

Data Submission User‘s Guide

Date	Version Number	Name	Activity
12/02/2022	1.0	Theagis Lynch	Document Creation
10/29/2026	2.0	Sylvester Hood	Updated document to include information on the new “Cytometer Serial Number” field. Corrected Table of Contents.

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I. Overview of System

This users' guide describes the features found in the IQA CD4 web-based system for a site participating in the IQA CD4 program.

The browsers currently supported by the application are:

- Microsoft Edge Version 105 and up
- Chrome Version 106.0 and up
- Firefox Version 105.0 and up.

Note: Internet Explorer is not supported by this application.

The IQA CD4 program is administered by the Duke Human Vaccine Institute (DHVI). In this program, sites are provided two samples for their analysis. The web application will be used by sites to submit their data for the IQA CD4 program. The system allows registration of sites and users at the approval of IQA management. Users will be associated with sites and sites will be assigned to specific IQA programs in which they are enrolled.

After a site submits their results, the results will be analyzed by the Duke Human Vaccine Institute's biostatisticians. A report will be uploaded which will contain the evaluation of the CD4 results. This report will inform each site about the accuracy of their results.

Within the IQA CD4 proficiency page, users can view both completed and active trials. Within an active trial, users can enter results and download site-specific reports. For completed trials, users will only be able to view/download reports but will not have the ability to edit documents.

The system will also enable sites to view their site's cumulative performance rating.

II. Site and User Registration

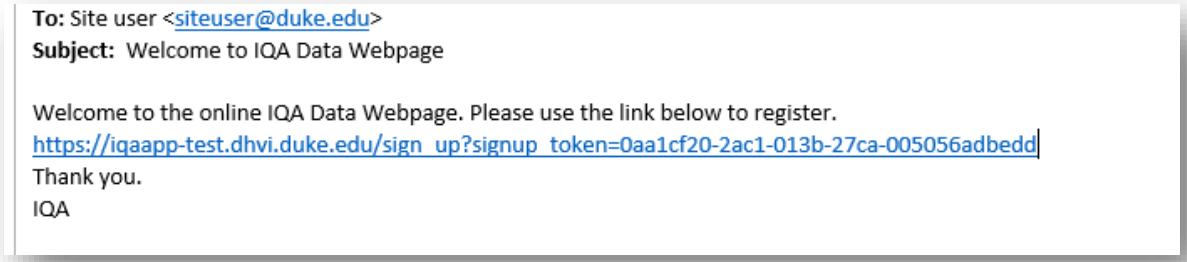
Sites

- To register a new site, IQA management will need to know the site's name, lab number and a primary contact email address. This information should be provided to raul.louzao@duke.edu
    - The primary contact will receive all email communication from the IQA system.
- IQA management will enter this information into the web-based application to begin the enrollment process.
- The primary contact will receive an email from the IQA system with a link to the IQA system.
- Once the primary user is registered in the system, the user can reset their password and enter in additional site and user information.
- The primary user can also add email addresses for other users connected to the site.

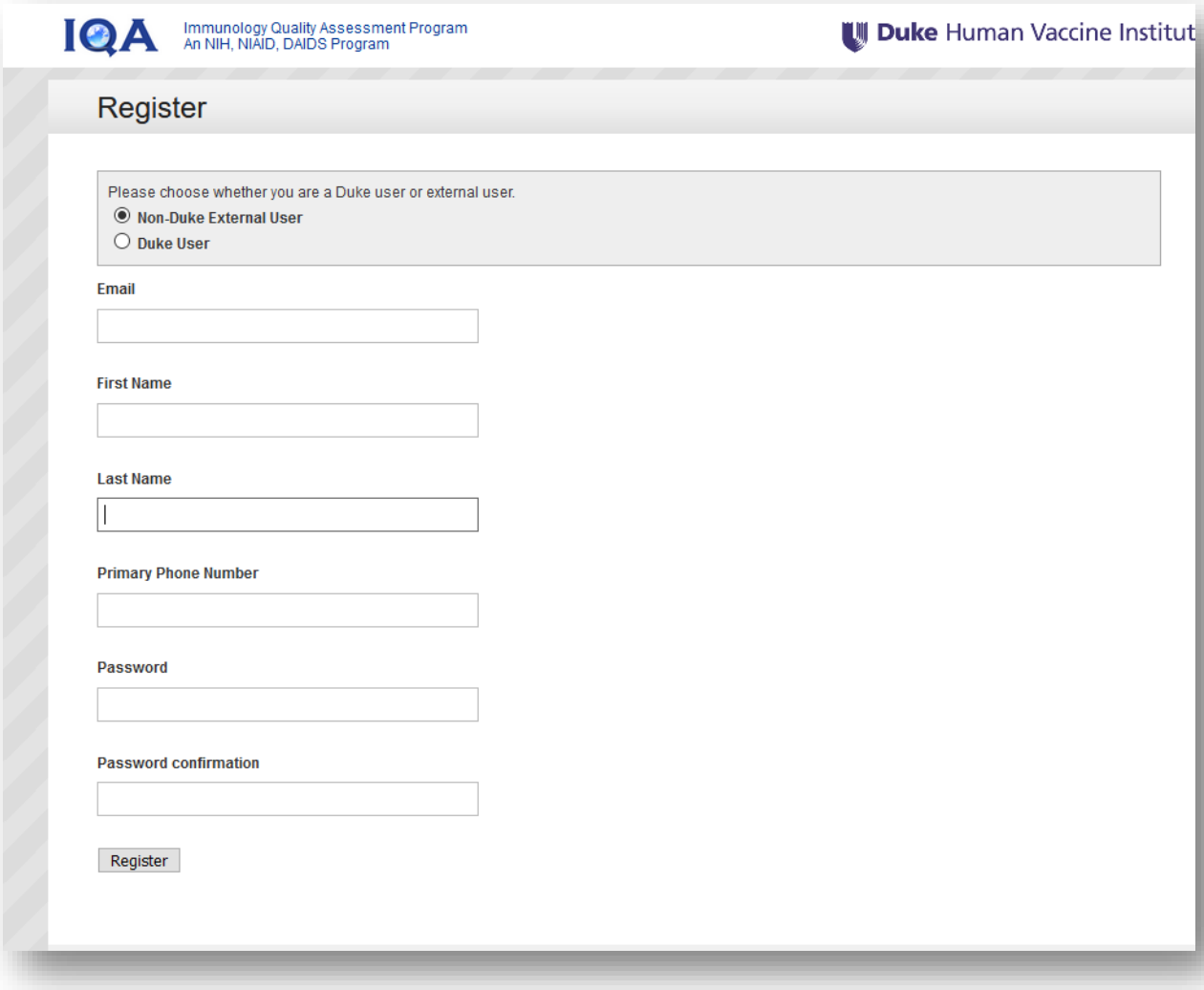
- Site-designated users will receive an email from the system to complete registering their id to the system.

