



Limited Antigen Avidity (LA_g) Incidence Assay EQA Program

Orientation: EQA Send-out Process

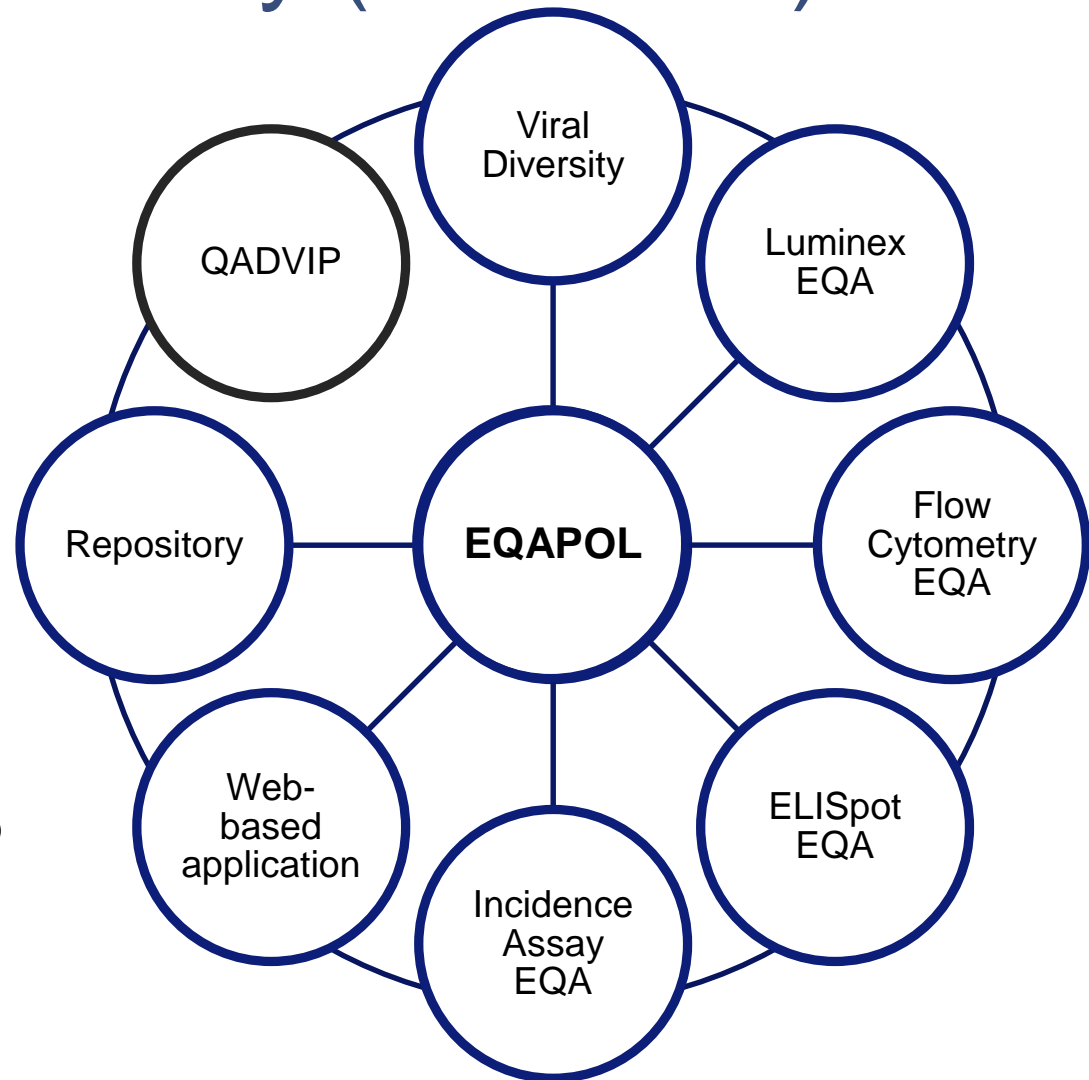
Overview: EQAPOL Web-based application

Presentation Outline

- Overview of EQAPOL
- Overview of EQAPOL LAg EQA
- General EQA Process
- Participation in a LAg-based EP
 - What you will receive
 - Web-based System
 - Reports and Remediation
- New EQAPOL document of recognition

