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Standard Operating Procedure

Title: NCAL Laboratory Testing Personnel Proficiency Testing Procedure		**Procedure Number** SLNSOP-0129 **Revision:** 1
Department: Quality **Area:** KFH San Leandro 2500 Merced Street San Leandro CA 94577-5627	*Approved & Released Standard Operating Procedure*	**Implementation Date:** 03/12/2014
Type of Document: Quality System		**Review Period** - 700 Days

1. **Purpose:**
   CLIA and California regulations, as well as CAP standards require participation in proficiency testing or a documented alternate performance assessment of the laboratory's primary methods/instruments as an assessment of analytical accuracy and reliability.

2. **Scope:**
   This document provides instructions for Testing Personnel in managing and testing PT materials received by the laboratory.

   Refer to separate NCAL Laboratory PT Policy for:
   - Definitions
   - Policy Statements
   - Proficiency Testing "Never Events" – Regulatory Agency Enforcement Action Risks, expanded version
   - Enrollment and Managing Changes
   - Receipt of Unacceptable PT Materials
   - Post-analytical (Non Technical) Review and Reporting
   - Semi-Annual Alternate Quality Performance Assessment for Non-PT Methods
   - Assessment and Review of PT Results
   - Record Retention
   - Record Review

   Refer to separate Gynecologic PAP Cytology PT Policy.
   Refer to separate PT Investigation and Corrective Action Policy and Form

3. **Proficiency Testing "Never Events" – Regulatory Agency Enforcement Action Risks**
   During the open survey window, until after the evaluation results/scores are received from the PT provider, *applicable to both regulated and unregulated analyte(s):*

1) **Never** send PT samples or images or any portion thereof to any laboratory with a different CLIA certificate during the PT test event period, including any other KP laboratory within a service area, for *any* reason even when patient specimens would be sent to another lab for reflex or confirmatory testing, to resolve quality issues, when equipment is not operational, for sample preparation, or for pathologist review, etc.
2) **Never** test PT samples received from any other laboratory, including any other KP laboratory within a service area, with a different CLIA certificate during the PT test event period. If PT samples are received from a different laboratory or there is suspicion that PT samples have been received from any other laboratory with a different CLIA certificate during the PT test event period, sequester the samples and notify a Manager, and/or Director on the same or next business day.
3) **Never** physically or electronically transfer PT results or any PT records to any other laboratory with a different CLIA certificate, including any other KP laboratory within a service area, for any reason. Never remove PT records from the CLIA certified laboratory location for transcription, review, reporting to the PT provider or to manage records from a central location within a service area.
4) **Never** engage in discussion about PT results with any laboratory with a different CLIA certificate, including any other KP laboratory, including those within a service area, until after the evaluation results/scores are received from the PT provider.
5) **Never** access and/or enter PT results for a given laboratory at the location of another laboratory with a different CLIA number. A Lab Supervisor/Manager overseeing more than one laboratory, including laboratories performing PT on POCT, must not access and/or enter PT results, manually or electronically, from a laboratory location with a different CLIA number until after the evaluation results/scores are received from the PT provider.

4. Tracking, Receipt and Storage of PT Materials:

1) Material management receives shipment of packaged PT samples kit, and delivers to a Clinical Laboratory Scientist as soon as possible on the same day. Contents are time and temperature sensitive and must be processed immediately.
2) When not received within 4 days from ship date, Supervisor will track the shipments on-line to establish date of delivery to the facility, and investigate delays in delivery to the laboratory when kits are likely not stored at recommended conditions.
3) The Supervisor are responsible to investigate kit tracking when not received within 4 days from ship date and to immediately re-order kits received in unacceptable condition.
4) Upon receipt of a PT kit in the laboratory, the Clinical Laboratory Scientist who receives the PT kit will initiate a Proficiency Testing Tracking/Chain of Custody Formand documents verification of kit specimen quality and appropriate receipt storage conditions.
5) When replacement is needed, notify the the Supervisor to reorder the same or next business day.
6) Store PT kits in the designated centralized kit storage ambient storage area, refrigerator and freezer located in the department where the PT is assigned to.
7) Retain PT paperwork with the PT kit. When applicable, reprint any missing paperwork from the PT provider's website.

5. PT Testing Assignments:

1) PT testing assignments are assigned by the Supervisor or designee within two days of receipt.
2) When the assigned Testing Personnel are not available within two days of kit receipt,

the Supervisor / Manager will reassigned the kit to available Testing Personnel.

3) Rotate PT test events among all Testing Personnel, including on-call personnel, on all shifts to the extent possible.
4) Follow PT kit instructions and approved lab procedures for any pre-analytical processing required on some kits. Hands kits to Testing Personnel whenever possible.
5) Track PT testing assignments to ensure they are rotated as much as possible.
6) Testing Personnel handling a specific PT test kit in any other laboratory excuse themselves from handling/testing the same kit in this laboratory. This attestation is documented on the Proficiency Testing Tracking/Chain of Custody Form.
7) When this is the case, the Supervisor/Manager will reassign PT testing to other available Testing Personnel.