Users

- IQA management will grant access to the IQA Web system.
- The user will receive a registration email once the user has been registered. **The following is an example of the email the user will receive:**



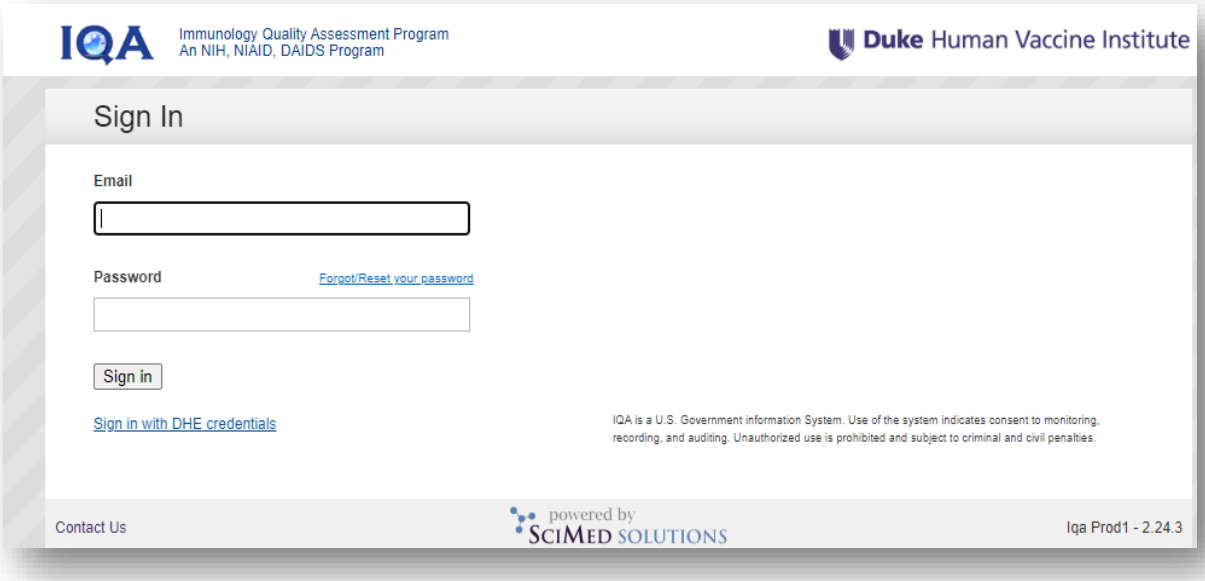
- The user will access the registration page via the emailed link. To register, the user will need to set up a password.
- **The following is an example of the screen that will appear after the link is accessed:**