External Quality Assurance Program Oversight Laboratory (EQAPOL)

- NIAID/DAIDS-sponsored 7-year contract
- Eight components to support HIV/AIDS research and vaccine trials
- Goal of EQAPOL: help sites improve



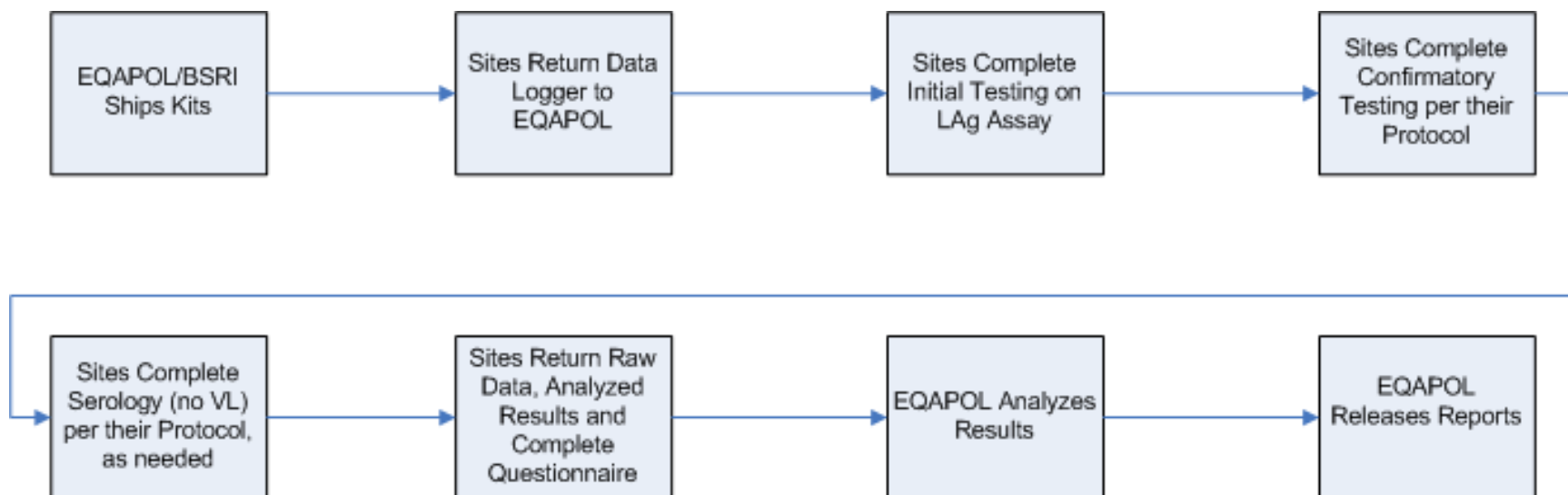
Introduction to LAg Incidence Program

- The EQAPOL LAg Program is modeled after the CDC BED Proficiency Testing Program
 - EQAPOL collaboration with VRI and CDC
- Program will initially only include Sedia and Maxim LAg assays
- The EQAPOL LAg EQA Program will assess the following measures:
 - the range of responses detected by the lab;
 - the precision of the measurements (i.e., replicates);
 - the comparison of the results to what is observed among labs;
 - the ability to properly classify recent vs. long-term infections as well as ability to properly run serology assays for HIV status
- **Site grading first implemented in EP3. The purpose of grading is to examine differences in assay results across multiple sites**

Pilot LAg Program

- A pilot study was conducted in December 2014 with EQAPOL, BSRI, the CDC, and two select sites to explore the feasibility of launching a proficiency testing program using the LAg Avidity Assays
- As a result of the study, EQAPOL was approved to launch a formal program in 2015
- EQAPOL used the participant list from the BED Program as a guide for enrolling sites

