

**Implementation Date: 01 February 2008**

Score	Step	PNL	Affiliated NL	VQA	DCLOT	SITE
<b>C</b>	1	PNL receives site individual analysis report. Enters "Certified" on the LFG tracking form.	--	--	--	--
⇒	2	--	--	Performs routine review of test results after VQAAB review. The change in status tracking sheet and cumulative tables should be updated monthly. Change in status letters should be sent within 3 weeks of VQAAB approval.	--	--
<b>PC</b>	1	PNL receives site individual analysis report. Enters "Provisionally Certified" on the LFG tracking form. The PNL has an option to contact the site at this point to provide regarding the problem noted. In this case, the PNL should copy the VQA on the correspondence.	--	Notified if correspondence with Site occurs	--	--
⇒	2	--	--	After the VQAAB review, sends the site an IR request within one week. The change in status tracking sheet and cumulative tables should be updated monthly. Change in status letters should be sent within 3 weeks of VQAAB approval. If the VQAAB does not feel that an IR is needed, the VQA will inform the PNL and the site.	--	With guidance from the PNL and/or the VQA, prepares a draft of the IR and sends it to the PNL for review within 30 days of receipt.
⇒	3	Reviews the IR, works with the site to complete the IR. Signs off on the draft version, and sends it to the VQA. The sign off by the PNL and transfer of the IR to the VQA are internal steps. The site should not be contacted at this point.	--	Reviews the IR, discusses any outstanding issues with the PNL, and either accepts the IR or works with the site 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 the VQA. Notifies the site and the PNL of IR acceptance.	--	--

## Guidelines for VQA Monitoring, Data and Communication Flow

### Appendix A. PNL Communication Procedure for VQA Proficiency Testing, 30 January 2008

Score	Step	PNL	Affiliated NL	VQA	DCLOT	SITE
P	1	PNL receives site individual analysis report. Enters "Probationary" on the LFG tracking form and initiates the XN PT Deficiency Response within 1 working day. Uses approved text to notify the site, copying affiliated NLs, the VQA, and DCLOT.	After consultation with DCLOT, adds NL actions to the XN PT Deficiency Response within 2 working days of receiving notification of the PT failure.	Notified	Has an option to assist the NLs in defining NL specific actions.	Begins investigation.
⇒	2	Sends XN PT Deficiency Response to the site, copying affiliated NLs, the VQA, and DCLOT. This should occur within one working day after the NLs have added their actions. If input from one or more networks is pending, the XN response should still be sent on time, with Pending indicated for that network. A revised response should be sent with the remaining network's actions as soon as possible.	Notified	Notified	Notified	Receives XN PT Deficiency response. Confirms action plan.
⇒	3			After the VQAAB review, sends the site an IR request within one week. The change in status tracking sheet and cumulative tables should be updated monthly. Change in status letters should be sent within 3 weeks of VQAAB approval. If the VQAAB does not feel that an IR is needed, the VQA will inform the PNL, DCLOT, and the site.		With guidance from the PNL and/or the VQA, prepares a draft of the IR and sends it to PNL for review within 30 days of receipt.
⇒	4	Reviews the IR, works with the site to complete the IR. Signs off on the draft version, and sends it to the VQA. The sign off by the PNL and transfer of the IR to the VQA are internal steps. The site should not be contacted at this	Has the option to review the draft IR before it is submitted to the VQA.	Reviews the IR, discusses any outstanding issues with the PNL, and either accepts the IR or works with the site 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 the		

## Guidelines for VQA Monitoring, Data and Communication Flow

### Appendix A. PNL Communication Procedure for VQA Proficiency Testing, 30 January 2008

Score	Step	PNL	Affiliated NL	VQA	DCLOT	SITE
		point.		VQA. Notifies the site, DCLOT, and PNL of IR acceptance.		
⇒	5	Finalizes XN PT Deficiency document (resolution). Sends final document to the site, copying affiliated NLs, the VQA, and DCLOT. This should occur within 1 week of acceptance of the IR by the VQA.	Notified	Notified	Notified	Notified

Abbreviations: XN = cross network; LFG = Laboratory Focus Group; IR = Investigative Report; PNL = Primary Network Laboratory; PT = proficiency testing; NL = Network Laboratory; DCLOT: DAIDS Clinical Laboratory Oversight Team; VQA = Virology Quality Assurance Group; VQAAB = Virology Quality Assurance Advisory Board; VQA Scores: C = Certified, PC = Provisionally Certified, P = Probationary

Note: The level of involvement of the PNL in working with the site on the preparation of Investigative Reports is expected to vary based on the type of PT 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 on the tracking form, to start the deficiency form, and send the notification text to the site (cc to NLs, the VQA, DCLOT)
4	Deadline for the affiliated NLs to complete the deficiency form on-line
5	Deadline for the PNL to send the deficiency response information to the site (cc to NLs, the VQA, DCLOT)

**EMAIL CONTACTS FOR PNL - VQA COMMUNICATIONS**

<b>Group</b>	<b>Contact addresses to use for PT communications</b>
PNL	PNL Logon
Affiliated NL	PNL Logon for each NL
DCLOT	DCLOT Logon - NIAIDDCLOT@niaid.nih.gov
Sites	Discretion of PNL
VQA	VQA logon: vqa@rush.edu

**TEXT FOR PNL NOTIFICATION OF PT PROBLEMS (VQA score PC) – OPTIONAL NOTIFICATION\***

The following text should be sent to a site from the PNL to notify the site of a PT problem (result of PC). The email should be copied to the VQA (via the VQA logon).

“In reviewing your VQA results, we determined that there was a proficiency testing problem (result of PC) for your site for the following panel(s) / analyte (s): [fill in panel name (s)] / [fill in analyte name(s)]. We have attached the VQA evaluation for your information.

Please begin investigating this proficiency testing problem at your site. Please document all activities related to your investigation on the VQA Investigative Report form. This form can be obtained from the VQA by emailing the VQA logon (see above). As your Primary Network Laboratory, we will need to review your Investigative Report before it is submitted to the VQA 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 the VQA after review. The VQA will then either accept the Investigative Report, or will contact you with recommendations for revision.”

**TEXT FOR PNL NOTIFICATION OF PT FAILURES (VQA score P)\***

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

- the VQA (via the VQA logon)
- all other affiliated NLs (via the PNL logons for those networks).
- DCLOT

“In reviewing your VQA results, we determined that there was a proficiency testing failure (score of P) for your site for the following panel(s) / analyte (s): [fill in panel name (s)] / [fill in analyte name(s)]. We have attached the VQA evaluation for your information.

Please begin investigating this proficiency testing failure at your site. Please document all activities related to your investigation on the VQA Investigative Report form. This form can be obtained from the VQA by emailing the VQA logon (see above). As your Primary Network Laboratory, we will need to review your Investigative Report before it is submitted to the VQA 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 the VQA after review. The VQA 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.”

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

Emails should use the following format for the subject header:

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