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Quality Control and Quality Assurance Guidelines

Prepared by: S.DeMarinis, MT (ASCP).

Revised/Adopted on 12/9/22 by Lab Director:Dr. J.Mills Barbeau JMB MD

Annual Review:

Reviewed by Medical Director	Date	Reviewed by Medical Director	Date

Revisions:

Bristol – MARI 1180 Hope Street Bristol, RI		**East Greenwich CC** 1454 S. County Trail East Greenwich, RI
Miriam Hospital 164 Summit Avenue Providence, RI	**Newport Hospital** 11 Friendship Street Newport, RI	**Rhode Island Hospital** 593 Eddy Street Providence, RI

Purpose and Clincial Significance:

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 assessment of pre-analytical, analytical, post analytical processes as well and quality control guidelines as defined by each test are presented in this document.

I. Pre-Analytical Guidelines

1. Specimens for coagulation testing must meet the criteria for identification by possessing barcode label imprinted with patient name, medical record #, unique order #, location, date and time collected, phlebotomist initials, status and tests ordered. Upon receipt, specimens are immediately placed into Pending/In Lab "status by central receiving personnel by barcode scanning.

2. In the event that a specimen is received accompanied by a downtime or other order slip, the specimen and slip should contain complete addressograph information (name, medical record #, location, date/time of collection, physician name and phlebotomist initials).

3. Improperly identified specimens (incorrect patient name/incorrect date or time of collection) cannot be processed until the individual who collected the specimen comes to the lab area, properly identifies the specimen, and signs the "Confirmation of Specimen Identification" form. This form must be generated and signed in the laboratory. Verification by phone is not acceptable. A copy of this form is found in Coagulation General Procedures manual "Guidelines for Specimen Acceptability" and Administrative Procedure Manual "1.7 Specimen Rejection" for details.

4. The criteria for specimen collection, volume age and condition (not clotted) as defined in "Guidelines for Specimen Acceptability" Procedure must be strictly followed. Specimens that are clotted, contain insufficient volume (QNS), overfilled, exceed the specimen stability age limit, collected in the incorrect container, or are not signed by the phlebotomist (or individual collecting the specimen) are unacceptable for processing. The unit secretary or/phlebotomist is notified and the reason for specimen unacceptability is noted in the LIS in place of a result.

5. All routine/stat specimens are processed immediately and centrifuged according to procedure "Guidelines for Specimen Acceptability, Sample Collection & Preparation" :

Routine Testing Specimens: Platelet poor plasma <10,000 plts/ul
Beckman Allegra 10 minutes at 3500 rpm
AccuSpin centrifuge 10 minutes at 3500 rpm
Stat Spin Express 3: 3 minutes/7200 rpm
Stat Spin Express 3: 5 minutes/5600 rpm
DASH Apex 12 centrifuges, 5 minutes at 5200rpm.
Routine specimens are held for 24-48 hours in the coagulation lab after completion of testing .

6. Specimens for special coagulation are centrifuged and then stored frozen at -70 C

Aliquots of plasma are prepared according to procedure for "Guidelines for Specimen Acceptability, Sample Collection and & Preparation" to ensure specimen stability.

Aliquots are identified using barcode label(s) with specimen order number, patient name, MR#, and date/time of collection and initials of the technologist preparing the aliquot. In the event that the LIS is not available, handwritten (legible) or downtime labels with complete patient information and time of collection may be used until barcode labels are printed and attached to specimen(s).

7. Specimens which require a new barcode label, because the original barcode has been damaged or is illegible, must retain the original label with phlebotomist initials. A second label be placed on top of the original label and must contain initials of the technologist that has attached the second label.
Pour off tubes utilized for any coagulation testing are labeled with LIS barcode labels for specimen identification, with the initials of technologist who prepared the pour off aliquot.

II. Analytical Guidelines

A. Summary

1. All Quality Control (QC) materials are commercial preparations, with assayed values, that are used to represent normal and abnormal levels of various coagulation parameters. The QC ranges of acceptability are determined by this laboratory (see Crossover Procedure for Reagents.) and validate the manufacturer's expected results.

