Quality Control and Quality Control Out of Range Action

Policy

Before patient results can be reported the Quality Control must be run and be within acceptable limits. Controls must be run in the same manner as the patient samples.

Safety

Laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety, the safety of others and adhering to all departmental and medical center safety policies and procedures. Refer to Policy and Procedures Safety Manual Infection Control 11-085-01

Frequency

Controls must be run every 8 hours at least once per shift. When Quality Control tolerance limits are exceeded, corrective actions must be performed and recorded before analyzing patient samples.

Controls are also run:

1) When new reagents are placed on the coagulation analyzer, which include the following:
   a. Neoplastin C Plus
   b. PTT Reagent
   c. Fibrinogen Reagent
   d. LIA Test Latex
   e. LIA Test Buffer
   f. Heparin Reagent
   g. Heparin Buffer

2) When repairs have been completed on the analyzer.

Quality Control and Quality Control Out of Range Action,
Continued

Rules & Actions

Two levels of control must be run at the beginning of each shift, when there is reagent change or corrective maintenance performed. **BEFORE ANY PATIENT RESULTS ARE TURNED OUT**, control values must be within established limits.

The following rule is used to determine if your control is OUT:

1. One value outside of posted limits.

If one control is outside posted limits, do one or more of the following, recording each step until controls are within limits:

1. Rerun the control that is out.
2. Reconstitute new controls using freshly poured reagent grade water. Pay special attention to pipetting and mixing and time of reconstitution and run with current reagents.
3. Reconstitute new reagents using freshly poured reagent grade water. Pay special attention to pipetting and mixing and time of reconstitution and run controls with new reagents.
4. Check temperature of system.
5. Perform preventive or corrective action on instrument.

If control is now in range or limits, indicate action taken on audit sheet. After thorough investigation, if controls are still “out of control", notify supervisor.

Quality Control and Quality Control Out of Range Action,
Continued

Single Test Out

Review all analytes to see how many tests are out of control. If only:

IF	THEN
PTT is high or low (PT & FIB OK)	• Check needle 2 • check reagent reconstitution time/water/date-time made • Check needle 2 syringe for leaks or bubbles. • Check wash well rinsing. • Watch dispense of PTT reagent into cuvette at incubation area. • Check mapping of Needle 2 to cuvette at incubation area. • Check Test setup analysis times, volumes. • Try fresh CaCL2
PT is high or low (PTT & FIB OK)	• check reagent reconstitution time/water/date-time made • Check if reagent made with proper diluents or water. • Check Test setup analysis times, volumes.
Shift in D-Dimer (other tests ok)	• Clean measurement wells with 20% ethanol • Make certain reagents were equilibrated to RT and instrument temperature before running • Check Halogen lamp • Usage %, Replace • Is a reducer being used in both reagent vials? • Buffer and Latex

Quality Control and Quality Control Out of Range Action,
Continued

Multiple Test Out

IF	THEN
PT & PTT high (FIB low)	• Could be block in Needle 1-check needle; check syringe. • Could be block in Needle 3-check needle; check syringe. • Could be bubbles in the line; watch tubing above syringe and tubing in the area of the cleaner solution.
PT & PTT low (FIB high)	• Check and Bleach wash wells; especially 1 and 3. • Watch rinsing of needles; especially 1 and 3. • Check that Waste and Cleaner are in correct position. • May need to do a Back-Bleach of the system. • Residual bleach will affect results-run QC prior to patient testing. • Combination lowers FIB but raises PTT.

Erratic Result on Any/All Assay

- Watch processing of samples at all stages.
- Watch for balls jumping out of cuvettes
- Check wells for balls. Use a strong magnet. Use dental mirror to look in wells.
- Watch measuring plate and see if the balls are moving back and forth in a consistent manner.
- If they are not, check area around cuvette wheel. Strong magnets near wheel may magnetize cuvettes.
- Put on a new cuvette wheel and watch measuring plate again.
- Watch processing of samples at all stages.
- Change Syringe tip and O ring for Needle 1.
- Needle 1 tip

Quality Control and Quality Control Out of Range Action,
Continued

Additional Policies

Also complete the following steps:

Step	Action
1.	Record Neoplastine CI+ lot number and expiration date on STAGO STAR Quality Control and Action Log in space provided on each shift as needed.
2.	At month end, printout a copy of the Levy-Jennings chart and all control result files. Review and file in Coag Quality Control book.

Monthly QC Review

Quality Control files for the STA Coag Control Plus, STA Liatest Control and UFH/Xa Controls are uploaded manually to the Clarity by STAGO Quality Assessment Program website monthly. The data is used for evaluation and comparison with other STAGO analyzers. The Interlaboratory Quality Management is a service provided by Diagnostica STAGO. The report provides interlaboratory comparison indicating precision and accuracy relative to peer data.

Procedure to upload Monthly QC to Clarity

Step	Action
1	At the end of each month, printout a copy of the Levy-Jennings chart and all control files
2	Login to the Clarity by STAGO website
3	Select instrument model no.
4	Select instrument ID.
5	Select the correct QC product
6	Select the month
7	Select the correct QC Lot no.
8	Click on “**Summary Data**” link under data entry
9	Click on “**Edit**” link at the bottom of the window
10	Enter the following from the monthly instrument printout: number of QC points ran for the month, monthly Mmean, and the SD for each analyte.
11	Click on “Submit” to submit the data to STAGO

Quality Control and Quality Control Out of Range Action,
Continued

Monthly QC Review, Continued

Printing the Clarity Monthly Report

Step	Action
1	Login to the Clarity by STAGO website
2	Select instrument model no.
3	Select instrument ID.
4	Select "**Monthly Summary**" under Reporting
5	Print the Summary Report
6	Select "**Histogram**" and "**Youden**" under Reporting
7	Print both the Histogram and Youden report

Reviewing the Clarity Summary Report

- Clarity by STAGO Quality Control Summary Report are printed monthly and reviewed by the Hematology/Coagulation Supervisor. Issues identified are noted and corrective action is taken as needed and documented.
- This review includes inspection of trends and small shifts that may indicate systematic or potential accuracy problems. Monthly SD and CV's are examined, and corrective action is implemented and documented as needed.

Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. reviewed/ date	Lab Manager reviewed/ date	Date change Imp.
Minor	Reviewed. 1) Updated the format. 2) Added SAFETY section.	Julius Salomon 10/01/14			
Minor	1) Updated format 2) Updated Index Number	Marlon Esguerra 6/25/18			
Major	1) Added Monthly QC review section with step by step procedure of how to print and upload data	Marlon Esguerra 6/25/18			

Imp. =Implemented