Dignity Health Central Coast Service Area

**SUBJECT**: Linearity Testing and Analysis on the DxH 800/600

**ORIGIN:** Clinical Laboratory/Hematology

| **Document Category:** | | | |
| --- | --- | --- | --- |
| ☒ Policy | ☒Procedure | ☐Standardized Procedure | ☐Other: |

| **Applies to:** | | |
| --- | --- | --- |
| ☒ Santa Maria Campus,  Marian Regional Medical Center | ☒Arroyo Grande Campus,  Marian Regional Medical Center | ☒French Hospital Medical Center |
| ☐St. John’s Pleasant Valley Hospital | ☐St. John’s Regional Medical Center | |

# purpose:

To provide instruction on the testing of the Coulter LIN-X (Linearity Control) and review of results. Coulter LIN-X Linearity Controls are intended to assess calibration and verify the reportable range of UniCel DxH 800/600 Coulter Cellular Analysis Systems. Linearity testing must take place at minimum, every 6 months.Testing should also be performed upon installation, following significant preventative maintenance, unusual trends/shifts in quality control, or when recommended by Beckman Coulter. 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 he established expected range, to assess the instrument’s calibration and to verify the reportable range.

# REAGENTS/SUPPLIES:

* COULTER® LIN-X Linearity Control 628029
* DxH 800/600

## LIN-X Linearity Control is stored at 2-8°C

## LIN-X Linearity Control expiration date

### Closed expiration date listed on box

### Open expiration is 7 days

# QUALITY CONTROL:

Quality Control material including Latron (628024), 6C Cell control (A59925), and Retic-X control (628028) is tested once every 24 hours of use, and/or after maintenance, calibration or while troubleshooting. Latron control is performed once daily after shutdown.

# procedure:

Before performing Linearity Testing, confirm that the three levels of 6C Cell control are acceptable. These procedures should be performed before linearity testing to verify instrument performance.

## Take instrument OFFLINE

## Temporarily disable the NRBC module: MENU>SETUP> SYSTEM>ANALYSIS (bottom of screen)>TEMPORARILY DISABLE NRBC.

## Place instrument ONLINE

## Menu>QA>Repeatability>Repeatability Setup

From the Repeatability Setup dialog box, a window will pop up stating “Existing data will be deleted”, Select <OK> to continue. From the Test Panel drop down list select the following:

### Cassette Presentation

### Test Panel (CBC)

### Number Aspirations (6)

## Allow LIN-X vials to come to Room Temperature (10-15 minutes)

## Mix each vial 8x8x8 times

## Run LIN-X linearity control tubes in consecutive order beginning with Level 0 and ending with Level 11. Repeat flagged samples with non-numeric values, System Messages (R), or ++++ (over range). Some levels may generate a non-blood (N) flag.

## Place Tube 0 in a cassette and load onto the instrument, it will automatically aspirate 6 times.

## When 6 runs are complete, exclude 1st run (the prime tube)

## Verify mean and SD is acceptable as compared to the Table of Expected Results that came with the LIN-X kit

### If unacceptable, repeat the vial. Continued unacceptability will require troubleshooting and service if necessary

### If acceptable, move to next step

## Print Summary Report – label printout with vial number and lot number

## Select Clear Runs button, accept message

## Select Resume button on the lower tab

## Individually run remaining vials (1 – 11) using steps F-K

## Vial 11 is used to clean the system. Run this vial 6 times but do not keep the printout.

## After the last vial (11) is finished, select CLEAR RUNS. Click RESUME. Select CANCEL. Make sure OFFLINE is in the upper left corner of the screen. If it says REPEATIBILITY, go back and select CANCEL

## Enable NRBC Module – See Step B

## Submit all data to the hematology lead for submission to Beckman Coulter

# Submission of data to beckman coulter by the hematology lead

## Log on to Beckman IQAP Website: [www.beckmancoulter.com/eiqap/](http://www.beckmancoulter.com/eiqap/)

### Select Go To Hematology IQAP

### Log in

## Create a new Lin-X Linearity Control data entry form

### Enter data manually or upload data via USB import.

## Report will be ready within 24 hours

# results

## Beckman Coulter will prepare tabular summary and graphic presentations of data. Retain copy for records.

# LIMITATIONS:

## Calibration and Linearity errors can be caused by:

### Inadequate mixing

### Excessive handling

### Exceeding time limits

### Failure to analyze sufficient number of samples

### Inadequate volume of reagents to complete test

# references:

**UniCel® DxH 800 Coulter® Cellular Analysis System,** Instructions for Use PN 629743AG (November 2010) System Manual.

**UniCel® DxH 800 Coulter® Cellular Analysis System Training,** Module PN A69207AB.2 (February 2012) Professional Development.

Beckman Coulter Technical Support. 2.0 Update Procedure Change. Hematology 6/25/14.

Beckman Coulter Tech Tip: LIN-X (Linearity Control) July 2016