III. Logging into the System

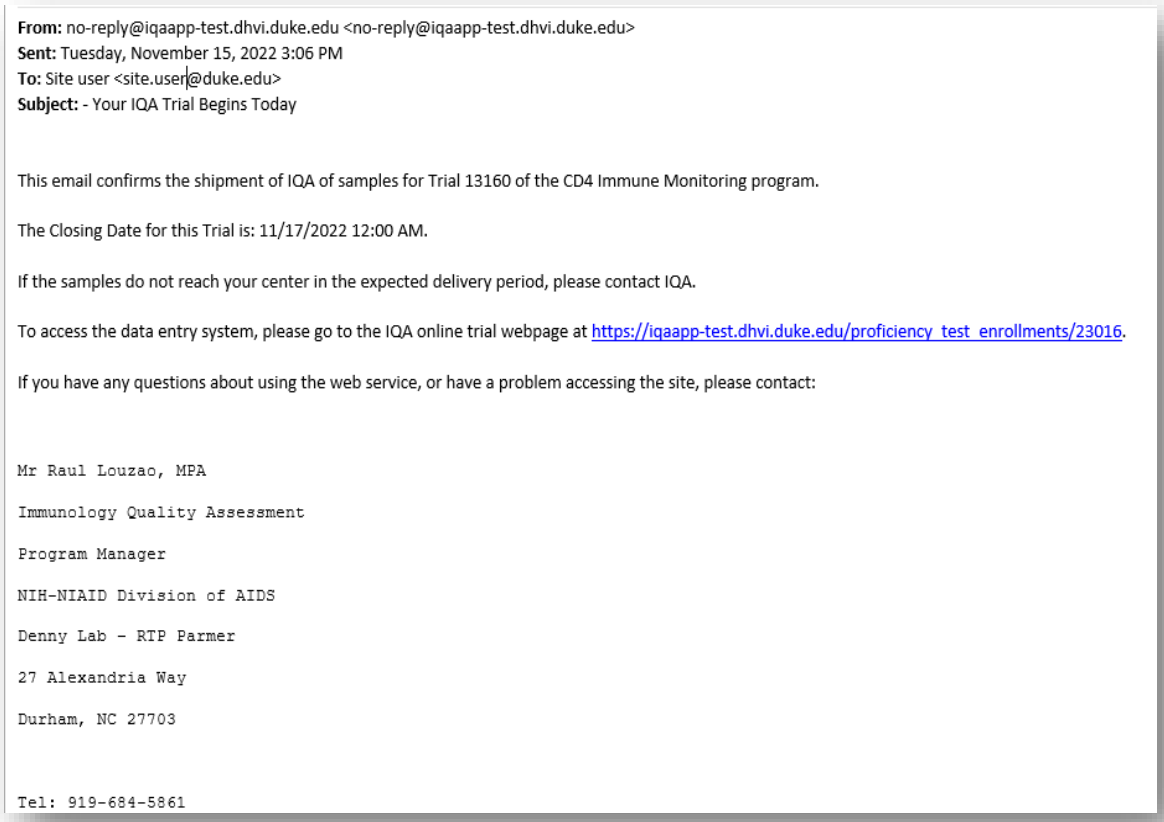
- The IQA system can be accessed through https://iqaapp.dhvi.duke.edu after completing the initial registration.
- The log-in page will prompt you to enter your email address and password.
- If a user fails to enter his/her password after four consecutive attempts, the account will be locked for 15 minutes. The user account will automatically unlock after 15 minutes.
- If a user forgets their password, select "Forgot/Reset your password" where the user will enter their email address.
    - Once you enter the user's email address, a link to reset your password will be sent to you via email.
- The selection "Sign in with DHE Credentials" is for Duke-based users only.

- **The following page is an example of the Sign in page.**



IV. Data Entry

- Once a trial becomes active, an email will be sent to the site informing them about the trial.
- If results are not submitted by the trial end date, the results will be counted as late.
- **The following is an example of the email the user will receive when a trial is available for submitting results:**



From: no-reply@iqaapp-test.dhvi.duke.edu <no-reply@iqaapp-test.dhvi.duke.edu>
Sent: Tuesday, November 15, 2022 3:06 PM
To: Site user <site.user@duke.edu>
Subject: - Your IQA Trial Begins Today

This email confirms the shipment of IQA of samples for Trial 13160 of the CD4 Immune Monitoring program.

The Closing Date for this Trial is: 11/17/2022 12:00 AM.

If the samples do not reach your center in the expected delivery period, please contact IQA.

To access the data entry system, please go to the IQA online trial webpage at https://iqaapp-test.dhvi.duke.edu/proficiency_test_enrollments/23016.

If you have any questions about using the web service, or have a problem accessing the site, please contact:

Mr Raul Louzao, MPA

Immunology Quality Assessment

Program Manager

NIH-NIAID Division of AIDS

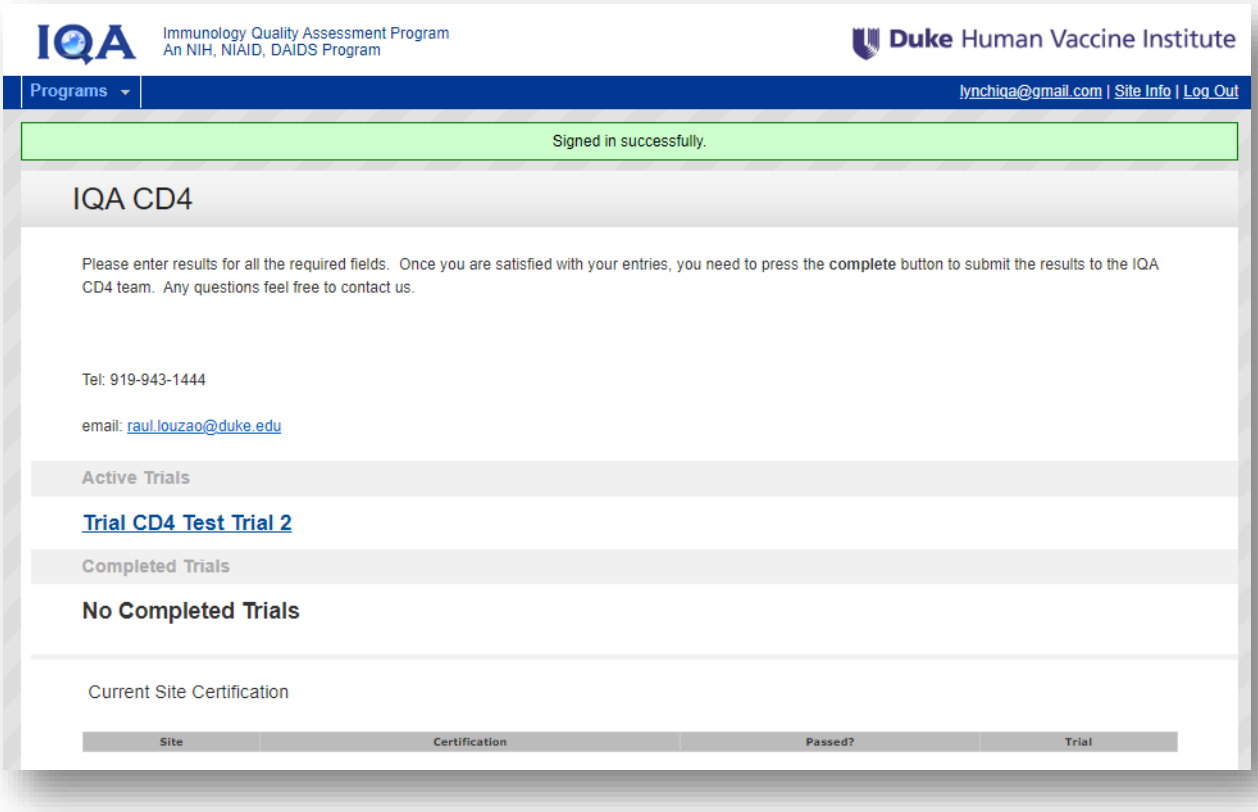
Denny Lab - RTP Parmer

27 Alexandria Way

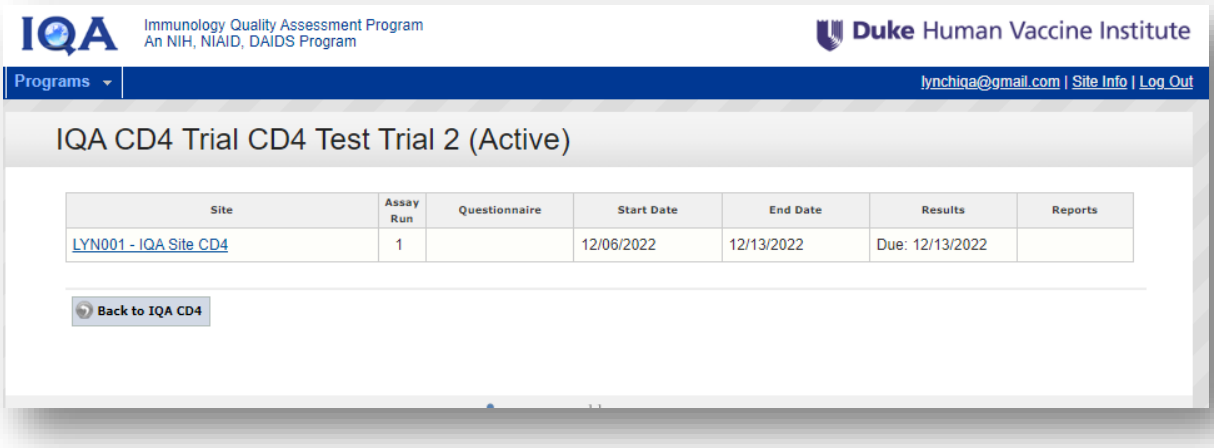
Durham, NC 27703

Tel: 919-684-5861

- After the site receives the email announcement, the user will have access to the IQA CD4 Proficiency program upon system log in.
- Once the proficiency test is active, the user will see a list of all active and completed trials. **The following is an example of the program page displaying an active trial:**