2. QC is run each shift by same personnel that assay specimens. QC is also run whenever new reagents or controls are prepared as designated in Section B of the Analytical Guidelines. QC for PT, PTT, Fibrinogen, Ddimer, are maintained by the instrument database. Results are entered manually into the instrument into the LIS.

3. QC results are reviewed and must fall within acceptable limits before patient results may be auto-verified or manually verified and released in the LIS. The LIS Error translation table signals the technologist of out of control situation by a "Q" message/flag with individual results, and prevents auto-verification of patient results.

4. QC results that are not acceptable must be repeated and appropriate action taken according to the procedure "QC Guidelines for the Coagulation Lab, ACL TOP Instruments".

5. All QC results which do not fall within acceptable limits must be recorded in the appropriate analyzer (database) Action Log along with action taken to correct/resolve the out of control situation.

6. Out of control QC results are reviewed monthly or more frequently, as needed by the designated technologist(s).

7. QC summary reports for PT, PTT, and Ddimer are compiled by and reviewed monthly by the lab director or designee. QC reports for special assays are reviewed monthly or as needed. QC results and % Failure for each test, are reviewed for drift and changes, by the designated technologists and/or laboratory manager. The total number of tests and % QC out of control are determined for the month. Dot Plots, LIS printouts and Action logs are reviewed. Unacceptable results (>5% out of control) are investigated to determine the reason for out of control values. Appropriate Corrective Action is implemented to resolve the errors, and recorded on the monthly QC summary form.

8. Calibration Verification is performed for quantitative assays that use a chromogenic or immunologic method including: D-dimer, whenever a new calibration curve is created or new active lot of reagent is in placed into use.

9. Material used for calibration verification is commercially manufactured assayed reference material, of a lot number same or different from the calibrator used to calibrate the assay, or material from a different manufacturer (external calibrator or reference material). All materials have matrix characteristics and target values that are appropriate for the normal and abnormal results of the method(s). Expected results must fall within +/- 10% of the value of the reference material.

10. Results of calibration verification and assayed value for each analyte used for comparison are stored in Calibration data book for periodic review.

11. Calibration verification is performed when a new lot of reagent is placed into use, QC fails to meet established criteria, a trend or change in QC warrants investigation and/or recalibration, or at least every 6 months or recommended by the manufacturer, of after major maintenance/repair. Results are stored separately from monthly QC data.

Quality Control and Quality Assurance Guidelines Summary

A. Quality Control as defined by Procedure

Prothrombin Time (PT): Two levels of QC (1 normal, 1 high abnormal) are assayed, every 8 hours on all shifts.

(Activated) Partial Thromboplastin Time (APTT/PTT): Two levels of QC are assayed, (1 normal, 1 high abnormal) every 8 hours on all shifts.
PT/PTT Verification of No Endpoint Clotting Time: Two levels of QC, a normal and high abnormal control are assayed on the STArt instrument once per shift as needed for patient testing.

Ddimer: A 5 point calibration curve for the immune-turbidometric assay on the ACL TOP analyzer is prepared and has a stability of 6 months. Two levels of control (low and high) are assayed every 8 hours.

B. Guidelines for QC Out of Control

See Procedure for Coagulation Lab QC out of Control.

1. Repeat any QC which does not fall within acceptable limits.
2. If QC fails again, prepare 1 new vial of the control that is out of range.
3. If QC fails using freshly prepared control(s), prepare new reagent.
4. If QC fails using freshly prepared control(s) and reagent, investigate analyzer. Discontinue testing on analyzer until QC failure is resolved. Use other analyzer for patient testing.
5. All out of control situations are recorded in the ACL TOP analyzer database Action Log, with description of corrective action and technologist initials.
6. Laboratory manager is notified as needed, and a call for Service is placed if instrumentation failure is the cause for QC failure.

C. Reporting and Verification of Patient Results

1. Specimen Identification and Analysis: Specimens are analyzed on the automated coagulation analyzers using robotic sampling and barcode identification. Specimens are placed directly onto the instruments. Pour off tubes, with barcode label identification /with tech initials are utilized only when necessary, for assay of previously frozen specimens.
Barcode labels are utilized on pour off tubes for identification. Technologists place their initials on pour off labels to identify tech that prepared the separate aliquot for testing.

