Proficiency Testing

Purpose

This document provides work instructions for the performance of proficiency testing (PT).

Scope

This procedure covers the preanalytical, analytical, and postanalytical aspects of PT performed by clinical laboratory staff or point-of-care testing personnel.

Policy

- All provisions of the *SCPMG/KFH Laboratory Systems Proficiency Testing Policy* (QM 5.6.4.100) must be met.
- Each person testing or reporting results on a PT sample must sign and date the Proficiency Testing Disclosure Statement on Page 1 of the *Proficiency Testing Tracking Form* (QM 5.6.4.400).
- Treat PT samples as if potentially infectious, and handle them as if they are capable of transmitting diseases (universal precautions).
- Test the PT samples with the routine patient workload, following the survey set instructions and the applicable procedures used for routine patient testing. Exceptions are noted in the Proficiency Testing Policy.
- PT samples are not to be referred to other laboratories.
- PT results are not to be discussed or shared with other laboratories.
- After completion of testing, store the remaining PT sample, if any, as specified in the survey/kit instructions.

Preanalytical Steps

Sample Receipt	
Step	**Action**
1	Upon receipt of PT samples, initiate a *Proficiency Testing Tracking Form* (QM 5.6.4.400).
2	Fill in applicable fields to include: • Testing Department • Kit # • Provider/Survey Name/Event • Due Date • Package received (Received by Name, Initials, Date, and Time).
3	Give the *Proficiency Testing Tracking Form* and box containing the samples to the testing department Supervisor or designee, documenting the "Handed off to Supervisor or designee" fields (Name, Date, and Time). Have the Supervisor or designee initial the appropriate field.

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Analytical Steps

Accessioning, Sample Preparation, Processing, and Testing	
Step	**Action**
1	• Remove the required PT documents from the shipping box. • Store the box at the temperature specified on the survey/kit instructions
2	For each analyte, perform the actions described in the *Proficiency Testing Tracking Form*, to include: • Handling upon arrival (determining acceptability of the shipment) • Accessioning samples, as required • Preparation (reconstituting samples, if indicated, according to PT provider instructions) • Processing and Testing (testing samples along with routine workload per the applicable procedures used for routine patient testing)
3	As accessioning, sample preparation, processing, and testing are completed, initial/date/time the designated fields on the *Proficiency Testing Tracking Form*.

Postanalytical Steps

Reporting Results	
Step	**Action**
1	Merge or perform manual entry, review, and release PT results in the LIS in accordance with the applicable procedures used for reporting results of routine patient testing.
2	Print reports for the PT samples from the LIS.
3	Follow the survey provider reporting instructions and enter the PT results on the survey result forms.
4	Sign the attestation form.
5	Submit the following records to the Supervisor or designee: • Intermediate or manual worksheets [e.g. antibody panels, log sheets showing calculations, etc.] • Instrument printouts • Printed interpretive data (e.g., chromatograms, scans) • LIS printouts • Completed survey result forms

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Proficiency Testing, Continued

Postanalytical Steps, continued

Reviewing Results	
Step	**Action**
1	Review all documentation submitted by the testing personnel as described in the *Proficiency Testing Tracking Form* Results Reporting section.
2	Check to ensure that the units of measure are in accordance with the survey instructions, as applicable. **Note:** • For some assays, PT provider reporting units may differ from internal reporting units. Prior to reporting, the reporting units must be reviewed to identify any difference between internal reporting units and those required by the PT provider. • If any reporting unit difference is found, then the results need to be converted and reported in the appropriate units of measure.
3	Verify that all individuals participating in the testing process have signed the attestation form.
4	Initial the designated field on the *Proficiency Testing Tracking Form*.

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Postanalytical Steps, continued

Submission and Sample Retention

Step	Action
1	Submit the results to the PT provider via fax, US mail, e-mail or internet as described in the survey instructions.

If to be submitted by…	Then before submission…
fax or U.S. mail	review the transcribed results for accuracy.
e-mail or internet to a non-CAP PT provider	review the electronically transcribed results for accuracy.
internet to CAP	• go to www.cap.org. • Verify that the electronic survey result form has the same kit number as the completed survey result form that came with the PT samples. • Transcribe the results on the electronic form. • For a survey with multiple kits, transcribe the result of regulated analytes on the first kit number, if any. • Review and release the results electronically. • Print a copy of the online result forms and the online attestation form.