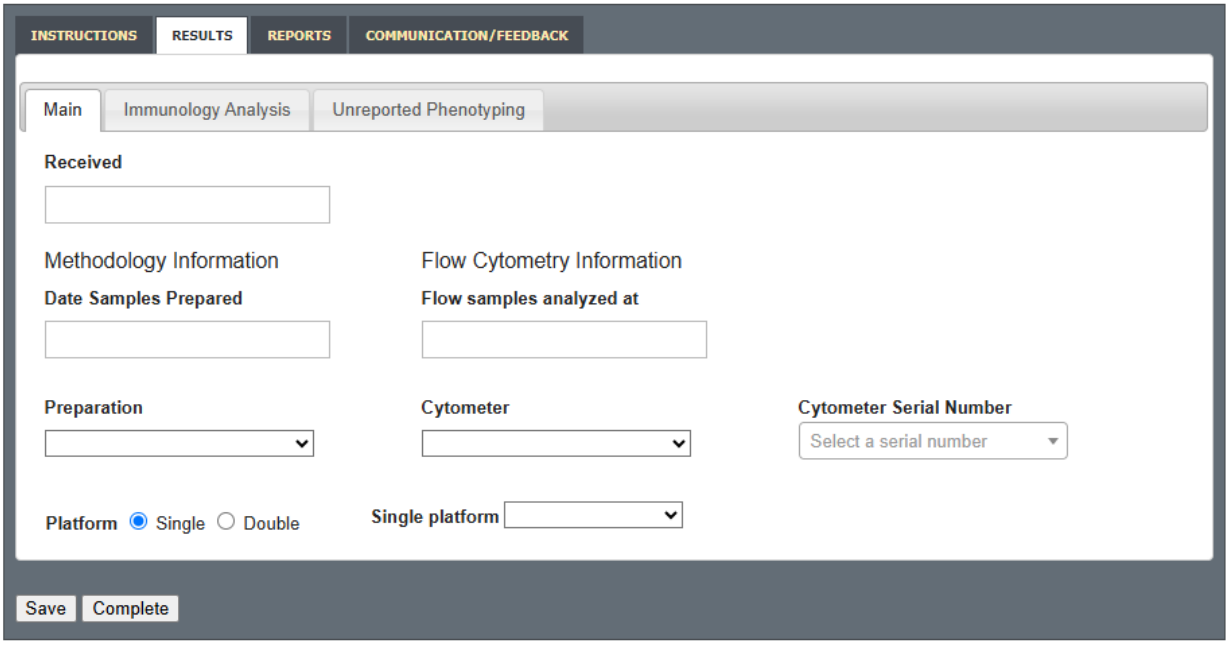
- Click on the name of the active trial. The next page (trial page) will display a row with your site name. The trial start date and the trial end date for submitting results will appear on the page. **The following is an example of this page:**



- **The following is an example of the page that will be displayed after a user clicks on their site's name:**



- To enter test results, click on the "Results" tab. **The following page will appear after clicking on the "Results" tab:**



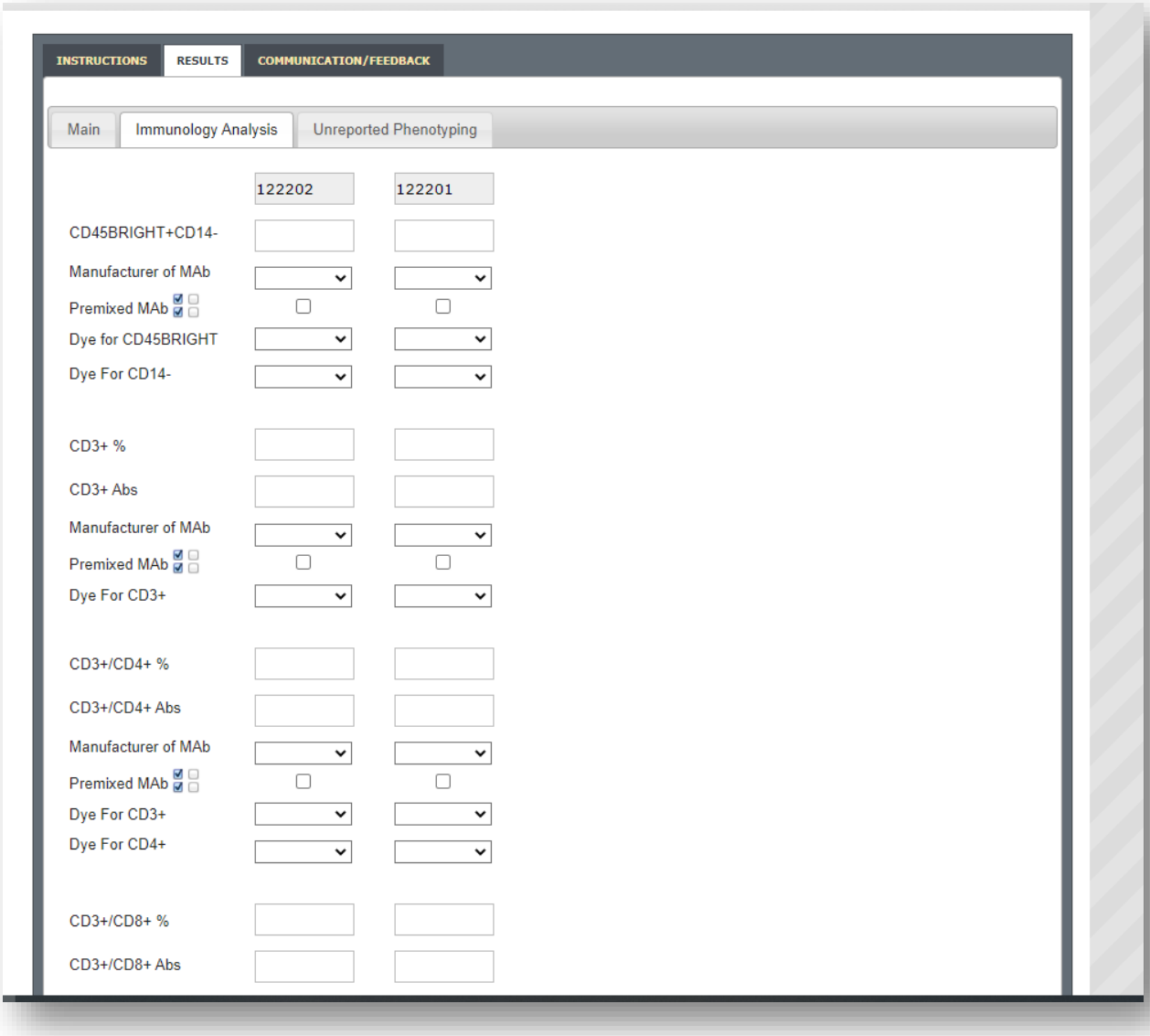
- The user will enter information on the tabs (Main, Immunology Analysis) located on the Results page. The "Unreported Phenotyping" tab will be used to report values not reported for samples.
- The following fields are required on the Main tab page:
    - Received -
    - Date Samples Prepared
    - Flow Samples analyzed at
    - Preparation
    - Cytometer
    - Cytometer Serial Number

