Regional Medical Center®

POLICY TITLE:	Proficiency Testing		
DISTRIBUTION:	Laboratory	**LAST REVISED:**	August 2024
OWNER:	Laboratory: General	**ORIGINATION DATE:**	February 1994
		LAB DIRECTOR:	

POLICY

To assure accurate and reliable reporting of all patient results the laboratory must enroll in an approved proficiency testing program. This program will include multiple shipments of different samples for each analyte tested in the lab.

PROCEDURE

A. Receiving API Product

1. Upon arrival of a kit from the proficiency testing service, open and check for damaged or missing specimens, instruction sheets, and report forms. Note the date received on the report forms and store specimens accordingly. If any specimens are missing or damaged, refer to API instructions for the appropriate phone number to request replacements as soon as possible. Proficiency testing specimens are supplied by a CLIA approved testing agency. Let the API designee know the samples are here and forward them all the paperwork.

2. The API designee will send an e-mail to all employees alerting them that the survey is here. Distribute worksheets to appropriate personnel following the rotation list indicating which employee is assigned to the survey material for each session (rotation list is kept inside the Proficiency Testing binder and updated annually). Let each employee know when the survey needs to be submitted for on-line review. Instructions for submitting results on-line are at the end of this policy.

3. Assigning Results On-line
   Before each testing event the API designee will login and assign tests to each user. To do this, go to www.api-pt.com and log in. Go to "My Account" then "Manage Sub-users". Assign the testing to be performed for the current event to each user. Techs with Supervisory rights have access to all tests and can review, correct and release results.

B. Testing and Processing of API Events

1. Testing staff must read all instructions carefully before beginning testing.

2. Commence testing. Testing shall be performed as part of the normal lab workflow in the appropriate department while treating all samples in the same manner as patient specimens. When necessary, reconstitute samples carefully following instructions provided. Note date of reconstitution or opening on the sample vials.

3. As testing is completed; the tech performing analysis shall record results on the appropriate

report forms. Refer to instructions for necessary units conversion where applicable. Sign and date the Attestation Statement with the date testing was performed. Verify method codes listed on the instruction sheets included with the specimens. Enter results for on-line submission.

i. Method data codes only need to be entered on report forms if the pre-printed method code is missing or incorrect. If it is already accurate - do not recode it.

ii. If a test listed on the report form is not performed in our lab, simply leave it blank, **do not** enter zeros or write N/A. Document when submitting the results the reason why testing is not performed. Follow the prompts on the data entry form to do this.

iii. Proficiency testing for all laboratory departments should be rotated between techs to reflect the actual work flow and assist in competency testing of all personnel. (Example: There should not be one tech that always does the Hematology PT, since all techs perform patient testing, all techs should at some point perform the proficiency testing.)

4. All testing must be completed in a timely manner to assure integrity of the sample and to allow sufficient time post completion for results to be reviewed by the API designee prior to submission. Submit copies of all test results controls and calibrations if indicated, along with survey results and a print off of the results entered for evaluation to the API designee.

5. When testing is completed and forms have been reviewed all reports will be retained in the Proficiency Testing binder.

6. The API designee is responsible for reviewing and submitting results will do so before the on-line submission deadline.

C. Result Submission

1. To report testing results for on-line submission log into www.api-pt.com. The home page will appear then go to Manage Results and Forms, log in using the assigned ID and password.

2. The next screen will appear which list the testing events, click on the current testing event. Click on the test results to be entered, it will open so results can be entered. Make sure the instrument and the method are correct and enter results. Verify results entered are correct. Verify the results are reported in the correct units and conversions are made if necessary. Color plates for Hematology Cell ID and the PPM for UA can be viewed by clicking on the microscope next to the result box. Scroll to the bottom of the page and Click "SAVE", print the results that have been entered. Forward all the paperwork to the API designee for submission.

3. Reminder Verification testing cannot be started until after the primary result submission deadline.

4. Submitting Results Online

a. To submit results the API designee will login to API then go to "Manage Results". Click on the event to be submitted and review all results. Click "Results Complete," then "Go to Attestation" complete this form, the signed (paper) form will be retained in our records. Print the final event it, will print all the submitted results with a time/date stamp. Place this report along with the signed Attestation Statement in the current Proficiency Result binder.

