PT Report will be located in the specific PT quarter IQA Cryo PT Menu under the **Reports** Tab.
- Click on the **Report Available** to view/download the report, refer to Figure 18.0.

Figure 18.0: Reports Tab - IQA Cryo PT Menu

**INSTRUCTIONS** | **SITE DATA** | **REPORTS** | **COMMUNICATION/FEEDBACK**

Site Report  
[Cryo\\_213\\_report\\_25042025\\_144941\\_491.pdf](#)

IR Report



- For the most current performance evaluation criteria refer to the **IQA Cryopreservation PT Program Description Document** located on the IQA website (Cryopreservation < Enrollment): (<https://dhvi.duke.edu/programs-and-centers/immunology-virology-quality-assessment-center/research-programs/immunology-5>).
- The first page of the IQA Cryopreservation PT Report provides the following:
  - Identifies the site and name of the PBMC processing technician.
  - The date the report is generated.
    - NOTE: If the IQA Cryopreservation PT Report is re-generated for any reason, the first page of IQA Result Report for a given PT quarter will include a “Revised” comment in the upper righthand corner with the date of revision.
  - Overview of the Percent Viability and Viable Recovery Scoring Systems, and the Performance Grading System.
- The second page of the IQA Cryopreservation PT Report provides the following:
  - The PBMC processor’s percentage viability and viable recovery percent, score and statuses.
  - Provides a site-specific comparison of cumulative results from the past four PT submissions.
  - Includes the required corrective actions in response to out of range results.
  - Provides the date that the IQA will begin accepting shipments for the next PT quarter.



## V. Investigational Review (IR) Form

- The IQA IR Form is due within working 5 days of IQA Cryo PT Report generation.
- For sites that are required to complete an IR form, the **IR Report** tab will appear on the IQA Cryo PT Menu.
- Click the **IR Report** Tab.
  - Click on the **IR Form** Tab.
  - Complete required entries on the IR form, refer to Table 6.0.

Table 6.0: IQA IR Form Data Entry Requirements

	<b>Date Entry Field</b>	<b>Required or Optional</b>
<b>Completed By</b>	First name of person completing the IR Form.	Required
	Last name of person completing the IR Form.	Required
	Phone Number of person completing the IR Form.	Required
	Email of person completing the IR Form.	Required
<b>FBS Information</b>	Confirm FBS manufacturer	Required
	Confirm FBS Lot Number	Required
	Confirm FBS Expiration Date	Required
<b>Area of Focus</b>	Click on the checkboxes that best describe the out of range results.	Optional Selections
<b>Investigation Steps</b>	Click on the checkboxes that best reflects the corrective actions performed.	Optional Selections
	If Back up vial vials were thawed and assessed for viability and viable recovery in-house is selected.	Required; text limit of 30,000 characters.
	If Additional investigation steps taken is selected	Required; text limit of 30,000 characters.
<b>Background/Summary of Incident</b>	Provide a detailed description of the error that caused the out of range results.	Comment Required; text limit of 255 characters.
<b>Plan of Action</b>	Describe in detail the measures taken to prevent this error from reoccurring	Comment Required; text limit of 255 characters.



- If a user requires more text capacity for any required IR form field or needs additional time to complete the investigation:
  - Contact the IQA management team via the **Communication/Feedback** tab on the PT Quarter menu.
  - IQA Cryo users can also email [carmela.archual@duke.edu](mailto:carmela.archual@duke.edu).
- Click the **Save** button, this will save the information for later submission.
- Click the **Submit** button to save and submit the IQA IR form.
  - No changes can be made after the IR form has been submitted unless the IQA management team unlocks the IR form.
    - Contact [carmela.archual@duke.edu](mailto:carmela.archual@duke.edu) to unlock the IR form.
- The IQA management team will review the submitted IR form and determine the investigation completion status.
- Upon IQA review completion, an IQA Cryo WBS email notification will be sent to both the primary user and the site user that submitted the IR form.
  - An acceptable IR form will not require additional site user feedback, refer to Figure 19.0.
  - An incomplete IR form will be indicated in the email notification, and will require additional feedback until the investigation is considered to be complete.

