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Proficiency Testing

Purpose

This document outlines the policy for enrollment and participation in Clinical Laboratory Improvement Act of 1988 (CLIA)-approved Proficiency Testing (PT) programs.

Scope

- This policy covers regulated and unregulated analytes for which PT materials are available.
- For an analyte for which there is no available PT material, refer to *Alternate Proficiency Testing Policy* (QM 5.6.4.101).
- This policy also applies to Point of Care Testing (POCT) except as noted or as defined by the local Medical Center area.

Definitions

Regulated Analyte: Any test found in Subpart I, Proficiency Testing Program, Final CLIA '88; a detailed listing of regulated analytes is available at www.cms.hhs.gov/clia

Unregulated Analyte: Any test not included in Subpart I, Proficiency Testing Program, Final CLIA '88

Acceptable PT Performance on a graded response:

- The laboratory receives an overall score of 80%, based on the number of challenges for each analyte
- The laboratory receives an overall score of 80% for each specialty or subspecialty, and 100% in immunohematology

Unacceptable PT Performance: Unsatisfactory performance for a single analyte in a single testing event

Unsatisfactory PT Performance: Failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event

Unsuccessful PT Performance: Failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events

Unsuccessful Participation in Proficiency Testing:

- Unacceptable performance for the same analyte in two consecutive, or two out of three testing events using a rolling calendar
- Unsatisfactory performance for the same specialty or subspecialty in two consecutive, or two out of three testing events using a rolling calendar
  Note: This includes subspecialties not graded by analyte, i.e., bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, and syphilis serology.
- Failure of a laboratory performing gynecologic cytology to meet CLIA regulations Part 493.855, Gynecologic Cytology Proficiency Testing

Note:
The terms "Unsuccessful PT Performance" and "Unsuccessful PT Participation" are interchangeable.

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Proficiency Testing, Continued

Policy

- SCPMG/KFH Laboratory Systems must participate in an approved PT program for each analyte, regulated or unregulated, which the laboratory intends to perform under current licensure and certification, and for which PT materials are available.
- PT is required for waived tests performed by a College of American Pathologists (CAP) accredited laboratory.
- PT is optional for Provider Performed Microscopy (PPM) performed under the purview of a non-CAP accredited laboratory.

Provisions

The following provisions are delineated in this document:

- Enrollment
- Testing of PT Materials
- Mandatory Alerts
- Reporting of PT Results
- Evaluation of PT Results
- Investigation of Unacceptable Performance
- Additional Actions: Unsuccessful PT Performance
- Record Retention

Enrollment

- PT enrollment and participation is required for each CLIA certificate.
- If the laboratory has a separate CLIA certificate for each site, then the laboratory must enroll in PT for the tests performed at each site.
- The Laboratory Manager, Quality Systems Manager, or designee maintains enrollment with the PT providers. Enrollment must be reviewed annually with the immediate Managers/Supervisors to ensure coverage of the laboratory's spectrum of testing.
- Laboratories operating under a new certificate and/or adding new testing must enroll in PT for the new test if PT enrollment is required and before the laboratory begins reporting patient results for the analyte, and must continue the PT for the remainder of the year, unless the laboratory discontinues testing of the covered analyte.
- The laboratory must not randomly change from one approved PT program to another.
  - The laboratory must enroll and participate in one approved program for three consecutive testing events before designating a different program.
  - The laboratory must not change a PT provider in the middle of a calendar year (January through December).

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Proficiency Testing, Continued

Enrollment, continued

- If the laboratory discontinues testing of an analyte, it is the responsibility of the laboratory to notify their PT provider within thirty (30) calendar days about the discontinuation of the analyte.
- If there is a change on a regulated analyte enrollment, the laboratory must ensure the accuracy of the Centers for Medicare & Medicaid Services (CMS) Analyte Reporting Selections.
- Proficiency Testing is required for only the test system, assay, or examination used as the primary method for patient testing during the event. "Primary" means the test system(s), assay(s), or examination(s) routinely used for patient testing at the time of the PT testing event; however, the primary method is determined after the laboratory has chosen the analyte(s) it performs for enrollment.
  - Do not perform proficiency testing using multiple or backup instruments.
  - A laboratory may rotate PT from one instrument to another on successive PT events as long as the testing menus of the instruments are the same.