Note: The platform defaults to Single but can be changed by clicking the Double checkbox.

- The "Single platform" field is optional.
- If "Double" is selected for the platform, the following fields are required on the Main tab page:
    - Date Samples Prepared
    - Flow Samples analyzed at
    - Preparation
    - Cytometer
    - Cytometer Serial Number
    - Platform

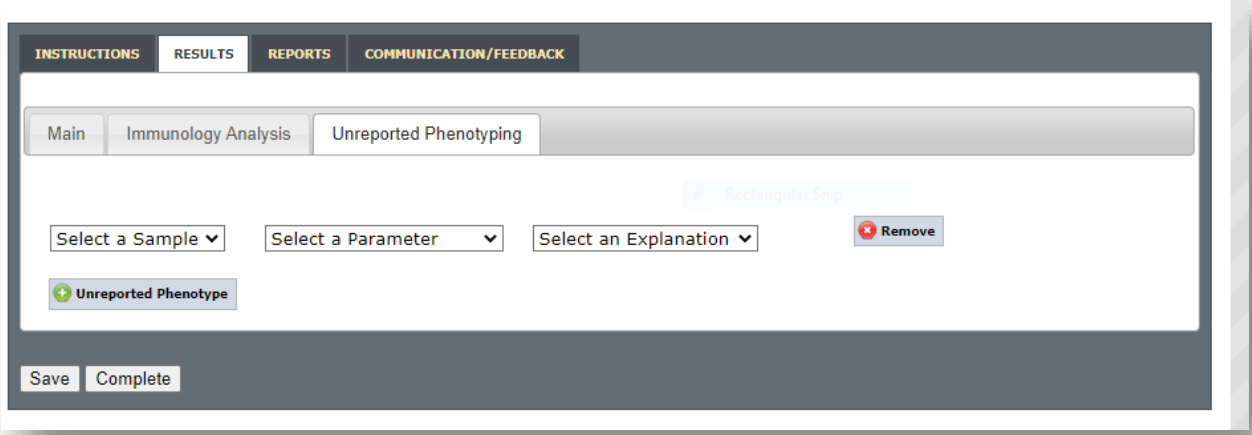
Note: Once a cytometer serial number is manually input one time, it will be available for future submissions as a drop-down option. The user should fill in the "Cytometer" field before the "Cytometer Serial Number" field.

- Complete the questionnaire if one exists by selecting the text “Fill out the Questionnaire”.
- Click on the Immunology Analysis tab to enter your sample results. **The following is an example of the Immunology Analysis page:**

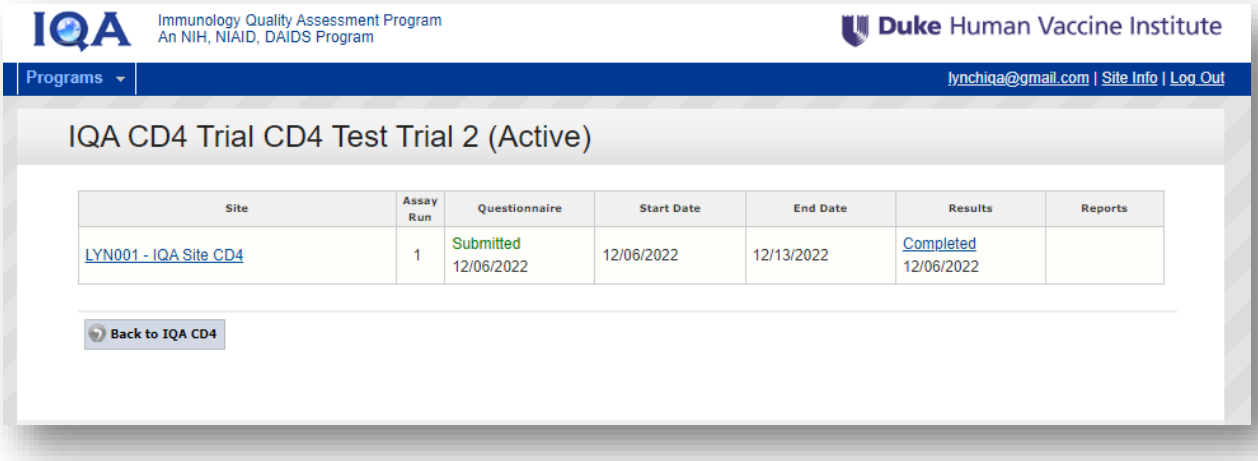


- All fields on the Immunology Analysis page are optional**.**
- Each field is validated when the user enters a value into a field. If the user enters an invalid value, an error message will be issued and the value can be corrected.
    - % values must be entered to 2 decimal places. If 2 decimal places are not available, use trailing zeroes to achieve 2 decimal places.
    - Absolute count values must be a whole number. If a whole number is not available, round to the nearest whole number.

