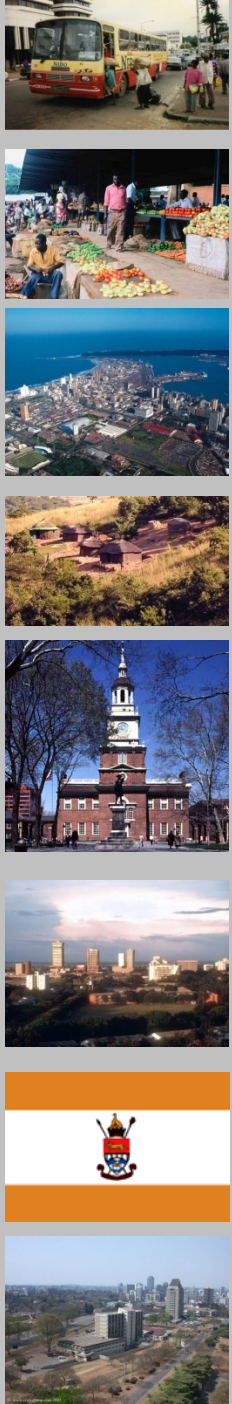# pSMILE, VQA, IQA Information

Or Everything you needed to know about IRs

Edward Livant MTN NL
Estelle Piwowar-Manning HPTN NL

Acronyms

pSMILE

PNL

DCLOT

LFG

X-network

HANC

EQA Review

pSMILE reviews CAP panels on a monthly basis. The week of the month depends on the staff assigned to the site.

PNL review CAP panels on a regular basis depending on the network/protocol. Typically HPTN and MTN reviews when notified that results are available on the CAP website (minimum weekly).

pSMILE

pSMILE will send out an email detailing the CAP results and any problems noted. The emails include the site CAP results, CAP booklet, a pSMILE report and an updated excel spreadsheet with all the sites on going results. Any IRs needed are included in the email with a 30 day deadline for submission. Any outstanding IRs are included.

Email is sent to DCLOT, all applicable network representatives, and site contacts.

IRs are needed for ANY failure < or = 80% on PROTOCOL ANALYTES

Internal Investigations are needed for any other failure on non Protocol analytes and shifts, trends, biases

Corrective version of the IR form must be used
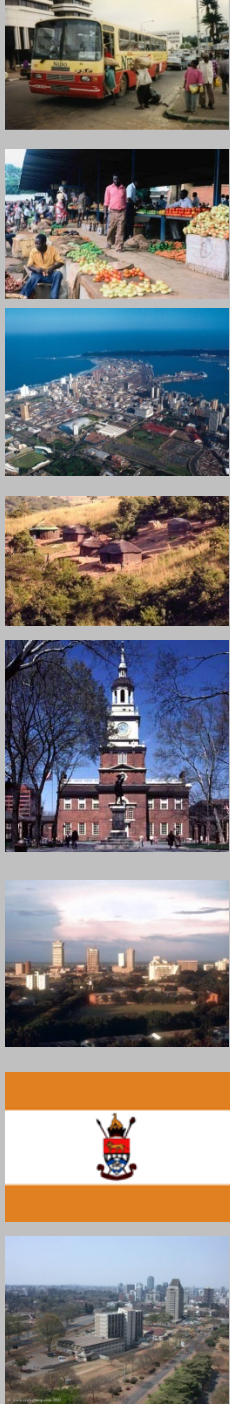
PNL

PNL will update the HANC portal with CAP information weekly:

    NO CAP results to report ***

    NO problems noted and the specific panel (100%) ***

    Problem Noted (80-99%) ***

    Failure

    Comment – detail information on problem or failure

*** No action taken, no communication with site

Failure will trigger the PNL to complete a form with information about the analyte and what the problem is. The PNL will state what their network decision is