Testing of PT Materials

- A *Proficiency Testing Tracking Form* (QM 5.6.4.400) must be initiated for every PT kit received by the laboratory.
- Upon receipt of PT samples, the laboratory must process them in the same manner as patient samples, i.e., the laboratory must accession PT samples if patient samples are routinely accessioned.
- Upon receipt of PT samples, the laboratory must note the date of receipt on the PT provider's worksheet, and PT samples must be integrated with the laboratory's workload as soon as practical.
- The laboratory must follow the PT provider's instructions, as some PT sample preparation may be necessary before testing. However, after preparation, PT samples must be tested in the same manner as patient specimens. Known exceptions, which must be documented in local area laboratory protocols, include, but are not limited to, the following examples:
  - Requirements to run PT in control mode, e.g., Sysmex, Spermalite
  - Exceptions that allow the reporting of results from two instruments under one PT event, e.g., routine chemistry and complete blood counts
  - Transfusion Service PT variance (see TS policy KQE:10.1-1-0001.00)
- Proficiency samples must be tested the same number of times as patient samples and at the same time that patient specimens are routinely tested.

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Proficiency Testing, Continued

Testing of PT Materials, continued

- Group review and consensus identifications are permitted only if **all** of the following circumstances are fulfilled:
  - The unknown sample is a morphologic identification that would ordinarily be reviewed by more than one person in an actual patient sample, e.g., identification of cell types or microorganisms, electrophoretic patterns, etc.
  - Such review or consensus identification of patient samples is explicitly defined by the laboratory or described in the assay testing procedure.
  - The testing personnel has obtained the signature approval of the Supervisor in the department in which the proficiency testing is being performed or the Laboratory Manager to consult with another testing personnel. The approving Supervisor or Manager should evaluate the appropriateness of consultation for that particular request.
- PT samples must be analyzed by routine testing personnel, and samples must be rotated among all testing personnel on all shifts to the extent possible.
- Testing personnel are prohibited from retesting the same PT materials from the same mailing event, e.g., if the testing personnel has tested the materials in another Kaiser Permanente (KP) or outside laboratory. If this is the case, the testing person must notify his/her Supervisor/Manager so the PT testing will be reassigned to other testing personnel.
- PT samples must be retained at least until the evaluation results have been received and reviewed.

Mandatory Alerts

- The laboratory must **never** send PT samples to a laboratory with a different CLIA certificate for any reason, even if the laboratory routinely sends out patient specimens for additional, reflex, or confirmatory testing. This includes physical or electronic transfer of samples, photographs, PT results, etc. to another laboratory with a different CLIA certificate.
- The laboratory must **never** split a PT sample with another laboratory with a different CLIA certificate.

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Proficiency Testing, Continued

Mandatory Alerts, continued

- The laboratory must **never** engage in discussion or share PT results with another laboratory with a different CLIA certificate, i.e., other KP laboratories or outside laboratories, about proficiency testing data on regulated or unregulated analytes until after the evaluation results/scores are received from the PT provider. The following examples must be avoided as they can be classified sharing of PT results:
  - Faxing or physical transfer of PT results to another laboratory with different CLIA number,
  - Faxing multiple PT results for multiple laboratories with different CLIA numbers to PT provider,
  - Accessing and/or entering PT results for a given laboratory in another laboratory with a different CLIA number,
  - A Lab Supervisor overseeing more than one laboratory must not access the results, manually or electronically, for a given laboratory from a laboratory with a different CLIA number until after the evaluation results/scores are received from the PT provider.
- If the laboratory receives, or has the suspicion that it receives, PT samples from another laboratory with a different CLIA certificate for testing, it **must** notify a Supervisor, Manager, and/or Director as soon as possible.
  - The laboratory must **not** test these samples.
  - As soon as the laboratory identifies them as PT samples:
    - The laboratory must notify the laboratory's accrediting agency, **or**
    - If the laboratory is not accredited and is under a CLIA Certificate of Compliance, the laboratory must notify the California Department of Public Health, Laboratory Field Services.
- Do **not** repeat PT testing unless the PT result falls under the laboratory's repeat testing policy, e.g., critical result/value, outside analytical measurement range, etc.
- Do **not** average PT results, unless averaging is allowed and clearly specified in the assay testing procedure, e.g., manual cell count using a counting chamber, etc.
- PT results on analytes that are reported through a Laboratory Information System (LIS) using a correlation factor (i.e., AST, ALT and Lipase) should be reported directly from the instrument (i.e., without the correlation factor).
- PT samples must **not** be used for any purpose other than the performance of proficiency testing. With the exceptions of PT results/scores, kodachromes, slides, or photographs may be used for educational and competency assessment purposes only after the evaluation results/scores have been received.