Figure 19.0: IQA Reviewer Comments - IQA Cryo PT Menu

The screenshot displays the 'IQA Review' section of the web-based system. At the top, there are tabs for 'INSTRUCTIONS', 'SITE DATA', 'IR REPORT', 'REPORTS', and 'COMMUNICATION/FEEDBACK'. The 'IQA Review' tab is active, showing two sub-tabs: 'IR Form' and 'IQA Review'. The 'IQA Review' sub-tab contains the following elements:

- IQA Review Results:** Two radio button options: 'Acceptable and complete investigation' (selected) and 'Investigation is incomplete (comments required)'. A 'Generate IR Report' button is also present.
- IQA Review Completed By:** Fields for 'First Name' (Carmela), 'Last Name' (Archual), and 'Date' (4/25/2025).
- Comments:** A text box containing a comment from Sarah Keinonen dated 04/25/2025 03:33 PM: 'Investigation is incomplete, please provide more information regarding the evaluation of back up vials and any additional investigation steps taken.'
- Submitted:** 04/25/2025, Submitted By: Sarah Keinonen.
- Buttons:** 'Save' and 'Submit' buttons.

At the bottom of the interface, there are navigation links: 'Back to Proficiency Test Q2 2025-1' and 'Back to IQA Cryopreservation'. The footer includes 'Contact Us', 'powered by SCIMED SOLUTIONS', and 'IQA Test - 4.4.0.rc-0'.



- To view the IR Form status and IQA Comments, click the **IQA Review** tab.
  - If the IQA is in the process of reviewing the IR comments, the system will display the message, “IQA Review is in process”.
  - The **IQA Review Results** section will include the status of the IQA IR form.
  - The **IQA Review Completed By** section will include the name of the IQA review and the date the review was completed.
  - The **Comments** section will include a time and date for any comments made by the IQA.
- To view the information entered on the IR form, click the **IR Form** tab.
  - The IR Form will automatically unlock for additional user input if the IQA management team determines that the investigation is incomplete.
- Select the Reports tab to view/download the completed IR Report, refer to Figure 20.0.

Figure 20.0: Report Tab: Completed PT Quarter Reports

The screenshot displays the IQA web interface. At the top left is the IQA logo (Immunology Quality Assessment Program, An NIH, NIAID, DAIDS Program) and at the top right is the Duke Human Vaccine Institute logo. A navigation bar includes a 'Programs' dropdown menu, a user email address 'iqatestuser0@gmail.com', and links for 'Site Info' and 'Log Out'. The main header area shows the test title 'IQA Cryopreservation Proficiency Test Q2 2025-1 - 213 - IQA Cryo WBS Test - Tech B' and 'Assay Run 1'. Below this is a tabbed interface with five tabs: 'INSTRUCTIONS', 'SITE DATA', 'IR REPORT', 'REPORTS' (which is active), and 'COMMUNICATION/FEEDBACK'. Under the 'REPORTS' tab, there are two sections: 'Site Report' with a link to 'Cryo\_213\_report\_25042025\_150017\_439.pdf' and 'IR Report' with a link to 'Cryo\_IR\_213\_report\_25042025\_154123\_431.pdf'. At the bottom of the report area are two buttons: 'Back to Proficiency Test Q2 2025-1' and 'Back to IQA Cryopreservation'. The footer contains 'Contact Us', the 'powered by SCIMED SOLUTIONS' logo, and the version number 'IQA Test - 4.4.0.rc-9'.



## VI. Current Site Performance Ratings

- The site user will be able to view the site’s current performance grading status from the most recent PT assessment.
- The performance grading status will appear on the IQA Cryo Program Page, the status is only visible to applicable site users and the IQA management team, refer to Figure 21.0.

Figure 21.0: Current Site Certification

### IQA Cryopreservation

Visit the IQA website for helpful resources <https://dhvi.duke.edu/programs-and-centers/immunology-virology-quality-assessment-center/research-programs/immunology-5>. The IQA Cryopreservation PT Program resource page includes information about enrollment requirements, collection, processing, shipping and training tutorials/presentations.

#### Completed Proficiency Tests

[Proficiency Test Q4 2023-1](#)  
[Proficiency Test Q4 2023-2](#)