2	Obtain verification of successful transmission of PT results such as fax verification of transmission, or a copy of the received status page from CAP or other PT provider, and attach to the completed PT provider result forms.
3	File the completed PT provider result forms, testing documentation, LIS reports, and the successful fax transmission or received status page in the designated location in the department.
4	Store any remaining PT sample(s) as specified in the survey/kit instructions at least until the evaluation is received.
5	• Check the applicable box in the *Proficiency Testing Tracking Form* Submission/Sample Retention section to document review of the PT result forms for clerical accuracy in relation to the deadline. • Initial and date the designated field.

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Survey Result Evaluation

Evaluating Results

Step	Action
1	Upon receipt of the survey results, the Department Supervisor, Assistant Manager, or designee reviews the evaluation report and determines the acceptability of the results, graded or not graded. **Note:** Results that are not graded and do not agree with the majority of responses must be evaluated as unacceptable results.

If results are…	Then…
Acceptable	• Initiate a *Proficiency Testing Evaluation Review Form – Regional Reference Laboratories* (QM 5.6.4.401) or a *Proficiency Testing Evaluation Review Form – Medical Centers and Medical Offices* (QM 5.6.4.402), as applicable. • Forward as specified.
• Unacceptable • Unsatisfactory	for each unacceptable or unsatisfactory result: • Initiate a *Proficiency Testing Exception Report Form* (QM 5.6.4.403). • Investigate the PT failure using the *Proficiency Testing Exception Report Form* as a guideline, and document action taken. • Obtain signatures as specified on the *Proficiency Testing Exception Report Form*. • Gather all documentation and forward for final review and approval.
Acceptable based on PT provider guidelines, but require an internal investigation due to more stringent local or departmental criteria	for each result requiring investigation: • Initiate a *Proficiency Testing Internal Investigation Form* (QM 5.6.4.410) or a *Proficiency Testing Exception Report Form* (QM 5.6.4.403), as applicable. • Investigate the PT failure using the designated form as a guideline, and document action taken. • Obtain signatures as specified on the designated form. • Gather all documentation and forward for final review and approval.

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Survey Result Evaluation, continued

Evaluating Results, continued	
Step	**Action**
2	Review all PT results with staff members and document the review according to departmental protocol.

Non-Controlled Documents

The following non-controlled documents support this procedure.

- Federal Register, 42 CFR 493 Clinical Laboratory Improvement Act of 1988; Final Rule
- College of American Pathologists, Laboratory General Checklist
- TJC Comprehensive Accreditation Manual
- COLA Laboratory Accreditation Criteria
- ISO 15189:2007 Medical Laboratory Standards

Controlled Documents

The following controlled documents support this procedure.

Record	
Document Number	**Document Name**
QM 5.6.4.400	Proficiency Testing Tracking Form
QM 5.6.4.401	Proficiency Testing Evaluation Review Form – Regional Reference Laboratories
QM 5.6.4.402	Proficiency Testing Evaluation Review Form – Medical Centers and Medical Offices
QM 5.6.4.403	Proficiency Testing Exception Report Form

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Reviewed and approved by:

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Reviewed and approved by (for Medical Center Area Approval Only):

SIGNATURE	DATE
Name:_____ **Laboratory Manager**	
Name:_____ **Laboratory Director**	

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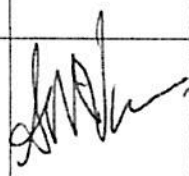
HISTORY PAGE

Type of Change: New, Major, Minor	Description of Change(s)	Person Initiating Change/Date	Laboratory Director Review/Date	Quality Systems Leader/Laboratory Manager Review/Date	Date Change Implemented
New		LMF / 06-08-09			
Major	**Postanalytical Steps, Page 4**: Added instruction for documenting review of the PT result form in relation to the deadline. **Survey Result Evaluation, Page 5**: Added section describing actions needed when survey results are acceptable based on PT provider guidelines, but which require an internal investigation due to more stringent local or departmental criteria.	LMF / 05-14-10		MF-17-10	