

## **VQA PROFICIENCY TESTING INVESTIGATION REPORT PROCEDURE**

### **1. Purpose**

- 1.1. This procedure will establish the process for identifying, tracking, completing and investigating the existence of problems that result in a deficiency in proficiency testing performance.
- 1.2. Written and retrievable documentation of actions taken in response to a problem is paramount for ensuring reliable testing results are obtained for clinical trial testing.

### **2. Scope**

- 2.1. This procedure is applicable to all laboratories that participate in the Virology Quality Assessment (VQA) Program
  - 2.1.1. Clients of the VQA program include laboratories that perform virologic testing for NIH-funded AIDS clinical trials, as well as manufacturer's of virologic assays and other laboratories that are approved for participation in the program.
- 2.2. Clients of the VQA program that are network-affiliated will follow the "PNL Communication Procedure for VQA Proficiency Testing" (see Attachment B)
- 2.3. Clients of the VQA program that are not network-affiliated will follow the "Non-Network Communication Procedure for VQA Proficiency Testing" (see Attachment A)

### **3. Responsibilities**

- 3.1. The VQA laboratory manager will initiate the "Investigation Report" template (see Attachment A)
  - 3.1.1. Section I. a - f will be completed at initiation
  - 3.1.2. Section V. a - b will be completed at initiation
  - 3.1.3. The initiated document will be emailed to the laboratory
    - 3.1.3.1. The laboratory PI and manager/supervisory will receive
    - 3.1.3.2. The laboratory will be asked to acknowledge receipt
- 3.2. The laboratory will complete the Laboratory Response Sections
  - 3.2.1. Section II. a - o will be completed in response
  - 3.2.2. Section IV. a - b will be completed in response
  - 3.2.3. The completed response will be sent back to the VQA or PNL within 30 days, as outlined in the appropriate communication procedure for that laboratory
  - 3.2.4. The VQA/PNL will be asked to acknowledge receipt

- 3.3. The VQA/PNL will review the corrective action response as outlined in the appropriate communication procedure
  - 3.3.1. The VQA manager/PNL will review and determine if response is appropriate
    - 3.3.1.1. If necessary, the site will be asked to provide more documentation
  - 3.3.2. The VQA PI/PO will review/approve the final "Investigation Report"
  - 3.3.3. The VQA manager will complete the review
    - 3.3.3.1. Section V. a - b will be completed
    - 3.3.3.2. File will be converted to PDF and an electronic copy will be stored at the VQA
    - 3.3.3.3. Site, PNL and DCLOT will be notified when the "Investigation Report" is final and approved
- 4. "Investigation Report"
  - 4.1. An "Investigation Report" will need to be completed for any deficiency noted in proficiency testing scoring
  - 4.2. Types of deficiencies requiring corrective action (this list is not inclusive)
    - 4.2.1. Technical deficiencies
      - 4.2.1.1. Equipment-related
      - 4.2.1.2. Kit-related
      - 4.2.1.3. Technician/technologist-related
    - 4.2.2. Data deficiencies
      - 4.2.2.1. Data timeliness
      - 4.2.2.2. Data integrity
        - 4.2.2.2.1. Transcriptional errors
        - 4.2.2.2.2. Computational errors
        - 4.2.2.2.3. Sample validity
        - 4.2.2.2.4. Run validity
  - 4.3. Clinical trial testing in the face of deficiencies
    - 4.3.1. The VQA does not impose testing restrictions
      - 4.3.1.1. Clinical Trial Networks/Leadership determine a laboratory's approval for clinical trial testing
      - 4.3.1.2. A laboratory must contact their clinical trial network/leadership whenever there is a proficiency testing deficiency
    - 4.3.2. The impact of the deficiency on clinical trial testing must be assessed prior to continuing protocol testing.
      - 4.3.2.1. An investigation should identify the cause of the deficiency
      - 4.3.2.2. The problem should be corrected
        - 4.3.2.2.1. equipment repaired/new kit lot obtained – manufacturer contacted
        - 4.3.2.2.2. Procedures may be need to be revised or created
        - 4.3.2.2.3. Corrections in computation or transcriptions should be made

- 4.3.2.2.4. Training/retraining should be performed
- 4.3.2.3. Root cause should be determined to prevent recurrence