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Proficiency Testing, Continued

Reporting of PT Results

- The laboratory must submit results to the PT provider within the required time period as determined by the PT provider.
- The PT provider's resulting instructions must be followed.
- The Laboratory Manager, Supervisor, or designee may review PT result forms for clerical accuracy of results entered and/or proper instrument or method coding before submission of results.
- If the laboratory is entering PT results online using the PT provider's website, the laboratory must retain a copy of the online result forms and the online attestation form.
- PT attestation forms must be signed by the testing personnel and the Laboratory Director or designee before submission of PT results, attesting that PT samples were tested in the same manner as patient samples. The list of designees must be documented in writing and approved by the Laboratory Director.

Evaluation of PT Results

- PT result evaluations and participant summaries must be reviewed as soon as possible after receipt from the PT provider. Receipt of PT result evaluation and participant summaries must be documented.
- PT result evaluation and **unacceptable** or **unsatisfactory result** investigations must be documented by the Department Supervisor or Assistant Manager, and reviewed by the Laboratory Manager, Quality Systems Manager, if applicable, and Laboratory Director or Pathologist designee, within **thirty (30) calendar days** after receipt from the PT provider. Exceptions will be considered on a case-by-case basis.

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Proficiency Testing, Continued

Evaluation of PT Results, continued

- In addition to defined failures requiring investigation and a formal response to the PT provider, the following situations require accuracy verification for the analyte, specialty, or subspecialty, and completion of an internal *Proficiency Testing Exception Report Form* (QM 5.6.4.403):
  - Any PT event with a score of less than 100%.
  - Any PT event that is assigned an artificial score, and the laboratory's result does not agree with the majority of responses.
    - An artificial score of 100% can result from the following situations:
      - Results were not evaluated due to lack of a peer group.
      - Lack of consensus within the peer group.
    - An artificial score of 0% can result from the following situations:
      - The laboratory did not test the samples (due to oversight, instrument problems, reagents on backorder, etc.).
      - The laboratory failed to submit test results.
      - The results were submitted after the cutoff date for submission.
  - Any PT event that is not graded, and the laboratory's result does not agree with the majority of responses due to:
    - Lack of participants' consensus
    - Other explanation provided by the PT program
- The following situations require quality assurance investigation for the analyte, specialty, or subspecialty, and completion of a *Proficiency Testing Internal Investigation Form* (QM 5.6.4.410) or completion of a *Proficiency Testing Exception Report Form* (QM 5.6.4.403), as applicable:
  - Educational challenge that does not agree with the majority of responses
  - Any PT event that has a score of 100% but may fall outside the more stringent criteria established by the department or local laboratory, as applicable, for example:
    - PT results on one side of the mean for the last two consecutive events
    - Any two or more PT results greater than 2 SDI (standard deviation index) from the peer group mean

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Proficiency Testing, Continued