2. Reportable Results: All procedures contain parameters that define the highest and lowest reportable results, critical values (if applicable), interferences to the assay and guidelines for determining un-reproducible or un-reportable results.

Results of calibrated assays are reported only within the defined limits of the calibrated/analytical range and are never extrapolated. Appropriate dilutions, as defined by the analyzer/reagent manufacturers' guidelines, may be used to achieve results within the assay calibration/analytical range. Results which fall outside calibrated range are reported as "greater than" or "less than" the limits of the assay and are defined for each individual procedure.

3. LIS (Bi-directional) interface: PT, PTT, Ddimer testing is performed on the analyzer via test orders on specimen barcode. Results are transferred from the analyzers directly to the LIS and are compared to instrument printouts as needed. The analyzer printouts identify specimen by specimen order number and patient name.

4. LIS and Analyzer Discrepancies: Any discrepancies between results that are displayed in the LIS and the instrument printouts are brought to the immediate attention of the laboratory manager and the LIS staff.

5. LIS Failure:
In the event that there is a discrepancy, a failure of the LIS, or in the auto-verification function:

The instrument interface for coagulation testing can be immediately **stopped** by the technologist, and no results will be sent from the instrument to the LIS.

- The interface can be immediately stopped by selecting the "Stop Interface" icon in the SOFT instrument menu. (See "Immediate STOP of Coagulation Interface" procedure in the general procedures section of the coagulation manual.)
- The HELP desk will be notified and the Pathology IS Manager of designee will immediately disable the auto-verification function in the individual instrument interface. The instrument interface will then be re-started and all results will be manually verified in the LIS.
- When the auto-verification problem has been resolved, auto-posting function will be enabled by the Pathology IS Manager or designee.

6. INR Calculation Verification: The INR calculation, reported with the PT result, is performed by the ACL TOP analyzer and is transmitted by the LIS to the patient's medical record. Calculation Verification of the INR calculation is performed when there is a change in lot of PT reagent and once throughout the year. Results of calculations representing the normal, therapeutic and critical INR ranges are checked using an Excel spreadsheet program. Results are stored with "Calculation and LIS Interpretation Verification" data and lot crossover data.

7. Result Entry of Critical Values: PT/INR, PTT, and (Ddimer test results that require off-line dilution), are accompanied by any analyzer codes/flags or are critical values,

are individually reviewed and manually verified by the technologist before the result is released and posted to the LIS. Specimen identification is accomplished by review by order #/name/medical record #.

8. Reference Intervals; All results are reported in the LIS with current reference intervals; Reference intervals are updated and approved by the Laboratory Director, whenever there is a change in lot/type of reagent, instrument, procedure, or as determined necessary by the Laboratory Director, as stated in "Crossover Procedures" for the coagulation laboratory.

9. Interpretation comments, along with reference intervals accompany appropriate results are by laboratory director. A list of Interpretation comments is presented in the Post-Analytical guidelines section of this procedure.

10. Critical Values: Critical values are to be repeated per assay guidelines. The specimen integrity should be checked (presence of a clot, qns, age, High HCT) proper identification and results are called to the unit RN or physician, and reported with a "critical results" comment in the LIS, including test name, name of individual receiving the result and time/date of the communication. Critical test results including patient identification, must be "read back" to technologist

    If physician/nurse is unavailable to receive outpatient results, a request to call the laboratory is left with the physician's answering service. If physician does not call and receive results within one hour, the on call physician is notified. If the event that the patient's physician does not return the call, the on call physician will contact the patient and then notify the Laboratory Director. A footnote that the result was not received by patient's physician and on notificationcall physician/Lab Director accompanies the results. (See Coagulation Lab procedure for "Critical Results").