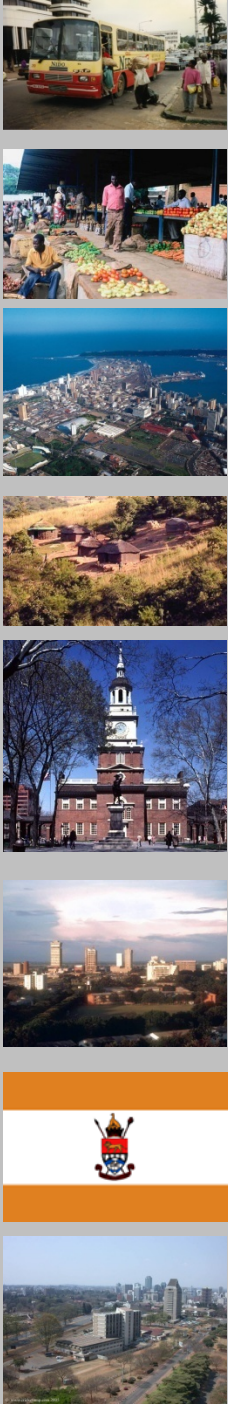   Continue testing

    Conditional testing

    STOP testing

Once completed, each network involved with the site is notified to complete the same form and make a decision.

NOTE that each network may have a different decision making process. Some use a 2 in a row or 2 out of 3 failure to STOP testing.

PNL is notified via email with the X Network decisions.

PNL EMAIL FAILURE Notification

In the meantime if a FAILURE is found by the PNL, the PNL will notify the site, DCLOT and xNetwork representatives:

Dear Lab Personnel

In reviewing your CAP results, we determined that there was a proficiency testing failure for your site for the following panel X-X 2008 ANALYTE (Previously X-X 2008 panel xxx%, X-X 2007 panel xxx%). We have attached the pdf of this CAP evaluation for your information.

Please begin investigating this proficiency testing failure at your site. Please document all activities related to your investigations on the SMILE Investigative Report form. This form can be found on the pSMILE website (www.psmile.org under "Quicklinks"). As your Primary Network Laboratory, we will need to review your Investigative Reports before they are submitted to SMILE. The major purpose of the PNL review is to ensure that the Investigative Report is consistent with network and /or protocol requirements. We will forward the Investigative Report forms to SMILE after review. SMILE will then either accept the Investigative Report or will contact you with recommendations for revision.

Within three working days you will also receive a Cross-Network Proficiency Testing Deficiency Response that will advise your site of the actions needed for each of the DAIDS-sponsored clinical trials networks currently active at your site.

Please let us know if we can be of any help.
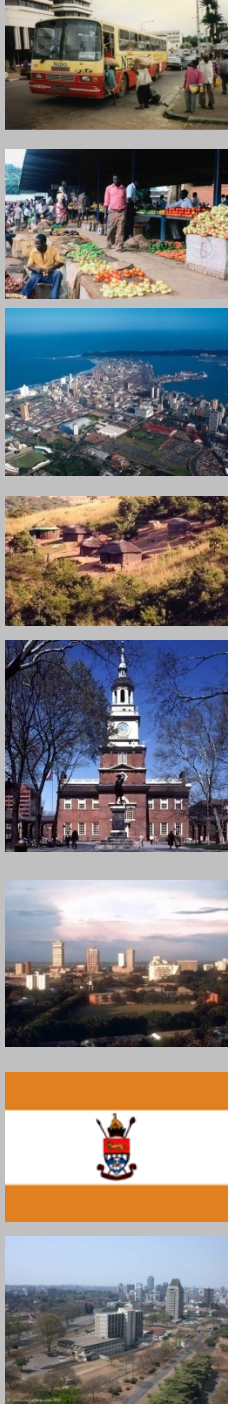
PNL X Network Decision

In the meantime the PNL will keep track of the X Network decisions on the HANC portal, assisting the other network representatives in completing the form. Once all involved networks have commented, the HANC portal sends the compiled X Network decision to the PNL. The PNL will forward the decision to the site, DCLOT and xNetwork representatives:

Detailed below is the cross network decision related to the recent failure on the X-X panel. The decision for the networks with active protocols at your site is to XXXX testing. (If stop testing, then this comment will appear - Please send your samples to your designated back up laboratory. This will need to be in place until you are reapproved for testing.)

