

PT	Step	PNL	Affiliated NL	SMILE	DCLOT	LAB
100%	1	Enters "No problems noted" in the PTPT System.	--	Performs monthly review.	--	--
80-100%	1	Enters "Problems noted" in the PTPT System. The PNL has the option to contact the lab at this point to provide input into the IR. In this case, the PNL should copy SMILE on the correspondence.	--	Performs monthly review, sends the lab an IR request and the IR report form.	--	With guidance from the PNL and/or SMILE, prepares the IR and sends it to the PNL (HPTN, MTN) or SMILE (ACTG, IMPAACT, HVTN) for review.
⇒	2A HPTN and MTN	Reviews the IR from the lab, works with the lab to complete the IR. Signs off on the IR and sends it to SMILE. The sign-off by the PNL and transfer of the IR to SMILE are internal steps. The lab should not be contacted at this point.	--	Receives the IR from the PNL, discusses any outstanding issues with the PNL, and either accepts the IR or works with the PNL and the lab to finalize the IR. If revisions are made after PNL sign-off, the PNL should review and sign off on the revised IR before it is accepted by SMILE. Sends the PNL- and SMILE-approved IR to the lab and affiliated networks.	--	--
	2B ACTG, IMPAACT and HVTN	Receives the IR from SMILE and reviews it. Either accepts the IR or asks SMILE to work with the lab to finalize the IR. Signs the IR and transfers it back to SMILE. IR communication between the network and SMILE are internal steps.	--	Receives the IR from the lab, discusses any outstanding issues with the lab and the PNL, and either accepts the IR or works with the lab to complete the IR. Sends the IR to PNL for review and sign-off. Sends the PNL- and SMILE-approved IR to the lab and other affiliated networks.	--	--

PT	Step	PNL	Affiliated NL	SMILE	DCLOT	LAB
<80%	1	Enters "Failure" in the PTPT System and initiates PTPT workflow. Sends the <u>PNL Notification of PT Failure</u> within 1 working day. Uses approved text to notify the lab, copying affiliated NLs, SMILE, and DCLOT. Note: this process is the same even if SMILE has already identified the failure and contacted the lab.	Adds NL feedback and decision to the PTPT workflow within 2 working days of receiving notification of the PT failure. Notifies DCLOT and consults with DCLOT as necessary.	Notified	Has the option to assist the NLs in defining NL specific actions.	Receives <u>PNL Notification of PT Failure</u> and begins investigation.
⇒	2	Using the feedback provided through the PTPT System, sends <u>XN PT Deficiency Response</u> to the lab, copying affiliated NLs, SMILE, and DCLOT. This should occur within one working day after the NLs have added their feedback.	Notified	Notified	Notified	Receives <u>XN PT Deficiency Response</u> and confirms action plan.
⇒	3	--	--	Performs monthly review, sends the lab an IR request.	--	With guidance from the PNL and/or SMILE, prepares the IR and sends it to PNL (HPTN, MTN) or SMILE (ACTG, IMPAACT, HVTN) for review.

PT	Step	PNL	Affiliated NL	SMILE	DCLOT	LAB
⇒	4A	Receives the IR from the lab. Reviews the IR, works with the lab to complete the IR. Signs off on the draft version, and sends it to SMILE. The sign off by the PNL and transfer of the IR to SMILE are internal steps. The lab should not be contacted at this point.	Have an option to review the draft IR before it is submitted to SMILE.	Receives the IR from the PNL. Reviews the IR, discusses any outstanding issues with the PNL, and either accepts the IR or works with the lab and the PNL to finalize the IR. If revisions are made after PNL sign-off, the PNL should review and sign off on the revised IR before it is accepted by SMILE. Notifies the lab, DCLOT, and PNL of acceptance. Sends the PNL- and SMILE-approved IR to the lab and affiliated networks.	--	--
	HPTN and MTN					
	4B	Receives the IR from SMILE and reviews it. Either accepts the IR or works with the lab to finalize the IR. Signs the IR and transfer it back to SMILE.		Receives the IR from the lab. Reviews the IR, discusses any outstanding issues with the lab and the PNL, and either accepts the IR or works with the lab to complete the IR. Sends the IR to PNL for review and sign-off. Sends the PNL- and SMILE-approved IR to the lab and affiliated networks.	--	--
	ACTG, IMPAACT and HVTN					
	5	Notified.	Follows up with the lab and notifies the PNL, SMILE, DCLOT and lab when it is approved to resume testing.	Notified.	Notified.	Notified.

Abbreviations: XN = cross network; PTPT = Proficiency Testing Performance Tracking; IR = Investigative Report; PNL = Primary Network Laboratory; EQA = External Quality Assurance or proficiency testing; NL = Network Laboratory; DCLOT: DAIDS Clinical Laboratory Oversight Team.

Note: The level of involvement of the PNL in working with the lab on the preparation of Investigative Reports is expected to vary based on the type of EQA failure, the resources of the PNL, and other factors.