11. Highly Unusual/Absurd Results (short PT, APTT, No Endpoint PT/APTT) should be repeated (and the clot signature should be viewed/evaluated). No endpoint PT/PTT results or PT/PTT results with clot signature error codes may be repeated using the STArt mechanical clot detection instrument to verify if a no endpoint clotting time is not a short clotting time which occurred during the "blank" time of the analyzer.

The specimen is checked in the same manner as for critical values. Results that differ dramatically (>50%) from previous patient results may be investigated by confirming specimen integrity, identification and clot signature or duplicate values.

12. PT/PTT on the STArt Instrument: Alternate Method (Mechanical Clot Detection): PT/PTT (endpoint) results performed on the STArt may be reported in the LIS, using only the normal reference intervals established for this instrument. PT/PTT performed by this alternate method is used if clotting endpoint cannot be determined by the ACL TOP due to an unusual clot signature and/or critically low Fibrinogen level or other interference. Results are reported as "See Note", with results (sec) entered in comment/footnote, accompanied by the STArt normal reference interval.

13. Unable to Obtain Reproducible Result Status: Results that are generated with a analyzer error codes/flags, abnormal clot signature or cannot be generated in duplicate on instrumentation are reported and verified manually in the LIS as "See Note" with a comment that states that states " Unable to obtain reproducible result. Suggest repeat specimen. Date, time and tech initials are included in the comment. The patient's nurse/physician is notified and a new specimen is requested.

14. Error Correction: Any verified result that has been found to be in error is corrected by the technologist using Error Correction procedure in the LIS. The unit/nurse/physician is notified immediately. (See: Coagulation Lab Procedure "Correcting Lab Errors"). The supervisor/designee daily reviews all error corrections on the Exception Report printouts. (See: Quality Assurance: Error Detection and Correction Procedure).

15. Interpretation Comments: The following interpretation comments automatically accompany patient results and reference interval in the LIS.

INR: Protime INR (International Normalized Ratio)
2.0-3.0 Less Intense Therapeutic Range
2.5-3.5 More Intense Therapeutic Range

D-Dimer: (DDIM1)
This test has been validated as being useful in the exclusion of venous thromboembolism (VTE). A cutoff value = 230 ng/ml is suggested. Results below this cutoff can be used in conjunction with clinical assessment, such as Wells Score, in assessing the need for further investigation for VTE.

Ddimer Deep Vein Thrombosis Level: (DVTD1)
This is an Emergency Room ddimer order for patients with clinical symptoms:

"Plasma d-dimer levels are known to increase with age. Patients over 50 years can be considered for VTE/PE exclusion if their measured D-dimer result is less than their chronologica age multiplied by 5, expressed in ng/ml. For example, a 72 year old patient could be considered for VET/PE exclusion if the D-dimer is less than 360 ng/mL (72x5 = 360)."

III. Post Analytical Guidelines

1. Specimen Tracking:
   - The technologist responsible for generating results will initial all worksheets and Pending/Non-verified Result reports for the tests performed on that shift. The Pending report is generated periodically during and at the end of the shift

- to ensure that all specimens are received, are "in lab" status, and have been processed.

- Specimens that have not been received in the LIS or have not been routed to the correct test site are automatically processed by the analyzer to perform only PT and PTT as default tests.
  Results will cross the interface, and be printed by the analyzer, and stored in the analyzer database; these results are **not** auto-verified by the LIS. When specimens are placed in "In lab/Received status", results can be posted to the LIS.

2. The Exception report, Verified Test report and Supervisor's result report is generated from the LIS and is reviewed daily or within 24 hours by the manager and/or designated technologist on the day the report is generated. Critical/panic values, error corrected verified results and absurd results are reviewed for completeness and continuity. Auto-verified results are not at the Bristol site accompanied by I/AUT tech initials and can also be reviewed using the Exception report.

3. Supervisor or designated technologist will make appropriate corrections in the LIS, using Error Correction procedure as necessary. All reviewed reports are signed with date and initials of technologist and are maintained in lab for one month.

4. Instrument printouts may be maintained in lab for 30 days. LIS worksheet and instrument printouts are maintained (stored in archives) for a minimum of 5 years. QC is maintained on instrument database and is readily available for review.