Tech Tip: LIN-X
(Linearity Control – Studies Mode)

COULTER UniCel DxH Series
DxH Series Tips for Running LIN-X Linearity Control

INTENDED USE

COULTER LIN-X Linearity Controls are intended to assess calibration and verify the reportable range of UniCel DxH Series Coulter Cellular Analysis Systems listed in the TABLE OF EXPECTED RESULTS, in conjunction with specific COULTER reagents.

SUMMARY AND PRINCIPLE

CLIA requires that laboratories establish and verify the performance specification, accuracy, precision and reportable ranges, of new instrumentation upon installation, following significant preventive maintenance, unusual trends/shifts in control recovery or when recommended by the instrument manufacturer. COULTER LIN-X Linearity Controls can be used on calibrated instruments to comply with these guidelines. The product's WBC, RBC, HGB and PLT concentrations span the instrument's reportable ranges. Results from repeated measurements for each concentration are compared to the established expected range, to assess the instrument's calibration and to verify the reportable range.

Follow the Instructions for Use on the Lin-X Linearity Control for instrument preparation and setup. This information is summarized below.

INSTRUCTIONS FOR USE
Before analyzing LIN-X Linearity Controls, review the following information to ensure accurate results are obtained:

IMPORTANT:

Flagging
When analyzing LIN-X Linearity Controls patient flags will occur. These flags should be ignored if a numerical result is obtained. When voteout (- - - - -), incomplete computation (.....) or over range (+++++) flags occur, the sample should be repeated. Some levels may generate a non-blood (N) flag. DO NOT ignore System messages (R).

INSTRUMENT SET UP
Prior to running the LIN-X Linearity Controls on UniCel DxH 800/600 Coulter Cellular Analysis Systems:

1. Ensure there is sufficient reagent to complete the analysis.

2. Perform quality control procedures/calibration according to the Instructions for Use or System HELP. If acceptable, proceed with running LIN-X.

At the DxH System Manager

1. Clear any previous runs from the Studies Mode.

2. Select **Worklist > Custom > Filter Name: Studies > Delete Order > All Test Orders in Current Filter > OK**.

3. Place the DxH **OFFLINE**.

4. Select **Menu > Setup > System > Analysis > Disable Temporarily > NRBC > OK** to disable the NRBC temporarily.

5. Select **System Status > Details Status > Batching >** select the **checkbox > OK.**

6. Select **Studies > Enable Studies > Aspiration/Tube 6 > OK**.

7. Set the **Default Test Order** to **CBC**.

Analyzing LIN-X Linearity Controls

1. Remove LIN-X Linearity Controls from the refrigerator and warm at AMBIENT TEMPERATURE for 15minutes.

2. After warming, mix BY HAND as follows:

   a. Roll tube slowly between the palms of the hands eight times in an upright position.

   b. Invert the tube and slowly roll it between the palms eight times.

   c. Gently invert the tube eight times.

3. Repeat steps 2a to 2c three times. Visually inspect the tube contents for complete re-suspension. If necessary, repeat steps 2a to 2c until tube contents are uniformly suspended.

4. Run LIN-X linearity control tubes in consecutive order beginning with Level 0 and ending with Level 11.

5. Place the DxH **ONLINE**.

   NOTE: Tube barcodes must face forward in the cassette. <u>Run one cassette at a time</u>. Wait until the cassette is in the Output Buffer to place the following cassette in the Input Buffer.

   <u>**Tube Order in Cassette:**</u>

   a. Cassette 1 containing tubes: (0 to 4).

   b. Cassette 2 containing tubes: (5 to 9).

   c. Cassette 3 containing tubes: (10 to 11).

6. Repeat flagged samples with non-numeric values.
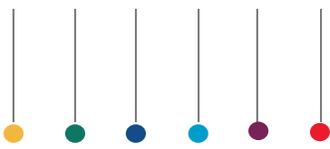
Export the Data to the E:\ drive

1. Select **Worklist > Custom > Filter Name: Studies**.

   NOTE: If needed, sort the runs in the folder by instrument column.

2. Select **Export**.

3. Select **Type > CSV**.

4. Select **Data Selection > All Result(s) in Current Filter**.

5. Select **Destination > Local Drive button (E:\)**.

6. Click on **Select Folder**.

7. Create Folder or select a folder from the list. If creating a new folder enter a name for the folder, select **OK**.

8. Highlight the folder you wish to use, then click **OK**.

   NOTE: The Export screen re-appears with a path to the folder you selected, and a file name. Rename the path to the folder as follows:

   Example: IQAPID#(space)InstrumentSerial#.CSV (750831 AM15005.csv)

9. Select **Start**.

10. The files will be moved to your selected folder on the **E:\ Drive**.

Moving the files to your USB drive

1. Insert your removable media into the USB drive of the System Manager.

2. Select **Menu > Advanced > Windows Explorer > User (E:)**.

3. Locate the folder(s) on the right side of the screen and highlight them.

4. Drag the selected file(s) to the USB drive.

5. Close the Windows Explorer.

6. Remove the USB device.

Uploading the files to IQAP

1. Use a computer with access to the Beckman Coulter website.

2. Select **Support**.

3. Select **Quality Assurance Programs**.

4. Select **Hematology eIQAP**.

5. Log into your IQAP account

6. Select the DxH instrument from the list according to the Serial Number.

7. Select **New Data Submission > Upload Instrument QC files > Add files**.

8. Locate the file on the USB device.

   Example: Use **ONLY** the IVD file. IQAPID(space)InstrumentSerial#_IVD.csv
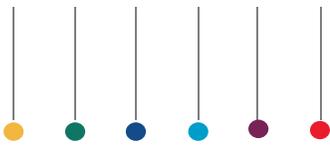
9. Highlight the file and select **Open**.

10. File will appear on the upload screen, select **Start Upload**.

11. The **Please Wait** prompt appears while the upload process completes.

12. Open the file, review the data.

    NOTE: Routinely, the file will be displayed as Pending. Open the file and verify all data. If the data within the file(s) is displayed in red, verify information or data and edit or repeat as necessary.

13. After all data has been reviewed and is ready for submission, select **Submit**.

    NOTE: If the data was submitted successfully, within 10 minutes or less, a copy of the report will be available to save as a .pdf file or print.

Return the System to Ready

1. Place the DxH **OFFLINE**, re-enable the NRBC; disable Batching and Studies Mode.
2. Change the Default Test Order on the Cassette Specimen to (CD) or according to your SOPs.

REFERENCE

UniCel DxH Series with System Manager Software (PN B26647)
IQAP Instructions for Use (PN 4206266)
COULTER LIN-X Linearity Control (PN A59930)