#### Current Site Certification

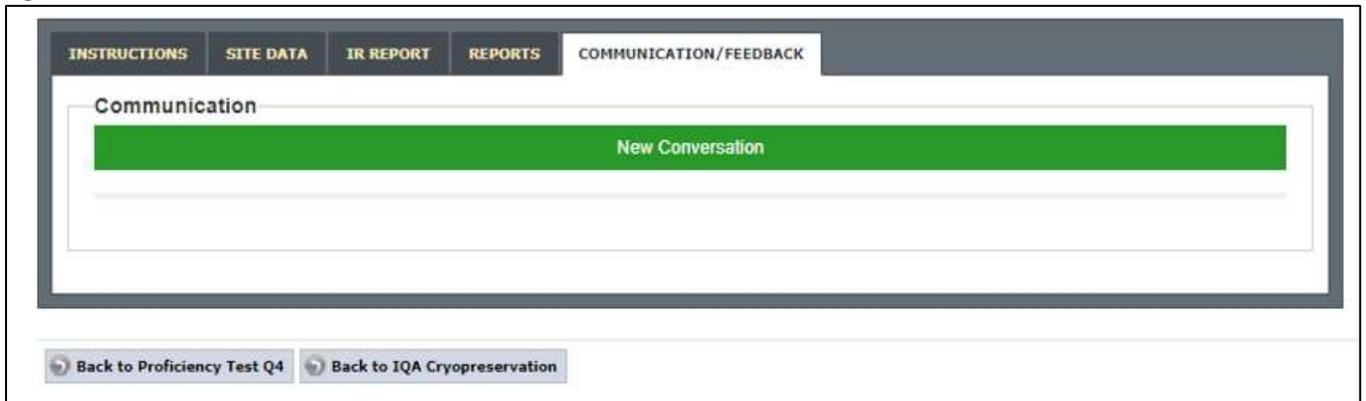
Site	Certification	Passed?	Proficiency Test
000 - IQA Cryo WBS Test C	Satisfactory	✓	Q4 2023-2



## VII. Communication/Feedback

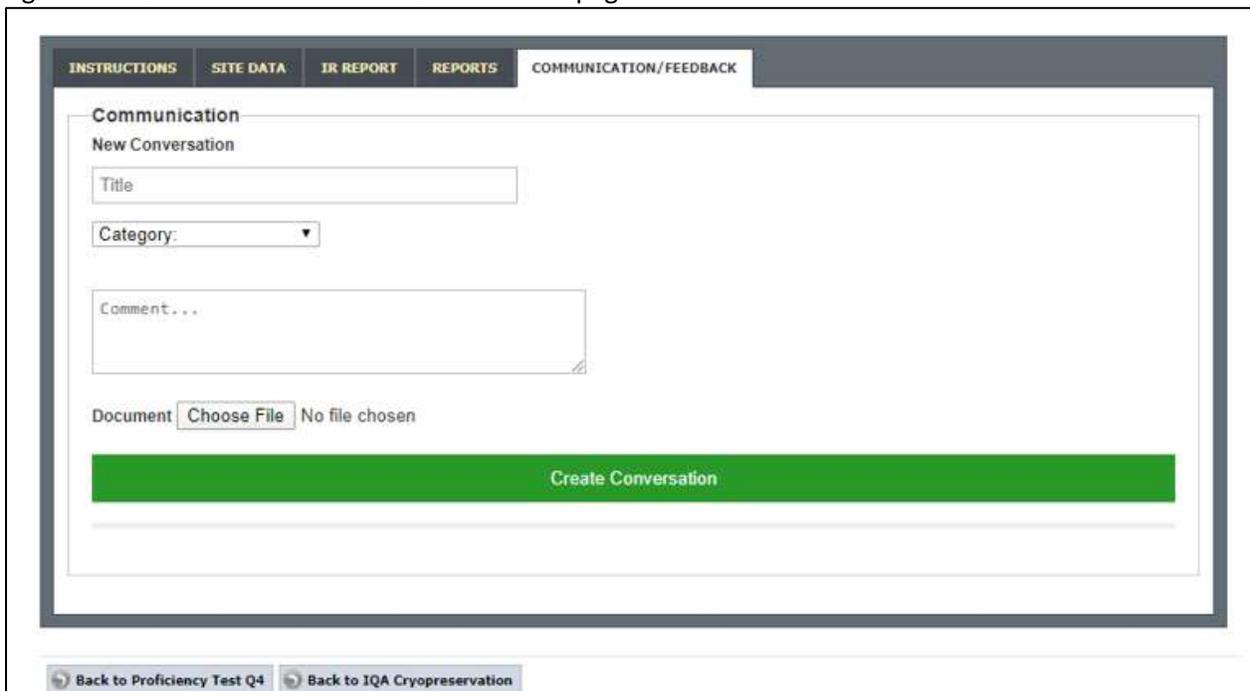
- If a site has a comment or feedback that needs to be addressed to the IQA management team, they can directly communicate using the **Communication/Feedback** tab during an active PT quarter. The communication will be documented and available to view in the applicable IQA Cryo PT Menu, in the Communication/Feedback Tab.
- If a site needs to contact the IQA team outside of an active PT quarter, the IQA team can be reached by emailing Raul Louzao ([raul.louzao@duke.edu](mailto:raul.louzao@duke.edu)) or Carmela Archual ([carmela.archual@duke.edu](mailto:carmela.archual@duke.edu)).
- Click on the **Communication/Feedback** tab, refer to Figure 22.0.