Time-line summary for PNL communication of PT failures:

Note: Only working days (M-F) are counted

Day	
1	The PNL finds a failure result
2	Deadline for the PNL to log in the result in the PTPT System and start the workflow, and to send the <u>PNL Notification of PT Failure</u> to the lab (cc to NLs, SMILE, DCLOT)
4	Deadline for the affiliated NLs to provide feedback through the PTPT System.
5	Deadline for the PNL to send the <u>Cross-Network Proficiency Testing Deficiency Response</u> to the lab (cc to NLs, SMILE, DCLOT)

EMAIL CONTACTS FOR PNL SAFETY LAB COMMUNICATIONS

Group	Contact addresses to use for PT communications
PNL	PNL Logon
Affiliated NL	PNL Logon for each NL
DCLOT	DCLOT Logon - NIAIDDCLOT@niaid.nih.gov
Labs	Discretion of PNL
SMILE	SMILE group (Kurt Michael; lab-specific primary and back-up listed on http://psmile.org)

TEXT FOR PNL NOTIFICATION OF PT PROBLEMS (80-100%)—OPTIONAL NOTIFICATION for HPTN and MTN*

The following text should be sent to a lab from the PNL to notify the lab of a PT problem (result of 80-100%). The email should be copied to SMILE (via the SMILE logon for that lab).

“In reviewing your EQA results, we determined that there was a proficiency testing problem (result of 80% - 100%) for your lab for the following panel(s) / analyte (s): [fill in panel name (s)] / [fill in analyte name(s)]. We have attached the pdf of this EQA evaluation for your information.

Please begin investigating this proficiency testing problem at your lab. Please document all activities related to your investigation 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 Report before it is submitted to SMILE for review. 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 form to SMILE after review. SMILE will then either accept the Investigative Report, or will notify your PNL, who will contact you with recommendations for revision.”

TEXT FOR PNL NOTIFICATION OF PT PROBLEMS (80-100%)—OPTIONAL NOTIFICATION for ACTG, IMPAACT and HVTN*

The following text should be sent to a lab from the PNL to notify the lab of a PT problem (result of 80-100%). The email should be copied to SMILE (via the SMILE logon for that lab).

“In reviewing your EQA results, we determined that there was a proficiency testing problem (result of 80% - 100%) for your lab for the following panel(s) / analyte (s): [fill in panel name (s)] / [fill in analyte name(s)]. We have attached the pdf of this EQA evaluation for your information.

Please begin investigating this proficiency testing problem at your lab. Please document all activities related to your investigation on the SMILE Investigative Report form. This form can be found on the pSMILE website

(www.psmile.org under “Quicklinks”). When your SMILE Investigative Report form is complete, please submit it to SMILE and send a copy to me.

TEXT FOR PNL NOTIFICATION OF PT FAILURE (<80%)—REQUIRED NOTIFICATION* for HPTN and MTN

The following text should be sent to a lab from the PNL within 24 hours of identifying a proficiency testing failure. The email should be copied to:

- SMILE (via the SMILE logon for that lab)
- All other affiliated NLS (via the PNL logons for those networks).
- DCLOT

“In reviewing your EQA results, we determined that there was a proficiency testing failure (<80%) for your lab for the following panel(s) / analyte (s): [fill in panel name (s)] / [fill in analyte name(s)]. We have attached the pdf of this EQA evaluation for your information.

Please begin investigating this proficiency testing failure at your lab. Please document all activities related to your investigation 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 Report before it is submitted to SMILE for review. 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 form to SMILE after review. SMILE will then either accept the Investigative Report, or will notify your PNL, who will contact you with recommendations for revision.

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

TEXT FOR PNL NOTIFICATION OF PT FAILURE (<80%)—REQUIRED NOTIFICATION* for ACTG, IMPAACT and HVTN

The following text should be sent to a lab from the PNL within 24 hours of identifying a proficiency testing failure. The email should be copied to:

- SMILE (via the SMILE logon for that lab)
- All other affiliated NLS (via the PNL logons for those networks).
- DCLOT

“In reviewing your EQA results, we determined that there was a proficiency testing failure (<80%) for your lab for the following panel(s) / analyte (s): [fill in panel name (s)] / [fill in analyte name(s)]. We have attached the pdf of this EQA evaluation for your information.

Please begin investigating this proficiency testing failure at your lab. Please document all activities related to your investigation on the SMILE Investigative Report form. This form can be found on the pSMILE website (www.psmile.org under “Quicklinks”). When your SMILE Investigative Report form is complete, please submit it to SMILE and send a copy to me.

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

***Header field for PNL notification of PT problems and PT failures**

Emails should use the following format for the subject header:

“PT Alert: [lab name, as listed on the PNL Assignment table] – [panel/analyte name(s)]”

TEXT FOR CROSS-NETWORK PROFICIENCY TESTING DEFICIENCY RESPONSE

The following text should be sent to a lab from the PNL within 5 working days of identifying a proficiency testing failure. The email should be copied to:

- SMILE (via the SMILE logon for that lab)
- All other affiliated NLs (via the PNL logons for those networks).
- DCLOT

“Dear [fill in Laboratory] Team:

Detailed below is a cross-network decision on the recent [fill in analyte name] failure. The networks recommend that [summarize network recommendation].

Please let us know if you have any questions or need any help with your corrective actions.

[fill in PNL Signature]

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

[Copy feedback summary from notice received from PTPT System]”