DXH QUALITY CONTROL

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PURPOSE

To provide instruction for performance and review of Quality Control on the DXH hematology analyzers.

BACKGROUND

Quality control for the DXH analyzers is performed during each shift of patient testing. QC Results, XB and Levey-Jennings Charts are reviewed for acceptability by the operator before performing patient testing. Failed or unacceptable results are investigated and corrective actions documented on the System Manager. A Look-back of patient results is performed, if indicated. Patient results are not released until the QC failure has been resolved and documented.

Quality control data is monitored monthly for shift and trend analysis by the laboratory MT-Coordinator, or Lead Technologist. Monthly, QC for the DXH 800 is submitted to Beckman Coulter IQAP Peer Comparison Program. QC results are evaluated for accuracy and precision in order to detect analytic imprecision. IQAP peer comparison data is reviewed as the survey reports are received and corrective action taken, if necessary.

RELATED DOCUMENTS

Failed Patient Run, R-P0-CH0808

QUALITY CONTROL MATERIALS

PRODUCT	INTENDED USE	STORE	STABILITY	HANDLING
COULTER® LATRON™ CP-X	QC for DXH Volume, Conductivity, and Light scatter for the Differential, Reticulocyte, and NRBC counts.	2-30º C.	**Unopened:** Manufacturer's Expiration. **Opened:** 30 days at ambient temp.	Bring to ambient temperature before use. Do not freeze. Mix 5 to 8 times by gentle inversion. Avoid foaming. Perform analysis in cassette mode after performing the daily shutdown procedure and daily checks.
COULTER® 6C CELL CONTROL	To confirm accuracy and precision of all parameters included in a CBC/Diff, as well as for NRBCs.	2-8° C.	**Unopened:** Manufacturer's Expiration. **Opened:** 16 days	Bring to ambient temperature. Mix vial gently per manufacturer's recommendation. Refrigerate within 30 minutes after use. Perform analysis in cassette mode.

PRODUCT	INTENDED USE	STORE	STABILITY	HANDLING
COULTER® RETIC-X CELL CONTROL	To confirm accuracy and precision of the Reticulocyte parameter.	2-8° C.	**Unopened:** Manufacturer's Expiration. **Opened:** 16 days	Bring to ambient temperature. Mix vial gently per manufacturer's recommendation. Refrigerate within 30 minutes after use. Perform analysis in cassette mode.

QUALITY CONTROL SCHEDULE / FREQUENCY

A minimum of two levels of 6C and Retic-X cell controls are performed once every 8 hour shift.

Latron-CP-X testing is performed every 24 hours after the system shutdown and daily checks have been performed.

PROCEDURE

1. Review results for XB and the LJ-charts for all QC levels as soon as possible when starting your shift, looking for recent QC outliers, trends, or corrective actions. Check for adequate reagent volumes and check if maintenance has been performed.

2. Document the XB and LJ review in the LIS. Note: Documentation should be completed within the 1st hour of the shift.

3. When you are later ready to perform QC at the recommended time, remove the 6C, and Retic-X QC from the refrigerator and warm to ambient temperature for 15 minutes. Review the expiration dating, lot numbers, and check the vials for acceptable volume.
   Note: For Latron CP-X control, refer to the work instruction, DXH-Latron QC.

4. Place the red STOP sign on the analyzer to prevent patient samples from being tested while the QC is being performed. Note: Do Not place the instrument back in service until the QC has been reviewed and documented.

5. After warming, mix the vials manually, as follows:
   a. Roll the tube slowly between the palms of the hands eight times in an upright position.
   b. Invert the vials and slowly roll them between the palms eight times.
   c. Gently invert the tubes back and forth 8 times.
   d. Inspect each tube for complete suspension. DO NOT RESUSPEND QC VIALS USING A MECHANICAL MIXER.

