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Quality Assurance
Stat Test QC Summary
Instrument Function Verification
Instrument Comparison Procedure

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Annual Review:

Reviewed by Medical Director	Date	Reviewed by Medical Director	Date

Revisions:

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Quality Assurance Testing, Instrument Function Verification and Instrument Comparison Procedure

Clinical Significance/Purpose:

This document outlines the Quality Assurance plan for Coagulation Laboroatory test performance to reduce errors while ensuring that each process or procedure determines the sensitivity, specificity, and predictive value of the new assay to aid in the diagnosis of coagulation disorders. Guidelines for the determination of instrument function verification and intr-laboratory instrument comparison are also presented in this document.

Quality Control Guidelines Summary

1. PT and PTT: Two levels of control, HemosIL Normal Assayed Control and High Abnormal are every 8 hours thereafter on the instrument(s) in use for each shift.

2. Ddimer: Two levels of QC, HemosIL Ddimer normal and high abnormal, are run every 8 hours.

4. All PT, PTT, Ddimer Quality Control results are automatically recorded by the analyzers. QC failures are recorded on the analyzer action log, along with comment describing the corrective action taken to resolve the QC failure along with technologist initials.

6. ACL TOP Analyzers: Scheduled maintenance procedures are daily, weekly, monthly, annually and on an "as need" basis as defined by the manufacturer. Analyzer function that does not meet minimum standards of operation as defined by the manufacturer and/or may result in QC failure or errors in testing will be corrected by repair by ACL TOP instrument service technician.

Evaluating QC and Reporting Patient Results

1. Two levels of control, normal and abnormal, must fall within established limits at all times, in order for patient results to be reported, for testing performed on the ACL TOP instrument.

2. Ddimer: Report patient results only when both levels of QC fall within acceptable limits as established by this laboratory.

4. QC is visually reviewed semi-monthly or as needed. QC data is printed monthly and subject to documented review by designated Specialist Technologists.

- The total number of QC performed and the number and % QC failure are calculated for each test performed.

- The Mean and SD are calculated by the analyzer for the interval of one month, or several months as selected for review by the technologist(s).

- QC data may be printed at any time when drift or frequent QC failure, or discrepancy occurs.

- Any apparent changes/drifts will be reported to the Coagulation Specialist(s) and the Laboratory Manager to investigate the need for recalibration, reagent or QC material investigation and/or analyzer repait/technical service.

- This laboratory participates in a peer group comparison of PT, PTT and Ddimer results as provided by the Instrumentation Laboratories, manufacturer of the ACL TOP Family (300, 500 and 700) of analyzers, used for testing in this laboratory.

- Peer review and inter laboratory comparison of monthly QC results are used to evaluate the relationship between the two TOP analyzers. Peer review reports (Instrumentation Laboratories, Accutrack®) are reviewed by Coagulation Specialist Technologist(s) and/or Laboratory Manager.

- Acceptability Criteria:

    - Peer Review: Expected variation between this laboratory's analyzers and peer group (representing all models of ACL TOP family of analzyers) is +/- 2SD.

    - Inter-Laboratory: Mean, SD, % Failure rate are reviewed on a monthly basis. Expected variation between analyzers is +/- 10% within this laboratory.

Corrective Action: Evaluating and resolving out of control QC

To resolve out of control QC

1. Repeat QC, using same vial of control and reagent currently on board the analyzer.

2. If QC fails again, prepare new vial of QC. Repeat testing.
   Check the lot number and expiration date of QC.
   Verify that QC was properly prepared according to laboratory guidelines.

3. If QC fails again, prepare new reagents. Repeat testing.
   Check the lot number and expiration date of reagent(s).
   Verify that reagent was properly prepared according to laboratory guidelines.

4. If QC fails again, Discontinue testing and use alternate instrument. Investigate instrument performance.

Review history of QC failures, instrument warnings.
Review reagent and QC preparation.
Repair instrument and/or Call instrument technical service as needed.

Quality Guidelines for Instrument Maintenance and Function Verification

1. The function of all instruments utilized in this laboratory is validated according to manufacturer's specifications, upon installation. Validation studies performed at the time of installation are maintained in the laboratory. Ongoing verification of performance is documented by quality control, scheduled maintenance and analyzer preventive maintenance/performance evaluation by the manufacturer.

2. Monthly QC review and performance of scheduled daily, monthly, annual maintenance procedures for is used to verify performance of analyzers. Documentation of scheduled maintenance (daily, weekly, monthly, annual and as needed) is maintained in database on board the analyzers. See attached Checklist.

ACL TOP Analyzers: Scheduled maintenance procedures are daily, weekly, monthly, annually and on an "as need" basis as defined by the manufacturer. Analyzer function that does not meet minimum standards of operation as defined by the manufacturer and/or may result in QC failure or errors in testing will be corrected by repair and documented by ACL TOP instrument service technician.

3. The function of all instruments is verified (performance of QC testing) after major repair and/or preventive maintenance. QC must fall within established limits as set by this laboratory.

4. Reports prepared by authorized service personnel provide documentation of repair and/or semi-annual preventive maintenance procedures and are stored in the laboratory.

Quality Guidelines for Inter-Instrument Laboratory Comparison Testing

1. RIH instrument comparisons (PT,PTT) are performed utilizing same lot numbers of reagents and controls on both ACL TOP 300/500/550 and ACL TOP 700/750 high volume instruments that perform PT, PTT and Ddimer testing as deemed necessary for comparison (lot and/or shipment of reagents, normal reference interval determination).

2. Comparison studies for PT and PTT testing are also performed on selected specimens (minimum 10 specimens) that represent the normal, abnormal and/or therapeutic ranges during reagent cross-over studies. The same specimens are assayed on both instruments, using the same lot number of reagent(s).

3. Comparison testing is performed twice a year as part of normal reference studies and/or patient comparison testing.

4. Acceptability Criteria: Comparison results: +/-10%. If results do not fall within guidelines, analyzer and reagent performance is evaluated to determine the reason for variation in results. Corrective action in the form of re-calibration, analyzer repair or lot reagent replacement is implemented as necessary.