

Tech Tip: LIN-X (Linearity Control)

COULTER UniCel DxH Series DxH 600/800 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 800/600 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.

1. Disable NRBC Module – Temporarily: Menu > Setup > System > Analysis > Disable Temporarily – NRBC.
2. Let LIN-X vials come to Room Temperature (10-15 min)
3. Mix each vial 8x8x8 (4 times).

NOTE: Run each vial (one at a time) 6 times in Repeatability Mode: Start with Vial number 0.

4. Menu > QA > Repeatability > Repeatability Setup: Cassette Presentation, Test Panel (CBC) – Number Aspirations (6). **NOTE:** Run 1 for each level is used as a Prime.
5. Exclude Run 1 and ensure the remaining runs are within the assayed range.
6. Print Summary Report (Click printer icon in upper right corner) – label printout with the number on the vial.
7. Select Clear Runs (lower left) – this pauses the instrument.
8. Click “Resume” button – lower right tab.
9. Individually run remaining tubes (1 – 11) using steps 5-8.
10. After last Vial number (11) click “Cancel”. **NOTE:** Vial 11 is used to clean the system – Run 6 times but don't need printout or recorded.
11. Enable NRBC Module – See Step #1.
12. Go onto IQAP website & “Create” Linearity form. Enter Kit# (Lot# on box), date.
13. Enter Lot number of each vial & values.
14. Submit Report.

Note: Report should be ready within 24 hours.

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