Send-out Workflow



What your site will receive

- **One shipment with packing manifests will be sent to your site**
 - **BOX 1:** Dry ice shipment containing 26 test samples – *store at -80°C*
 - **Please note that your site must supply the assay kit (Sedia and/or Maxim)**
- **Data Logger**
 - Temperature monitor that is a USB drive in the shipment box. It tracks the temperature of the box/samples to ensure that they maintain -80°C.
 - Upon receipt deactivate the data logger according to the protocol and submit the data in the web portal.
- **Assay Protocol**
 - Thoroughly familiarize yourself with all aspects of the EP-specific protocol
 - Be sure your plate reader is fully functional and QC'd prior to thawing any kit components
 - Please do not deviate from the provided protocol
 - Submit data to EQAPOL within 4 weeks of kit receipt
- **Files on Web-based System**
 - Protocol
 - Excel Reporting Template/Data Management Tool
 - Questionnaire

Excel Data Management Tool for LAg Testing Results

- File provided is essentially identical to CDC data management tool for LAg assays
- When saving the file, please use the following naming convention:
 - EPX_LAg Data Management File Maxim_SiteXXX
 - Simply replace the XXX with your site number
- There are multiple tabs within the file for the various steps in the assay process
- This file will be uploaded to the EQAPOL Web System

What to do with your EP data

- **Determine ODn of Test Samples**

- Using your lab-specific method, your site will determine the following:
 - ODn values for all 13 human plasma samples; 3 of these are near cutoff that are not graded
 - Prepare Excel Data Reporting Template with ODn values and classifications

- **Data Reporting**

- Sites will upload XLS File
- Sites will Report ODn values, serology results and sample classifications.
- Sites will complete post-assay questionnaire
- All EP data reporting will take place via the EQAPOL web-based application:
 - Please make sure you have access to the web system and have completed registration
 - Upload results using the provided Excel Template and post ODn values and classifications using the web-based Application

<https://eqapolapp.dhvi.duke.edu>



Overview: EQAPOL Web-based application

EQAPOL Web-based System: Log In

<https://eqapolapp.dhvi.duke.edu>



External Quality Assurance Program Oversight Laboratory
An NIH, NIAID, DAIDS Program



Sign In

Email

Password

[Forgot/Reset your password](#)

Sign in

[Sign in with DHE credentials](#)