Investigation of Unacceptable Performance

- The department must review, determine the cause of the error or errors, and document any remedial action or corrective action for each result exceeding acceptable limits.
- This review includes, but is not limited to, a review of quality control, e.g., shifts and trends, calibration, instrument and reagent checks, etc., including a retrospective review of patient results affected by the failed PT event, as appropriate.
- In some cases, the laboratory will have to take additional steps to verify the accuracy of its results, such as conducting split sample analysis or other external assessment.
- The scope of patient retrospective review depends on the outcome of the PT failure investigation within that particular PT event.
- The Laboratory Director or Pathologist designee will determine the scope of patient retrospective review. The review may span patient results within hour(s), day(s), week(s), or month(s) **before** and/or **after** the failed PT event.
- If an inservice or training of staff is part of the remedial action, the Supervisor must attach documentation of inservice or training with the remedial action response form.
- The Laboratory Director or designee must ensure that all identified remedial or corrective actions are implemented to prevent any recurrence of the PT failure.
- The laboratory must only use the approved *Proficiency Testing Exception Report Form* (QM 5.6.4.403) to document every step taken in the investigation of the PT failure, any remedial or corrective actions taken, patient retrospective review, etc.
- A copy of the completed *Proficiency Testing Exception Report Form* (QM 5.6.4.403), reviewed and approved by the respective Laboratory Director or Pathologist designee from any of the Southern California KP Medical Centers, must be submitted to the Regional Quality Assurance Department.
- The laboratory must review all PT results, even those with passing scores, the outcome of PT failure investigation(s), and any remedial or corrective actions taken, with the laboratory staff. The staff review must be documented.

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Proficiency Testing, Continued

Additional Actions: Unsuccessful PT Performance

- The laboratory must take the following actions when PT results meet the definition of Unsuccessful PT Performance:
  - Notify the Laboratory Director, or Pathologist designee, the Laboratory Manager, Quality Systems Manager (if applicable), and the Regional Quality Assurance Department immediately.
  - Testing for the unsuccessful analyte, subspecialty, or specialty may be voluntarily stopped at the discretion of the Laboratory Director, Laboratory Manager and/or designee.
  - Notify the laboratory's accreditation agency within thirty (30) calendar days of the unsuccessful PT performance as well as the decision to stop testing, if applicable.
  - If the laboratory is not accredited and is under a CLIA Certificate of Compliance, the laboratory must notify the California Department of Public Health, Laboratory Field Services.
  - Complete the *Proficiency Testing Exception Report Form* (QM 5.6.4.403).
- If the laboratory fails to attain a satisfactory PT performance for the same analyte, subspecialty, or specialty subsequent to an unsuccessful PT performance, the laboratory **must** stop testing until the laboratory has identified the root cause of the problem and corrected it.
  - Reinstatement of testing occurs **only** if the laboratory is able to successfully perform two consecutive PT events for the analyte, subspecialty, or specialty that was unsuccessful.
  - One of the two PT events may be purchased, if available, and performed immediately thereafter or off cycle for this purpose.

Record Retention

- Records of test handling, preparation processing, examination, results reporting, PT evaluation results, and any applicable PT exception reports must be retained by the laboratory for at least 3 years (5 years for immunohematology departments accredited by AABB). This includes the following documents:
  - *Proficiency Testing Tracking Form* (QM 5.6.4.400)
  - PT provider result forms
  - Attestation form
  - Copy of the online PT results and online attestation form, as applicable
  - Instrument printouts or testing work-ups, as applicable
  - Copy of LIS result printouts
  - PT evaluation results
  - *Proficiency Testing Evaluation Review Form – Regional Reference Laboratories* (QM 5.6.4.401), as applicable
  - *Proficiency Testing Evaluation Review Form – Medical Centers and Medical Offices* (QM 5.6.4.402), as applicable
  - *Proficiency Testing Exception Report Form* (QM 5.6.4.403), as applicable.

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Proficiency Testing, Continued

Non-Controlled Documents

The following non-controlled documents support this policy.

- 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 policy.

Policy	
Document Number	**Document Name**
QM 5.6.4.101	Alternate Proficiency Testing

Process	
Document Number	**Document Name**
QM 5.6.4.200	Proficiency Testing Program Pathway - Laboratory

Procedure	
Document Number	**Document Name**
QM 5.6.4.300	Proficiency Testing
QM 5.6.4.301	Responding to a Report of Unacceptable Proficiency Testing (PT) Results

Record	
Document Number	**Document Name**
QM 5.6.4.400	Proficiency Testing Tracking Form – Medical Centers and Medical Offices
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
QM 5.6.4.404	Proficiency Testing Tracking Form – Regional Reference Laboratories
QM 5.6.4.410	Proficiency Testing Internal Investigation Report Form

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Proficiency Testing, Continued

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Signature Manifest

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New Lab Director - QMS

Initial Approval

Name/Signature	Title	Date	Meaning/Reason
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Final Approval

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Proficiency Testing

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

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