D. Review and Print Performance Results

1. The API designee will go to www.api-pt.com and login.

2. Go to Evaluation Reports, click on the event that needs to be reviewed and print the full evaluation report. For any sample not receiving a score of 100% a data summary sheet will need to be printed. A Performance Review and Corrective Action Documentation form must also be printed and completed for each testing event scoring <100%.
    a. Techs must complete the corrective action documentation. Corrective action must be performed with documentation completed and returned to the API designee within 2 weeks of having the final testing results.

3. The API designee will then review the corrective action, making sure all documentation is complete and will then forward the reports to the Lab Director or designee.

4. Results are then kept for two years in the appropriate binder.

E. Interpreting Results

1. Failure to attain at least 80% (100% for all Blood Bank) scores is considered unsatisfactory. Clerical errors or data omissions are not given special consideration. All unsatisfactory results including those at 80% must be investigated and documented. Documentation includes remedial actions, documentation and review to see if patient results were potentially affected. (ie: Comment patient results are not affected due to clerical error, patient results are interfaced.)

2. Not Graded Samples: while being given an artificial score of 100% this does not reflect actual performance or accuracy. Results must be reviewed and documented on the corrective action form verifying our results compared to the expected results and performing any corrective action if indicated.

F. Sanctions

1. Single event failure: Lab must take corrective action, but no regulatory action will be taken.

2. Multiple Event Failures:
    a. **Initial PT Failure**: Unsuccessful performance in proficiency testing means any of the following. Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events. If this happens we will be contacted by CLIA about the failure and be issued a statement of deficiencies. **During this time patient testing can still be performed.**
    These failure would include the following:
        i. Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspeciality.
        ii. An unsatisfactory testing event score for those subspecialities not graded by analyte (that is bacteriology, mycobacteriology, virology, parasitology, mycology compatibility testing, and unexpected antibody detection) for the same subspeciality for two consecutive or two out of three testing events.
    b. **Non-Initial PT Failure**: A failure in 3 consecutive or 3 out of 4 consecutive events. This will then get the Kansas City CMS Branch Location involved. If this would occur it is best to immediately and voluntarily suspend patient testing for the analyte.
    c. Steps to follow if there is an unsuccessful event:
        i. If the lab has not had any prior unsuccessful performances for any analyte, subspecialty, or speciality, the CLIA regulations under certain circumstances may permit technical assistance and training to take place, rather than a more serious sanction. However, repeated unsuccessful performance for that same analyte,

subspecialty, or speciality may result in the laboratory no longer being allowed to perform the failed testing.

ii. **As soon as you receive your PT results indicating an Non-intial PT Failurel you must notify your Regional Office CLIA consultant at shl-clia@uiowa.edu of the unsuccessful test and that testing has been voluntarily stopped.**

NOTE: ***The notification that you have ceased testing must be made before you receive a letter from your CMS Regional Office imposing a cease testing sanction. If you voluntarily cease testing and then perform two consecutive PT events for the unsuccessful test, your Medicare and Medicaid reimbursement may not be affected.***

3. Steps to resume testing
    a. Demonstrate that the laboratory has identified the reason(s) for the unsuccessful performance and corrected it (them). Be sure everything is documented.
    b. Once you are certain the problem(s) have been corrected, the lab must perform two consecutive PT events (reinstatement PT) successfully, which will demonstrate correction of the problem(s).
    c. You must pass 2 off-cycle PT events and submit a credible allegation of compliance to CMS before you can begin patient testing again. If we voluntarily stop testing this process can be done in less than 6 months. If CMS tells us to stop patient testing the process may take close to a year.

If sanctions have been imposed and you have been required to cease testing, your Medicare and Medicaid reimbursement and your CLIA certificate will be suspended or limited for a six month period. However, you may purchase reinstatement PT events at any time after the problem(s) has been identified, documented and corrected. Reinstatement samples may be ordered by contacting API out PT sample supplier. If they have samples available they can usually be shipped the same or next day. API requires payment for these samples either by check or credit card.

REFERENCES

Clinical Laboratory Improvement Amendments (CLIA): Proficiency Testing and PT Referral Dos and Dont's. September 2017

Westgard The New Poor Lab's Guide to the Regulations 2023-2024 pages 17-45

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