5. PT Testing Procedure:

1) Initiate a Proficiency Testing Tracking/Chain of Custody Form on every PT kit received in the laboratory to accompany the PT material for documentation of receipt, pre-analytic and analytic handling as well as post-analytic reviews.
2) Upon receipt, document date of receipt on the PT provider's worksheet and on the Proficiency Testing Tracking/Chain of Custody Form. Integrate PT samples with the laboratory's workload as soon as practical. Add the in-lab due date, not to exceed the kit's stability and no more than 5 days from receipt.
3) Testing Personnel must read and follow the PT provider's instructions, as sample preparation may be necessary before testing. Testing Personnel attest to having read and followed instructions on the Proficiency Testing Tracking/Chain of Custody Form.
4) After preparation, routine Testing Personnel analyze PT samples with the regular patient testing workload, using the same methods used at the time of the testing event for patient specimens.
5) Testing is done in the same manner as patient specimens, with no special handling other than as described in the kit instructions and in the approved laboratory procedure. Do not perform extra or out-of-cycle QC, maintenance, or calibration.
6) Follow the kit instructions to run PT in control/PT mode on some analyzers. When specified only by the analyzer manufacturer, such instructions must be added to the approved test procedure.
7) Lab-specific PT medical record numbers may be used to accession PT test samples or PT test samples may be manually programmed into the analyzer. Use RILIS labels or PT specimen identifiers on all manual worksheets, tubes, cassettes, test cards, etc.
8) One lab's confidential PT medical record number will not be accessed in or used by any other KP laboratory.
9) Unique PT sample identity must be documented on RILIS labels, on analyzer printouts and on PT worksheets. Verify accurate specimen and label identity before testing, as usual.
10) Repeat PT testing only when the PT result falls under the laboratory's repeat testing policy for patient testing, such as an analyzer error code, a critical value or when outside the analytical measurement range. Repeat only the applicable analyte. For multiple tests performed on a single accession number, verify completed results in RILIS before repeating any missing analytes. Do not repeat all analytes or repeat the affected analyte multiple times.
11) When patient testing is equally shared on two identical analyzers, the analyzer in use for patient testing at the *time* will be used to test PT. Do not run PT on more than one analyzer for the same analyte.
12) When identical analyzers are routinely used concurrently, rotate PT testing events

between analyzers, and among POCT testing units, as applicable. Unless specimen matrix differs such a serum and whole blood, do not run PT on more than one analyzer for the same analyte.

13) Test all the kit's specimens on the same patient run by the same Testing Personnel, whenever possible. Limit splitting PT samples among more than one Testing Personnel to the immunohematology specialty due to limited PT kit volume.
14) Limit PT testing and reporting to primary test methods, even when the PT provider allows for secondary instrument reporting. All PT samples must be run on the same analyzer per CLIA surveyor interpretive guidelines.
15) When a set of PT specimens must be tested on multiple analyzers, Testing Personnel will aliquot mixed, prepared PT materials into labeled, capped aliquot containers and complete timely testing. This will reduce contamination and PT material concentration due to evaporation. Never recombine the PT aliquot back into the primary PT material container.
16) Test PT specimens and report results only to the degree for those tests or examinations performed by the laboratory for patient testing.
17) Document reasons for any repeat testing on PT samples on the raw data records. The reason needs to be consistent with criteria specified in the approved procedure for the same test / test result on patient specimens.
18) Do not average PT results, unless averaging is allowed and clearly specified in the assay testing procedure, such as a manual cell count using a counting chamber.
19) Record all interpretations onto the logsheet or PT worksheet. Do not transcribe interpretations directly into the PT provider's coded results (e.g. morphology or cellular identity). If the PT interpretation is documented *real-time* into RILIS, a RILIS printout of each sample may be printed as the logsheet.
20) Group review and consensus identifications is permitted only when:
    - The unknown sample is ordinarily reviewed by more than one testing personnel on a patient specimen, such as antibody identification and morphologic identification, such as identification of cell types or microorganisms.
    - Criteria for this secondary review of patient testing must is described in the approved test procedure to be applied to PT.
21) "Pathology Review" of abnormal cells is acceptable, as long as the morphologic review is consistent with criteria for Pathology review done on patient specimens per the approved procedure. Any Pathologist review of any PT materials *must* be done in the same CLIA certified laboratory, and *never* sent to a separately licensed Pathology laboratory.
22) Ensure the identity of the analyzer used to test PT is printed or documented on all PT raw data records, such as analyzer printouts. For testing device identity, iSTAT raw data records may be uploaded and printed from the central data station or photocopies made of heat-sensitive tapes generated from the testing device with tape printer.
23) Keep the raw data as complete as possible. The instrument serial number or identity and the date/time run must be documented on each portion of PT test records. If possible, do not cut up raw data records. Patient test records may be intermingled with PT.
24) Complete PT testing within the week of kit receipt, if possible. This will ensure time to order new samples, complete testing, complete post-analytical non-technical reviews and submit results well within the reporting timeframe.
25) Store remaining PT samples and any unopened duplicate sample sets at optimal sample stability storage conditions after testing is complete, until the final report is available and reviewed.

26) Retained PT samples will be used for investigation and verification of effective corrective action, as indicated by review of the report. When the report is reviewed and a determination made that samples are not needed for these purposes, PT samples may be used for other purposes, such as blind samples for training or competency assessment or for quality assessment purposes.
27) Submit all completed PT worksheets, PT test records, signed PT Handling attestation and Proficiency Testing Tracking/Chain of Custody Form to *the* Supervisor/Manager.

6. References:

1) 42 Code of Federal Regulations 493, Clinical Laboratory Improvement Amendments, 2003, Subparts H &I and Appendix C, "Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services", 2003.
2) College of American Pathologists, Laboratory Common Checklist standards COM.01000 – COM.01900, September, 2012.
3) ISO 15189:2007 Medical Laboratory Standards
4) Northern California Kaiser Regional Quality and Compliance PT Risk Remediation Assessment Tool, v2, May 4, 2012
5) SCPMG/KFH Laboratory Systems Proficiency Testing Policy, Proficiency Testing Procedure, Proficiency Testing Tracking Form, Alternate Proficiency Testing, Alternate Proficiency Testing Result Form, 2009.

Associated Documents:

External Documents

Associated Quality System Documents - None

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