Dignity Health Central Coast Service Area

**SUBJECT**: Beckman DxH Calibration Procedure 7500.H.CC.33

**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:

 Calibration assures that an instrument's data output accurately reflects sample input.

# REAGENTS/SUPPLIES:

 COULTER® S-CAL Calibrator 628026

 COULTER® 6C Cell Control A59925

 Sufficient DxH 800/DxH 600 REAGENTS to complete calibration

# CALIBRATION:

Calibration verification is required every six months, if controls begin to show evidence of unusual trends or exceed the manufacturer’s defined acceptable limits, or if ambient room temperature changes more than 6oC from the calibrating temperature. Calibration should be performed at installation, after the replacement of any component that involves dilution (such as BSV) or the primary measurements (such as apertures), if the calibration verification fails, or when advised to do so by Beckman Coulter Representative.

# 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:

1. **Preparation**

Before performing S-Cal procedure, confirm that Carryover, Background, and Reproducibility are acceptable (refer to policy# 7500.H.CC.35 and 7500.H.CC.36). These procedures should be performed before S-Cal to verify instrument performance.

1. **S- Cal**

Remove S-Cal from the refrigerator and warm at Ambient Temperature for 15 minutes.

After warming the S-CAL Calibrator, mix by hand as follows:

 **NOTE:** Do NOT use a mechanical mixer.

* 1. Roll the tube slowly between the palms of the hand 8 times in an upright position.
	2. Invert the tube and slowly roll between the palms of the hand 8 times.
	3. Gently invert the tube 8 times.
	4. Inspect the tube contents to determine if all cells have been uniformly distributed.
	5. Repeat the mixing procedure if tube contents have not been uniformly distributed.
1. **Calibrate with COULTER S-CAL Calibrator**

 **NOTE:** Before you can start or restart the calibration process, the SPM must be offline.

* 1. Select **Menu>QA>CBC Calibration**
	2. Select **Calibration Setup** on the CBC Calibration Screen to display the CBC Calibration Setup dialog box.
	3. If calibration data exists, the system will display: “Existing Data will be deleted”. Select OK to continue”.
	4. Type “11” in the **Number of Aspirations** text box. This will allow the user to discard one value if necessary.
	5. Select **Cassette** from the Presentation drop-down list.
	6. Select **BCI** from the Calibrator Typedrop-down list.
	7. Select **New Control From Bar Code** and use the handheld barcode scanner to scan the 2D barcode on the product insert or type/select the following information:
* **Lot #**
* **Expiration Date**
* **Reference Values**
	1. Select **OK** and follow the screen prompts.
	2. Place the calibrator in a cassette.
	3. Place the cassette in the input buffer and select **OK**.
	4. Review the calibration results, as well as, graphs <Details>, and apertures <additional data> (refer to INTERPRETATION OF RESULTS).
	5. Select the **Finish** button at the bottom of the screen.
	6. When all results are acceptable, the **Edit System Recommendations** button at the bottom right hand corner of the screen is enabled. This button allows one to modify the calibration recommended by the system by selecting or deselecting checkboxes or Verify the Calibration.

 NN = Not Needed R = Recommended NR = Not Recommended NA = Not Allowed

**NOTE:** If the new calibration factor does NOT make a change in the direction expected, do not change the factor. Question the acceptability of the product or instrument performance.

* 1. Verify calibration with the 6C Controls. When the calibration procedure is complete, the CBC Calibration (Summary) screen is displayed. If acceptable print CBC Calibration Summary Report and three levels of 6C control results performed after calibration and retain for records.

# Interpretation of results:

The background color of the Factor %Diff, %CV, and Difference cells change color when the presented value is out of the reference value as follows:

* Yellow for Difference indicates that the value is out of range, therefore calibration is recommended
* Red only applies the %CV and indicates that the statistical value in NOT within range and the system does NOT allow calibration

**NOTE**: Calibrated parameters are for CBC only. NRBC, and Retic parameters are calibrated by the service engineer upon realignment of lasers.

Under CBC Calibration Summary Statistics: Calibration is recommended if the result for **Difference** is greater than DIFFERENCE LOWER LIMIT MAX and the result for **Factor % Diff** is greater than the FACTOR % DIFFERENCE LOWER LIMIT MAX (refer to Calibration Criteria table below).

| **PARAMETER** | **CALIBRATE IF DIFFERENCE LOWER LIMIT MAX** | **CALIBRATE IF FACTOR % DIFF LOWER LIMIT MAX** |
| --- | --- | --- |
| WBC | >0.1 | >1.25% |
| RBC | >0.03 | >0.7% |
| HGB | >0.1 | >0.78% |
| MCV | >1.0 | >1.18% |
| PLT | >6.0 | >2.70% |
| MPV | >0.5 | >5.0% |

*TABLE: Calibration Criteria*

# LIMITATIONS:

DO NOT PROCEED IF INSTRUMENT PERFORMANCE DOES NOT MEET SPECIFICATIONS.

Calibration errors can be caused by:

* Inadequate mixing
* Excessive handling
* Exceeding time limits
* Failure to analyze a sufficient number of samples
* Inadequate volume of reagents to complete test

If your cell control results are not within the expected range, repeat the sample. If the results of the second sample are not within the expected range, follow the Troubleshooting Procedure on the 6C Cell Control package insert or the DxH Quality Control procedure.

# 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