6. Place the control vials for 6C and Retic-X in a cassette and analyze in the same manner as a patient sample.

7. After analysis and within 30 minutes, return the vials to the refrigerator.

REVIEWING CONTROL RESULTS:

1. Select the Quality Control status icon on the System Manager screen.

2. If a QC has failed, a dialogue box will open with a list of the failed controls.

Comment [m1]: Deleted: If all QC was within range, the Data View screen will open.

3. Choose SELECT CONTROL from the bottom of the screen.

4. Highlight the control and the level to be reviewed. Then, select OK to open the file.

5. The result of the most recent run is on the far right-side of the screen and the column is highlighted in blue. Failed results are in red. The left-side of the screen lists the statistical data for the control level.
    - Note: For Latron QC: Use the scroll bar on the left side of the page to view QC results that are hidden below the edge of the page.

6. Select the VIEW GRAPH button to review the Levy-Jennings graphs. Click on the individual thumbnail graphs to open the enlarged LJ chart for each parameter.
    - Data points displayed in Red and located on the 2SD limit will not flag, as they are considered acceptable.
    - Data points displaying in Red located outside the 2SD limit will flag and will stop the instrument. Corrective action must be performed. Evaluate if a look-back is indicated.

7. In VIEW DATA, select COMMENT to enter your tech ID and your review or corrective action comments. All QC must have documentation.
    - Do not perform patient testing until all QC issues have been resolved and documentation completed.
    - When documentation is complete, select CLICK TO REVIEW at the bottom of the QC results, to put a date and time stamp on your review.

8. For FAILED QC results, document the following in the Comment box and perform the additional steps:
    - Document Corrective action taken and troubleshooting steps
    - Document if a look-back is indicated.
    - Documents if patient testing was performed after the failure.
    - Document your Tech ID on all QC results.
    - Close the dialog box by selecting OK.
    - Exclude failed QC's which are possible outliers (i.e. QNS vials) by clicking on the SQUARE box. A checkmark will appear removing the data from the statistics.
    - When documentation is complete, select CLICK TO REVIEW at the bottom of the QC results, to put a date and time stamp on your review.

9. Repeat the previous steps for all controls that were tested.

10. Remove the red STOP sign and replace with the green GO sign only when the QC is acceptable. Patient testing may then be performed.

QC CORRECTIVE ACTION PLAN:

The following quality control corrective action steps should be followed if the immediate problem is unable to be identified:

1. Check control for open vial/reconstitution stability.

2. Check reagents for appearance, volume, and expiration date.

3. Review history of analyte in question for results for the last 10 data points to observe for shifts or trends.

4. Repeat the control (same bottle of non-expired control or fresh bottle of control if expiration or shelf life is questionable).

5. Review other QC levels that were performed currently and those performed on previous shifts to identify similar problems.

6. Check for previously performed or pending instrument maintenance. Perform maintenance, if indicated.

7. Review the Troubleshooting section in the HELP manual on the instrument. Perform related Troubleshooting procedures using Diagnostic tools or contact Beckman-Coulter Technical Support.

8. Document all corrective actions taken to resolve the problem.

9. Perform a look-back of patient results, if indicated. The look-back should cover patient samples performed and reported since the last acceptable test run. Results must be re-evaluated to determine if there is a significant clinical difference. This may be performed by reviewing reported results and comparing them to prior reported results and/or repeating the samples. Follow laboratory policy, Failed Patient Run, R-P0-CH0808.

10. If unable to resolve the failed QC, take the instrument out of service and notify a MT-Coordinator, lead technologist, key operator, and/or schedule a service call.

REFERENCE:

Instructions for Use UniCel® DXH 800 Coulter® Cellular Analysis System PN 629743AE (March 2009)

DOCUMENT APPROVAL	**Purpose of Document / Reason for Change:**		
Modified to meet the CAP QC review requirement.			
☐ *No significant change to process in above revision. Per CAP, this revision does not require further Medical Director approval.*			
Committee Approval Date	☐ Date: ☐ N/A – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	