Figure 22.0 Communication/Feedback Tab



- Click **New Conversation** to communication with the IQA Management team. Refer to Figure 23.0.

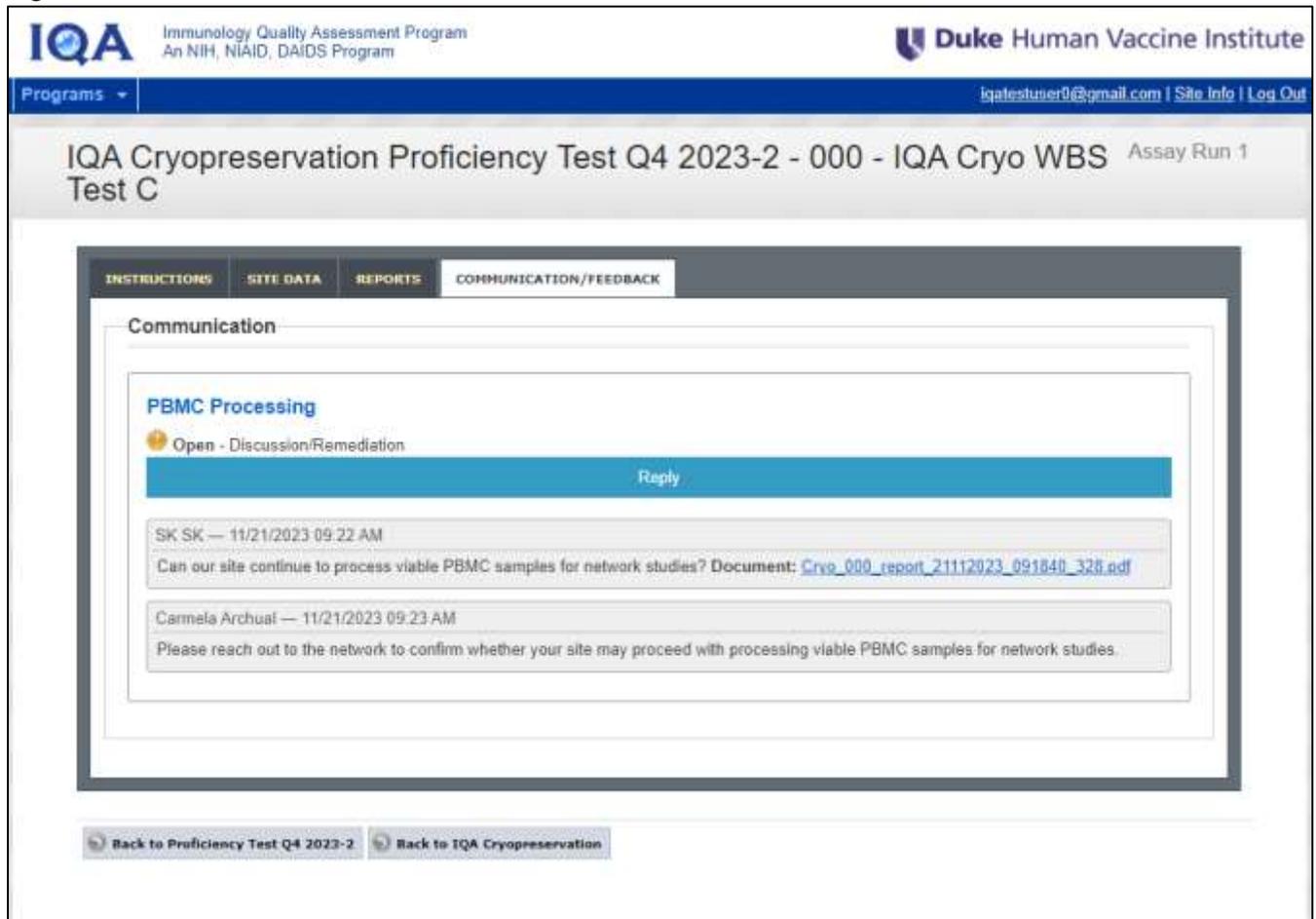
Figure 23.0 Communication - New Conversation page





- Enter a **Title**.
- Select a **Category** from the dropdown menu.
- Enter **Comment**.
- A file can be uploaded by selecting the **Choose File** button.
- Click **Create Conversation** to notify the IQA team of the conversation.
- The conversation will be displayed, refer to Figure 24.0.

Figure 24.0: IQA Communication Confirmation



- Upon IQA response to the conversation, an IQA Cryo WBS email will be sent to the site user further documenting the correspondence, refer to Figure 25.0.



Figure 25.0: IQA response to web-based system communication