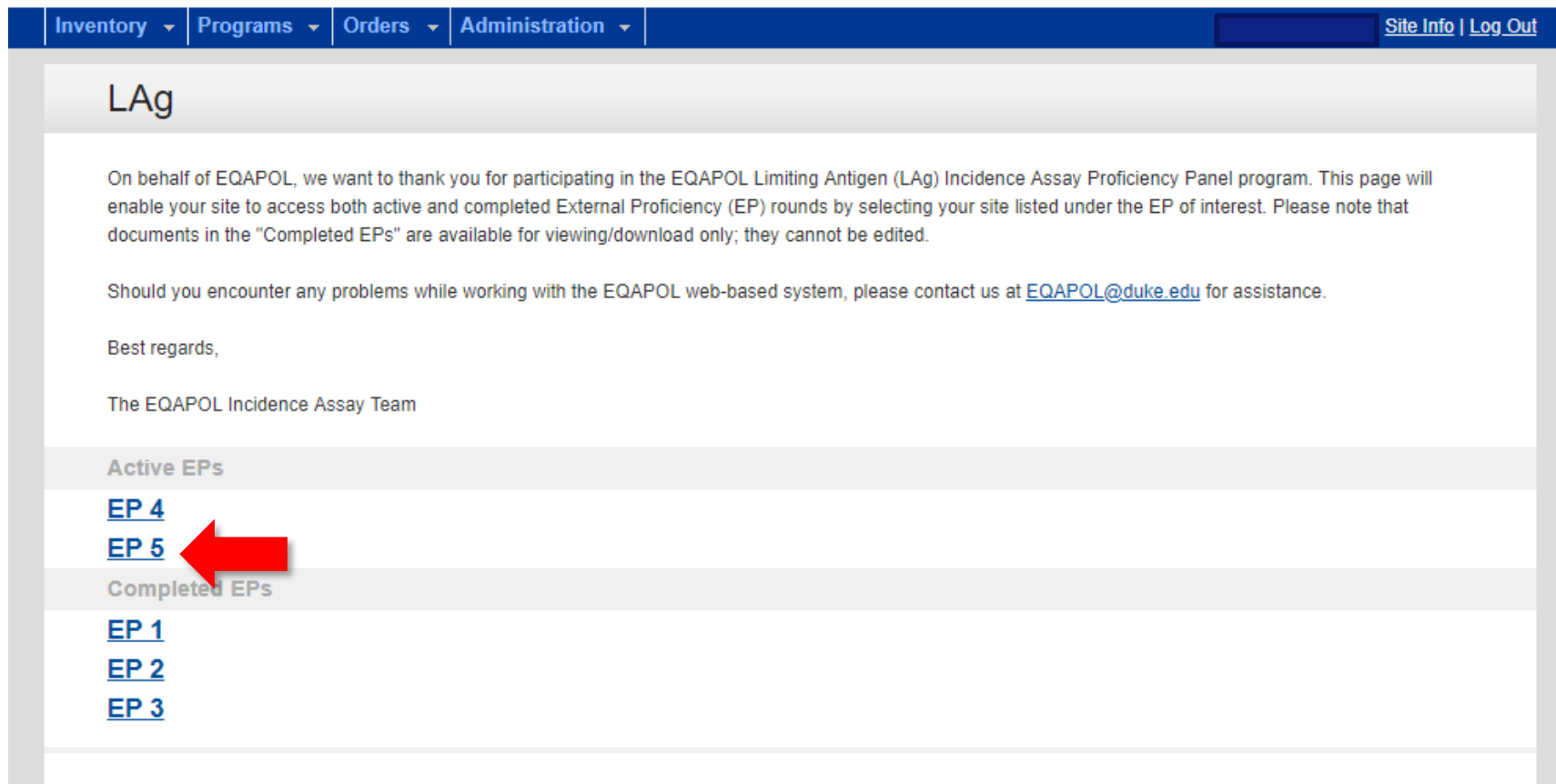
EQAPOL is a U.S. Government information System. Use of the system indicates consent to monitoring, recording, and auditing. Unauthorized use is prohibited and subject to criminal and civil penalties.

[Contact Us](#)

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Eqapol Prod1 - 2.18.1

Select Active “EP” from the LAg Program Page



The screenshot shows a web application interface with a dark blue navigation bar at the top containing the following tabs: Inventory, Programs, Orders, and Administration. On the right side of the navigation bar, there is a search box and links for Site Info and Log Out. Below the navigation bar, the page title is "LAg". The main content area contains a welcome message from EQAPOL, a contact email address (EQAPOL@duke.edu), and a sign-off from the EQAPOL Incidence Assay Team. Below the sign-off, there are two sections: "Active EPs" and "Completed EPs". Under "Active EPs", there are links for EP 4 and EP 5. A red arrow points to the EP 5 link. Under "Completed EPs", there are links for EP 1, EP 2, and EP 3.

Inventory ▾ Programs ▾ Orders ▾ Administration ▾ Site Info | Log Out

LAg

On behalf of EQAPOL, we want to thank you for participating in the EQAPOL Limiting Antigen (LAg) Incidence Assay Proficiency Panel program. This page will enable your site to access both active and completed External Proficiency (EP) rounds by selecting your site listed under the EP of interest. Please note that documents in the "Completed EPs" are available for viewing/download only; they cannot be edited.

Should you encounter any problems while working with the EQAPOL web-based system, please contact us at EQAPOL@duke.edu for assistance.

Best regards,

The EQAPOL Incidence Assay Team

Active EPs

- [EP 4](#)
- [EP 5](#)

Completed EPs

- [EP 1](#)
- [EP 2](#)
- [EP 3](#)

*** Some options will not be available for your site*

Select your Site under the Current EP

LAg EP 1 (Active)

We appreciate your participation in the Limiting Antigen (LAg) Incidence Assay External Proficiency Program developed and managed by EQAPOL.