#### 4.4. Retesting of proficiency testing panels

- 4.4.1. Situation where retesting is NOT required
  - 4.4.1.1. Data submitted after the due date – data timeliness deficiencies
- 4.4.2. Situations where retesting is optional
  - 4.4.2.1. Deficiencies in panels that do not utilize cumulative scoring
    - 4.4.2.1.1. HIV GENO
    - 4.4.2.1.2. HIV DNA
    - 4.4.2.1.3. HIV CUL
  - 4.4.2.2. Minor deficiencies that result in score of PC
  - 4.4.2.3. Make note of deficiencies that will affect future analyses
    - 4.4.2.3.1. Invalid results
    - 4.4.2.3.2. False negative – false positive results
- 4.4.3. Situations where retesting is required
  - 4.4.3.1. Major deficiencies that result in a score of P
  - 4.4.3.2. Retesting can involve multiple panels to “fast-track re-approve”
    - 4.4.3.2.1. Multiple panels for HIV RNA MAY NOT be run in a single batch
    - 4.4.3.2.2. Multiple panels for HIV GENO MAY NOT be run in a single batch
    - 4.4.3.2.3. Multiple HIV DNA panels MAY be combined in a single batch
    - 4.4.3.2.4. Multiple HIV CUL panels MAY be combined in a single batch
  - 4.4.3.3. Retesting may involve re-qualification panel
    - 4.4.3.3.1. re-qualification panels need to be tested prior to proceeding to real-time testing panels
    - 4.4.3.3.2. real-time panels may be submitted only after successfully passing re-qualification panel

#### 4.5. Documentation

- 4.5.1. The corrective action report must be completed, approved, and filed
  - 4.5.1.1. The VQA must approve
  - 4.5.1.2. The laboratory director must approve
- 4.5.2. Supporting documentation must be kept with the corrective action report

#### 4.6. Attachment

- 4.6.1. The VQA corrective action investigation form (Attachment A)
- 4.6.2. Corrective action investigation flow chart (Attachment B)

## **ATTACHMENT A** **VQA Investigation Report Form**

### I. Panel Identification and Laboratory Status (To be completed by the VQA)

- a. VQA Lab Name: \_\_\_\_\_ VQA Lab #: \_\_\_\_\_
- b. VQA Program: \_\_\_\_\_ Panel Configuration: \_\_\_\_\_ Panel Round: \_\_\_\_\_ Samples: \_\_\_\_\_
- c. Current Panel Score: \_\_\_\_\_ Previous Panel Score: \_\_\_\_\_ Current Cumulative Score: \_\_\_\_\_
- d. first Problem Noted:
  - i. Comment: \_\_\_\_\_
- e. Second Problem Noted (if applicable):
  - i. Comment: \_\_\_\_\_
- f. Third Problem Noted (if applicable):
  - i. Comment: \_\_\_\_\_

### II. Laboratory Response (Attach supporting documentation/data)

- a. Type of Error Noted: \_\_\_\_\_ Explanation: \_\_\_\_\_
- b. Were the proficiency testing (PT) panels received in good condition: Yes  No
- c. Were the PT panels stored under the proper conditions: Yes  No
- d. Was the kit stored and handled according to manufacturer's guidelines? Yes  No
- e. Were the data from the original run reviewed? Yes  No
- f. Did the original data match the submitted data? If no, explain: Yes  No 
  - i. Explanation: \_\_\_\_\_
- g. Has there been any previous documentation of this type of error? Yes  No 
  - i. Explanation: \_\_\_\_\_
- h. Are controls/calibrators performing as expected and within range? Yes  No 
  - i. Explanation: \_\_\_\_\_
- i. If equipment/kit related, has the manufacturer been contacted? Yes  No 
  - i. Explanation: \_\_\_\_\_
- j. If equipment related, has the problem been corrected? Yes  No 
  - i. Explanation: \_\_\_\_\_
- k. If kit related, has a new kit lot been obtained? Yes  No 
  - i. Explanation: \_\_\_\_\_

- a. If technical, have the personnel been informed and educated/retrained? Yes  No 
  - i. Explanation:
- b. Has the impact on patient results been reviewed/amended/repeated? Yes  No 
  - i. Explanation:
- c. What type of retesting will be performed:
  - i. Explanation:
- d. Additional Comments:

II. Investigation Report Initiation:

- a. Prepared by:  
Name/Title
- b. Date of Initiation:  
mm/dd/yyyy

III. Investigation Report Response:

- a. Prepared by:  
Name/Title
- b. Date of Response:  
mm/dd/yyyy

IV. Investigation Report Approval:

- a. Reviewed/Approved by (VQA):  
Name/Title
- b. Date of Review:  
mm/dd/yyyy
- c. Reviewed/Approved by (PNL/DCLLOT):  
Name/Title
- d. Date of Review:  
mm/dd/yyyy
- e. Additional Comments:

**ATTACHMENT B**

**PNL COMMUNICATION PROCEDURE FOR VQA PROFICIENCY TESTING\***

**Draft 1a –11 December, 2007**

**Implementation Date: XXX**

CAP	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 QASC 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 QASC 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 QASC 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 QASC approval. If the QASC 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	--	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	--	--

		not be contacted at this point.		revised IR before it is accepted by the VQA. Notifies the site and the PNL of IR acceptance.		
<b>P</b>	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 QASC 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 QASC approval. If the QASC does not feel that an IR is needed, the VQA will inform the PNL, DLOT, 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	Has the option to review the draft IR before it is	Reviews the IR, discusses any outstanding issues with the PNL, and either accepts the IR or works with		

		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.	submitted to the VQA.	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, 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; QASC = Quality Assurance Subcommittee; 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)]”

**APPENDIX C**

**NON-NETWORK COMMUNICATION PROCEDURE FOR VQA PROFICIENCY TESTING\***

**Draft 1 – 29 November 2007**

**Implementation Date: XXX**

CAP	Step	VQA	DCLOT	SITE
<b>C</b>	1	Performs routine review of test results after QASC 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 QASC approval.	--	--
<b>PC</b>	1	After the QASC 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 QASC approval.	DCLOT receives final PT scores. The DCLOT has an option to contact the site at this point to provide regarding the problem noted. In this case, the DCLOT should copy the VQA on the correspondence.	With guidance from the VQA, prepares a draft of the IR and sends it to the VQA for review within 30 days of receipt.
⇒	2	Reviews the IR, discusses any outstanding issues with the SITE, and either accepts the IR or works with the site to finalize the IR. Notifies the site and the DCLOT of IR acceptance.	--	--
<b>P</b>	1	After the QASC 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 QASC approval.	DCLOT receives final PT scores and initiates the XN PT Deficiency Response (if applicable) within 1 working day. Uses approved text to notify the site, affiliated contacts and the VQA.	Receives XN PT Deficiency response. Confirms action plan with DCLOT. With guidance from the VQA, prepares a draft of the IR and sends it to VQA for review within 30 days of receipt.
⇒	2	Reviews the IR, discusses any outstanding issues with the site, and either accepts the IR or works with the site to finalize the IR. Notifies the site and DCLOT of IR acceptance.		

Abbreviations: IR = Investigative Report; PT = proficiency testing; DCLOT: DAIDS Clinical Laboratory Oversight Team;  
VQA = Virology Quality Assurance Group; QASC = Quality Assurance Subcommittee; VQA Scores: C = Certified,  
PC = Provisionally Certified, P = Probationary

**EMAIL CONTACTS FOR PNL - VQA COMMUNICATIONS**

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

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

The following text should be sent to a site from the DCLOT 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)].

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 found on the [Cheryl, please fill in if the form is available on the web]. The DCLOT will review your Investigative Report after it is submitted to the VQA for review. The major purpose of this review is to ensure that the Investigative Report is consistent with DAIDS clinical trial requirements. We will forward the Investigative Report back to the VQA if there is a problem after the review. The VQA will notify you when the IR is final and approved.”

**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 contacts
- 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)].

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 found on the [Cheryl, please fill in if the form is available on the web]. The

DCLOT will review your Investigative Report after it is submitted to the VQA for review. The major purpose of this review is to ensure that the Investigative Report is consistent with DAIDS clinical trial requirements. We will forward the Investigative Report back to the VQA if there is a problem after the review. The VQA will notify you when the IR is final and approved.”

Within three working days, you will also receive a 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 DCLOT notification of PT problems and PT failures**

Emails should use the following format for the subject header:

“PT Alert: [site name] – [panel/analyte name(s)]”