Feedback has been collected for this item. Here is a summary:

Network: ACTG
PNL: OIRP\bokeefe
Date Submitted: 5/16/2008 6:16:34 AM
Feedback: The site will need to complete their corrective action.
Decision: continue testing

Network: HPTN
PNL: OIRP\epiwowa
Date Submitted: 5/14/2008 5:24:25 AM
Feedback: Site s0% on analyte A. This is a first failure.
Decision: continue testing

Network: IMPAACT
PNL: OIRP\kbanks
Date Submitted: 5/16/2008 7:33:23 AM
Feedback: First failure
Decision: continue testing

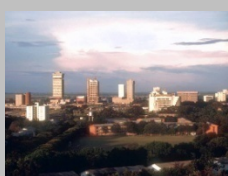--

Network: MTN
PNL: OIRP\rsiel
Date Submitted: 5/19/2008 7:47:02 AM
Feedback: First failure
Decision: continue testing

Site Responsibility

Review CAP participant report, pSMILE report, pSMILE excel file.
Review Results reported for clerical errors
Survey Material Issues
Method and instrument History review
QC information
Manufacturer consulted
Repeat analysis
Instrument calibration
Linearity review
Employee competency
Effect on participant results
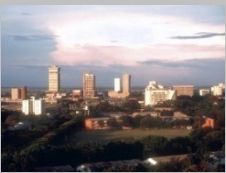Type of error
Root Cause Analysis
Future Preventative Measures

Complete, review, seek guidance from PNL and sign off by PNL

PNL submits to pSMILE for sign off

PNL, pSMILE, site work to resolve any queries

PNL

Deems corrective action has been met and or 2 panels have been successfully passed.

Closes the loop in the HANC portal.

VQA and IQA

VQA –sends results to site , DCLOT, X Network representatives
	PC results – site communicates with VQA about issues, potentially may repeat	panel
		P – VQA completes IR, sends to site and PNL
			site completes, may enlist PNL or VQA help in troubleshooting
			VQA and PNL sign off

IQA – work in progress.

Who Answers This Question?

For the following questions, who would you contact for the answer:

- **SMILE**

- **PNL**

- **A Network Lab**

- **Google**

- **DCLOT**

- **PPD**

Who Answers This Question?
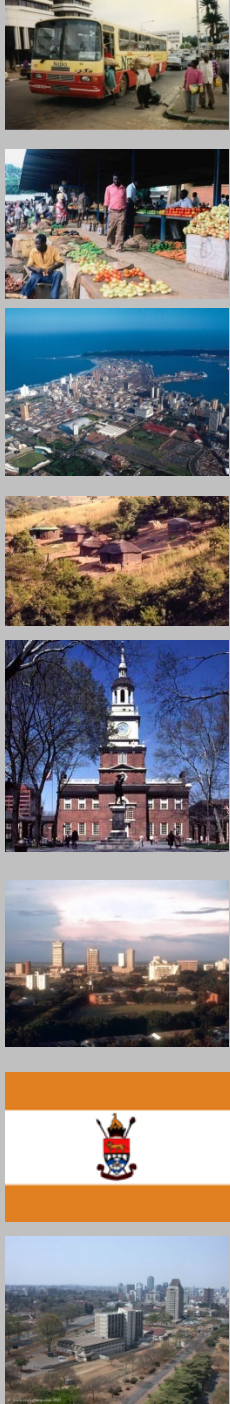
How do I validate a new method for viral load?

Answer:

Your PNL can help you. They will put you in touch with VQA.

For other safety tests the PNL or SMILE will handle the validation.

Flow Cytometry will be coordinated with IQA.

Note: If the test to be validated is very network specific, the PNL may refer you to the network.

Who Answers This Question?

Can I use non FDA-approved HIV rapid tests for an ACTG protocol?

Answer:

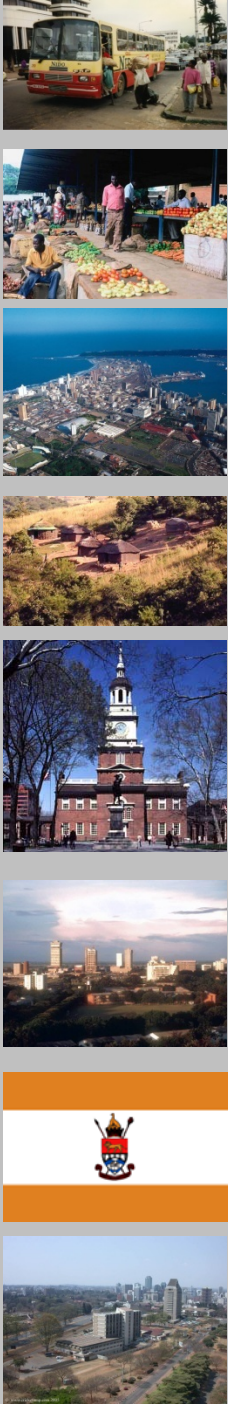## You must direct this to ACTG.