Please follow the instructions below to complete EP1:

1. Upon receipt of your LAg EP1 shipments, navigate to the "Send-out" tab and mark shipments as "received." If any shipment issues were noted, please record them here.
2. Download the protocol provided below and use it to perform the LAg assay using the EQAPOL-provided samples. *Please do not deviate from the protocol.*
3. Download the Excel template below and complete it using the instructions provided in the protocol. Copy and paste the values into the appropriate cells of the template.
4. Once you have completed the assay, please navigate to the "Results" tab and complete the post-assay questionnaire and upload your Excel file. Complete the questionnaire by selecting "Fill out the Questionnaire."
5. For data upload: Browse for and upload your completed Excel data template as a "Results Spreadsheet." *There is no need to upload results as "Additional Files." Only the completed Excel workbook is required for EP1.*
6. Once the workbook is uploaded, you must save and then submit your results. *Note: Pressing "Save" will only save a copy of the file to the system. It will not be recorded as final until you press "Submit". Shortcut: pressing "Submit" will both save and submit the file as final in one step.*
7. Once your file is submitted you will not be able to add or edit files unless you contact us at EQAPOL@duke.edu.
8. Once your file is submitted, you will navigate to the "Direct Entry Results" tab to manually enter your results.

Should you have any questions about EP1 or need assistance with

Thank you for your participation in EP1,

The EQAPOL LAg Incidence Assay Team

Snapshot of EP status

Site	Assay Run	Send-Out	Results File	Direct Entry Results	Reports
EQAPOL	1		Due date not yet set	Due date not yet set	
EQAPOL	2		Due date not yet set	Due date not yet set	

- Only sites for which you are a part of will display on this page
- Sites running two kits will see their site listed twice as above

Download
Protocol and
Template

Shipment
Information

Upload Excel
Reporting
Template and
Complete
Questionnaire

Directly enter
results

Discussion between
Site and EQAPOL

Assay Run 1

INSTRUCTIONS

SEND-OUT

RAW RESULTS

DIRECT ENTRY RESULTS

COMMUNICATION/FEEDBACK

We appreciate your participation in the Limiting Antigen (LAG) Incidence Assay External Proficiency Program developed and managed by EQAPOL.

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8. Once your file is submitted, you will navigate to the "Direct Entry Results" tab to manually enter your results.

Should you have any questions about EP1 or need assistance with the web-based system, please do not hesitate to contact us.

Thank you for your participation in EP1,

The EQAPOL LAG Incidence Assay Team

Acknowledge Receipt of Shipments

INSTRUCTIONS RAW RESULTS TITER RESULTS SEND-OUT CENTRALIZED ANALYSIS DISCUSSION/REMEDATION

Shipment #11301

Shipped: 07/22/2014 12:45 PM
Courier: FedEx
Tracking #: 6873413684
Documents: No Documents

Item	Global Spec ID	Quantity	Volume
5G4F7	5G4F7	1	80.0 µL
7G39G	7G39G	1	80.0 µL
J9K3P0	J9K3P0	1	80.0 µL
O4P2L1	O4P2L1	1	80.0 µL
HIV-TRO.11.LucR.T2A.ecto.293T/17	201404087181P	1	1.0 mL
HIV-CH119.10.LucR.T2A.ecto.293T/17	201404087177P	1	1.0 mL
F5E5G	F5E5G	1	80.0 µL
T5Y6U	T5Y6U	1	80.0 µL
M4B9H	M4B9H	1	80.0 µL
X5E4L	X5E4L	1	80.0 µL
S4Q8N	S4Q8N	1	80.0 µL
R4G2K	R4G2K	1	80.0 µL
B3Y6O	B3Y6O	1	80.0 µL
Z9E5W	Z9E5W	1	80.0 µL
V7R2Y	V7R2Y	1	80.0 µL
C2A3T	C2A3T	1	80.0 µL
A4M1S	A4M1S	1	80.0 µL
B1J2L	B1J2L	1	80.0 µL
N5K2Q	N5K2Q	1	80.0 µL
F5E4U	F5E4U	1	80.0 µL
S4Q6M	S4Q6M	1	80.0 µL
X2G5R	X2G5R	1	80.0 µL