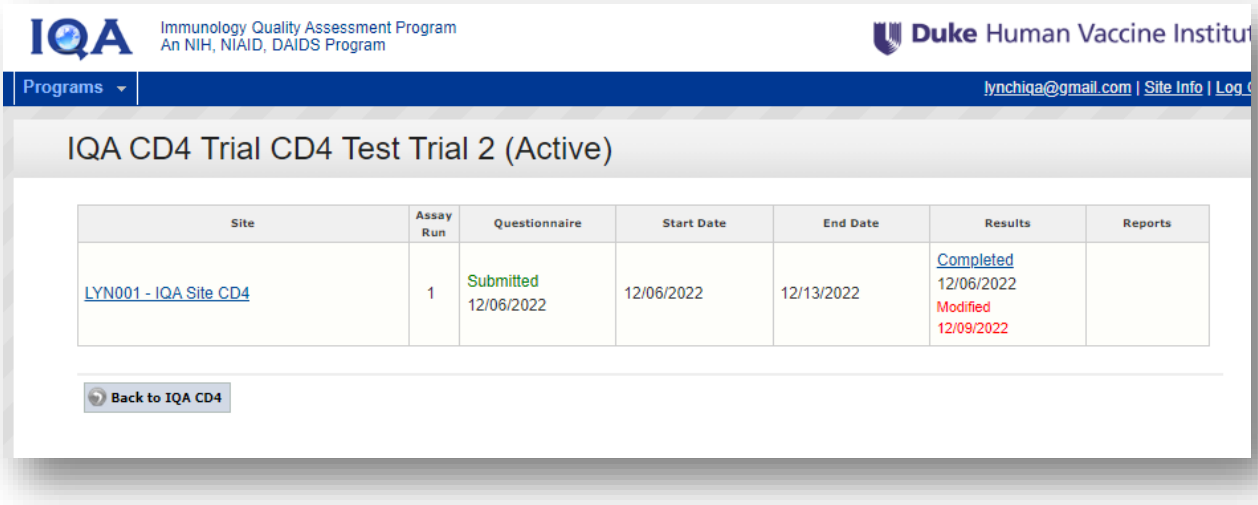
- **The following is an example of the Unreported Phenotyping page:**



- After the user enters their results, they can click the "Save" or the "Complete" button. By pressing "Save", a copy of the results will be saved in the system, but it will not be recorded as final until you mark your results as "Complete".
    - Selecting "Save" will save a copy of the results data
    - Selecting "Complete" will both save your results data and submit your results as final.
- After the data results have been submitted successfully, the date the site submitted their results will be displayed on the trial page. **The following is an example of the page after the questionnaire and the results have been submitted.**

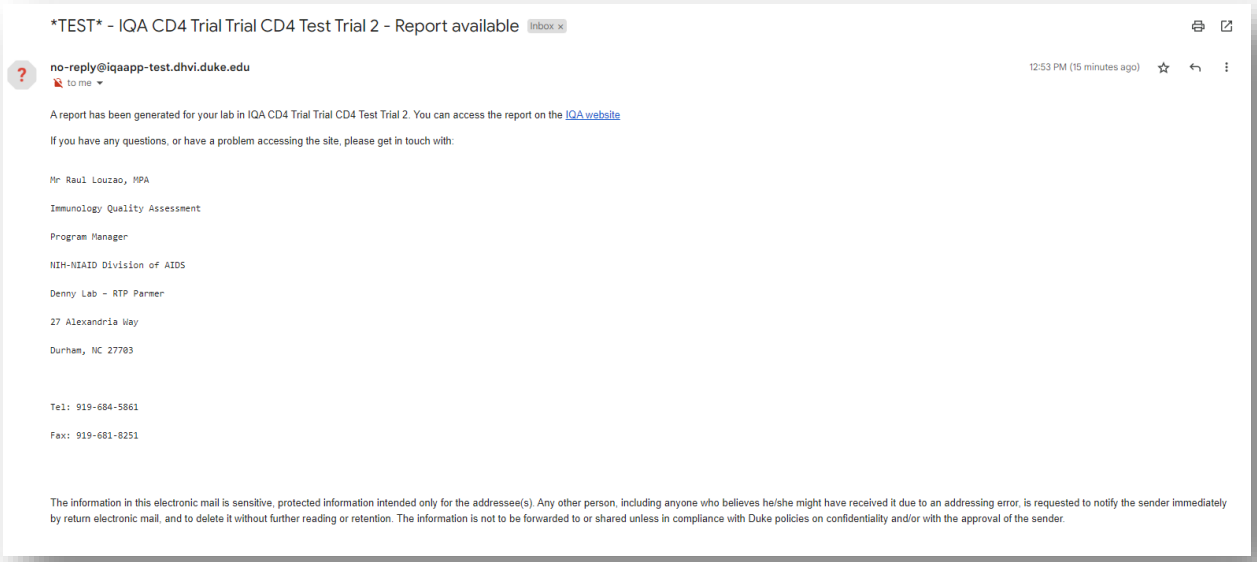


- If changes are needed after submitting your results, IQA management can unlock your results, which will allow modifications to be made. The results will display the word, "Modified" under the Completed date if the results were changed and re-submitted. **The following page shows the results were modified:**