Who Answers This Question?

My Creatinine QC is running high and Roche isn't answering my emails. What do I do?

Answer:

The person to help you would be Paul Richardson, pricha18@jhmi.edu

Or The PNL, SMILE or Network Lab can help you.
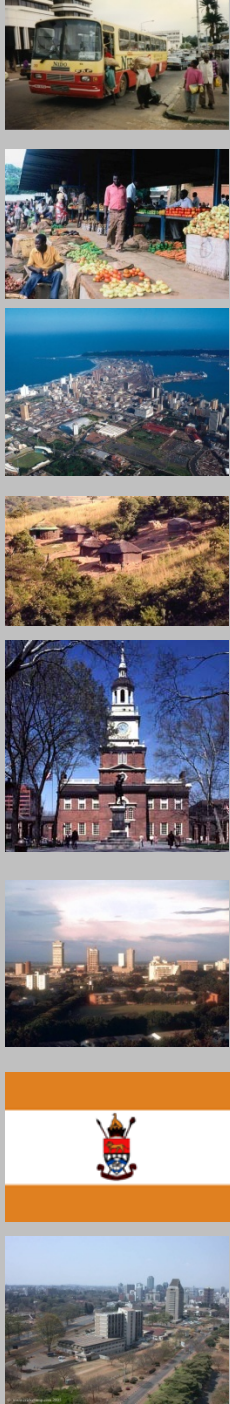
Who Answers This Question?

Prices have increased for Western Blot kits and I need the budget increased. Who do I ask?

Answer:

Site budgets come from **DAIDS** and do not involve **PNL** or **NL**. We can assist with justifications and help put you in touch with the correct people.

Contact the company to see if you can negotiate a better price.

Who Answers This Question?

I had 5 samples for MTN 015 that were not stored per protocol. How should I follow up?

Answer:

Contact the MTN Network Lab.

Who Answers This Question?

We run cholesterol for patients in our lab but not for any network studies. We discovered that expired reagents were used for a week. How should I follow up?
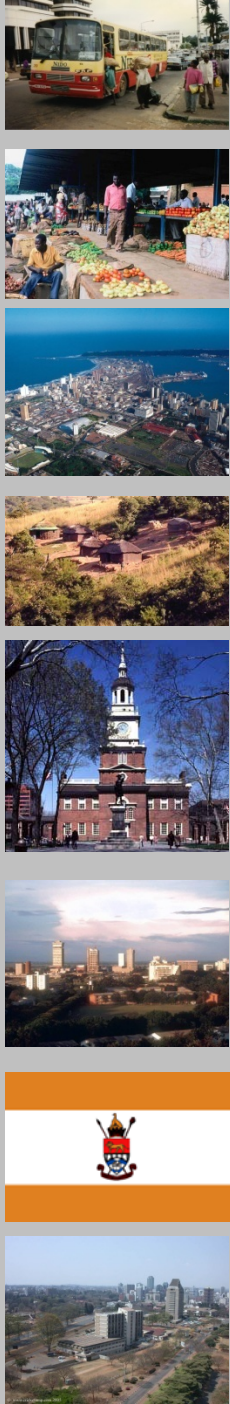
Answer:

You do not need to contact anyone from the networks if no network testing was affected. We can assist with advice in some cases but cannot make official recommendations.
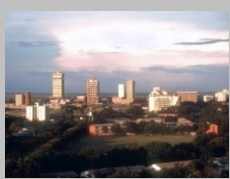
Follow local rules and laws for patient management.

Or Contact Paul Richardson pricha18@jhmi.edu

Who Answers This Question?

The PPD monitor said we needed an SOP for using the bathroom, that we had to calibrate our pipettes every 20 minutes and that we had to vortex all our EDTA samples before running FBC. Help!

Answer:

You should contact the PNL; both the HPTN and MTN Network Labs will also assist.

It is not allowable for site labs to contact PPD directly with questions.