Received at:

Shipment issues:

Enter date when your shipment arrives and state whether there were issues with the samples

Acknowledge Receipt of Shipments

V7R2Y	V7R2Y	1	80.0 µL
C2A3T	C2A3T	1	80.0 µL
A4M1S	A4M1S	1	80.0 µL
B1J2L	B1J2L	1	80.0 µL
N5K2Q	N5K2Q	1	80.0 µL
F5E4U	F5E4U	1	80.0 µL
S4Q6M	S4Q6M	1	80.0 µL
X2G5R	X2G5R	1	80.0 µL

Received at:

Shipment issues:

Please describe the issues with your shipment:

Update Shipment

Change "Shipment Issues" to "Yes" to note any shipping issues and select "Update Shipment"

Completing Questionnaire

LAg EP 1 - Assay Run 1

INSTRUCTIONS **SEND-OUT** **RAW RESULTS** **DIRECT ENTRY RESULTS** **COMMUNICATION/FEEDBACK**

Questionnaire [Fill out the Questionnaire](#) ← **Select to take Questionnaire**

Results spreadsheet No file chosen

Additional files No file chosen

Comments [Add Comment](#)
There are no comments

All answers will be lost unless you press the submit button. You cannot change your answers after they are submitted unless you contact us (EQAPOL@duke.edu).

Upload Completed XLS Template: Select “Raw Results”

LAg EP 1 - Assay Run 1

INSTRUCTIONS **SEND-OUT** **RAW RESULTS** **DIRECT ENTRY RESULTS** **COMMUNICATION/FEEDBACK**

Questionnaire [Fill out the Questionnaire](#)

Results spreadsheet No file chosen

Additional files No file chosen

Comments [Add Comment](#)

There are no comments

Upload data logger PDF
under “additional files”

Save will enable you to delete and upload new documents if needed. Results will not be final

Submit will indicate you are done with the EP. Documents can no longer be uploaded without contacting EQAPOL

Direct Entry

INSTRUCTIONS SEND-OUT RAW RESULTS **DIRECT ENTRY RESULTS** COMMUNICATION/FEEDBACK

Not yet submitted

Kit Type

Calibrator Data

Initial Test QC		Confirmatory Test QC	
	Initial OD		Confirmatory OD
Neg a	<input type="text"/>	Neg a	<input type="text"/>
Neg b	<input type="text"/>	Neg b	<input type="text"/>
CAL a	<input type="text"/>	CAL a	<input type="text"/>
CAL b	<input type="text"/>	CAL b	<input type="text"/>
CAL c	<input type="text"/>	CAL c	<input type="text"/>
LPC a	<input type="text"/>	LPC a	<input type="text"/>
LPC b	<input type="text"/>	LPC b	<input type="text"/>
LPC c	<input type="text"/>	LPC c	<input type="text"/>
HPC a	<input type="text"/>	HPC a	<input type="text"/>
HPC b	<input type="text"/>	HPC b	<input type="text"/>
HPC c	<input type="text"/>	HPC c	<input type="text"/>


Paste Spreadsheet Results here to auto-fill columns:

Paste Spreadsheet Results here to auto-fill columns:

Select Sedia/Maxim

Calibrator Results

Copy these cells from Excel File (Initial Results and Confirmatory Results)



Spec ID	OD	Media	ODn
Neg 1a	0	0.000	#DIV/0!
Neg 1b	0		
CAL 1a	0	0.000	#DIV/0!
CAL 1b	0		
CAL 1c	0		
LPC 1a	0	0.000	#DIV/0!
LPC 1b	0		
LPC 1c	0		
HPC 1a	0	0.000	#DIV/0!
HPC 1b	0		
HPC 1c	0		