V. Retrieving Site Specific Report

- After the results have been submitted, the IQA management team will complete their analysis of the site's results, and a site-specific report will be generated and uploaded to the website.
- Once the report has been uploaded, an email will be sent to the primary site user informing them the report is ready to be reviewed. **The following is an example of the report available email:**



TEST - IQA CD4 Trial Trial CD4 Test Trial 2 - Report available Inbox ×

no-reply@iqaapp-test.dhvi.duke.edu 12:53 PM (15 minutes ago)

to me

A report has been generated for your lab in IQA CD4 Trial Trial CD4 Test Trial 2. You can access the report on the IQA website

If you have any questions, or have a problem accessing the site, please get in touch with:

Mr Raul Louzao, MPA

Immunology Quality Assessment

Program Manager

NIH-NIAID Division of AIDS

Denny Lab - RTP Parmer

27 Alexandria Way

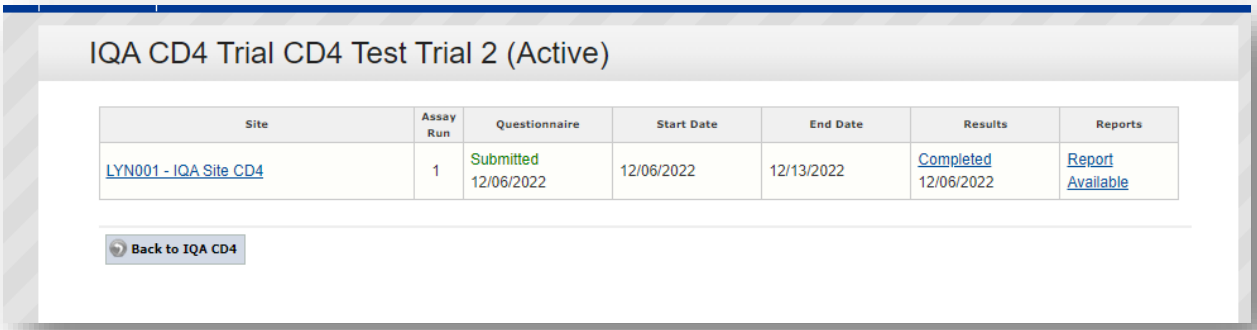
Durham, NC 27703

Tel: 919-684-5861

Fax: 919-681-8251

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- When the report is available for review, the text under the report column will state "Report Available". **The following is an example:**

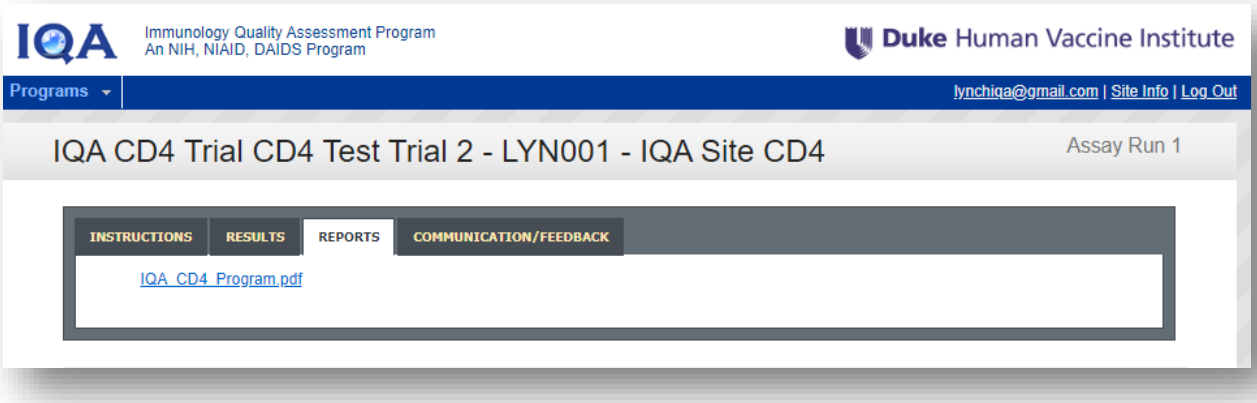


IQA CD4 Trial CD4 Test Trial 2 (Active)

Site	Assay Run	Questionnaire	Start Date	End Date	Results	Reports
LYN001 - IQA Site CD4	1	Submitted 12/06/2022	12/06/2022	12/13/2022	Completed 12/06/2022	Report Available

Back to IQA CD4

- To access the report, select the "Reports" tab.
- After the report has been uploaded, the user can view/download the report by selecting the file. **The following is an example of the Report tab:**



VI. Current Site Performance Ratings

- The site user will be able to see their site's current performance rating based on the last trial assessment. The ratings will appear on the IQA CD4 program page. **The following is an example of the performance rating displayed for a site:**