Direct Entry

INSTRUCTIONS SEND-OUT RAW RESULTS **DIRECT ENTRY RESULTS** COMMUNICATION/FEEDBACK

Not yet submitted


Kit Type

Calibrator Data

Initial Test QC		Confirmatory Test QC	
	Initial OD		Confirmatory OD
Neg a	<input type="text"/>	Neg a	<input type="text"/>
Neg b	<input type="text"/>	Neg b	<input type="text"/>
CAL a	<input type="text"/>	CAL a	<input type="text"/>
CAL b	<input type="text"/>	CAL b	<input type="text"/>
CAL c	<input type="text"/>	CAL c	<input type="text"/>
LPC a	<input type="text"/>	LPC a	<input type="text"/>
LPC b	<input type="text"/>	LPC b	<input type="text"/>
LPC c	<input type="text"/>	LPC c	<input type="text"/>
HPC a	<input type="text"/>	HPC a	<input type="text"/>
HPC b	<input type="text"/>	HPC b	<input type="text"/>
HPC c	<input type="text"/>	HPC c	<input type="text"/>

Paste Spreadsheet Results here to auto-fill columns:

Paste Spreadsheet Results here to auto-fill columns:

Paste data here 

Direct Entry of Results

Panel Results

Sample Code	Initial ODn	Confirmatory ODn (if done) <input type="checkbox"/> N/A	Confirmatory Replicate 1 OD	Confirmatory Replicate 2 OD	Confirmatory Replicate 3 OD	Serology	Classification
C4E8Z8	<input type="text"/>	<input type="text"/> <input type="checkbox"/> N/A	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Pos <input type="radio"/> Neg <input type="radio"/> IND <input type="radio"/> N/A	<input type="radio"/> Recent <input type="radio"/> Long Term <input type="radio"/> N/A
D2D4H0	<input type="text"/>	<input type="text"/> <input type="checkbox"/> N/A	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Pos <input type="radio"/> Neg <input type="radio"/> IND <input type="radio"/> N/A	<input type="radio"/> Recent <input type="radio"/> Long Term <input type="radio"/> N/A
U5O4T8	<input type="text"/>	<input type="text"/> <input type="checkbox"/> N/A	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Pos <input type="radio"/> Neg <input type="radio"/> IND <input type="radio"/> N/A	<input type="radio"/> Recent <input type="radio"/> Long Term <input type="radio"/> N/A
C8H9M7	<input type="text"/>	<input type="text"/> <input type="checkbox"/> N/A	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Pos <input type="radio"/> Neg <input type="radio"/> IND <input type="radio"/> N/A	<input type="radio"/> Recent <input type="radio"/> Long Term <input type="radio"/> N/A
I4N8X3	<input type="text"/>	<input type="text"/> <input type="checkbox"/> N/A	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Pos <input type="radio"/> Neg <input type="radio"/> IND <input type="radio"/> N/A	<input type="radio"/> Recent <input type="radio"/> Long Term <input type="radio"/> N/A

Manually enter ODn values in the text boxes and click the appropriate radio button for final classifications. Click save and/or submit at bottom of screen when you are ready. You must click submit for results to be viewed at EQAPOL.

EQAPOL LAg: Grading Scheme

Criteria	Target	Max. Points
Timeliness	On time EP valid data and questionnaire upload	10
Protocol Adherence	Following protocol instructions and algorithm	24
Classification	Correct classification of recency status	48
Accuracy/ Precision	Statistically different from consensus average	18
	The within site variability must be included in 95% CI boundary	

Overall Performance:	
Excellent	91-100
Good	75-90
Fair *	66-74
Poor *	0-65

* Remediation Required

Reports

- Once the EP is closed and the Centralized Analysis is completed, reports will be made available in the EQAPOL web system.
- A new tab “Reports” will appear with the report file available for download.
- The reports will summarize the results and provide your site with a numerical score and grade category.
- Remediation calls are held with sites that receive a Fair or Poor score to help troubleshoot potential issues.

Troubleshooting, Support, Questions

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