BIOGENIX

SOP FOR CELL-DYN EMERALD-22

(CBC)

	NAME	DESIGNATION	SIGNATURE	DATE
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1. Table of Contents

2.REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

3.REVIEW HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

4.PURPOSE

4.1. To guide the laboratory personnel in performing CBC by using the CELL DYN EMERALD 22

4.2. CBC is used to evaluate morphology of red cells and platelets, anemia, leukemia, reaction to inflammation and infections, peripheral blood cell characteristics, state of hydration and dehydration, polycythemia, hemolytic disease of newborn, inherited disease of red cells, white cells, and platelets. CBC is also used to monitor chemotherapy.

5.TEST PRINCIPLE

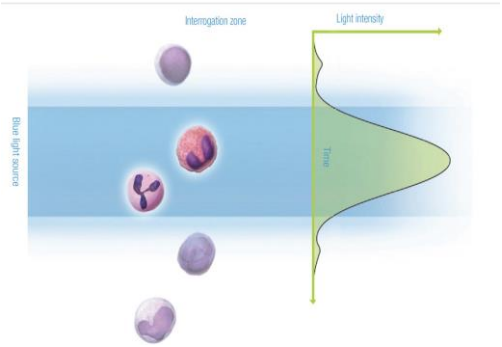
The CELL-DYN Emerald 22 performs three types of measurements which are used to count, size and classify blood cells and to measure hemoglobin. The three types of measurements are:

5.1. **Electrical Impedance Counting**: is based on the measurement changes in an electrical current produced by particles (cell suspended in conductive liquid) as they passed through an aperture known as dimensions. As each cell passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses indicates the number of cells that traversed the aperture. The change produces a measurable electrical pulse and the number of pulses is proportional to the volume and size of the cell that produced it. It is used for WBC, RBC and PLT count measurements.

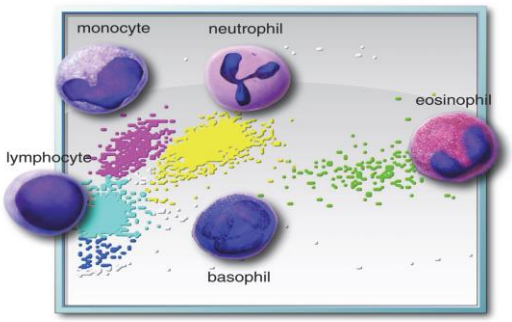
5.2. **Absorption Spectrophotometry** – is the method used to measure Hemoglobin (Hb). An oxyhemogobin chromogen is formed and measured when sample is mixed with lytic reagent. A LED light source and photo detector are used to detect the chromogen. The Hb concentration is directly proportional to the light absorption of the sample. The blank and sample readings are compared to determine the haemoglobin concentration of the sample. Three parameters are obtained: HGB – Hemoglobin Concentration, MCH – Mean Cell Hemoglobin MCHC – Mean Cell Hemoglobin Concentration

5.3. **UNI-FLOW technology (Optical flow cytometry)** - is based on a concept of active sample flow and passive sheath. The diluted sample is introduced into flow cell under pressure and the sheath is utilized only to maintain the sample stream. The five-part WBC differential is obtained by scatter gram analysis after action of the lyse reagent. This reagent destroys the RBC and RBC stroma, generates a hemoglobin chromogen, and protects the WBC membrane to keep the cell in its

native state. For each cell entering the optical detection area, two pulses are generated, one for Axis Light Loss (ALL) measurement and one for the Forward Side Scatter (FSC) measurement.



The cluster separation is enhanced with the low wavelength (455nm) blue solid state light source (3WLED). The blue wavelength enhances differentiation of intra cellular contents, improving the identification and separation of eosinophils and monocytes from neutrophils.



6.PERFORMANCE CHARACTERISTICS

The test run on CELL DYN are verified by doing Start Up Background Counts, Carryover, Linearity/Analytical Measurement Range (AMR), Imprecision (Reproducibility), Comparability (Correlation**)**

6.1 Start Up Background Counts

6.1.1 A background count is automatically run at the end and as part of the Start Up cycle.

6.1.2 Background counts can be run at any time by performing a Start Up from the Main Menu.

6.1.3 Background values must be within the following specifications before testing patient samples, running QC, or performing calibration:

(Background Specifications)	
Parameter	**Specification**
WBC	< 0.5 K/µL
RBC	< 0.1 M/µL
HGB	< 0.2 g/dL
PLT	< 10.0 K/µL
DIF*	< 100 cells

6.2 Carryover:

6.2.1 Carryover is determined by running whole blood specimens with high target values of WBC, RBC, HGB and PLT.

6.2.2 Each specimen is run in triplicate followed by three aspirations of whole blood specimens with low target values.

6.2.3 While assaying these samples, no other specimen or tests is assayed in the instrument, and the samples must be assayed in the following order, otherwise the experiment is invalid (**3 Low specimens,2 High specimens,1 Low specimen,2 High specimens,4 Low specimens,2 High specimens,1 Low specimen,2 High specimens, 1 Low specimen,2 High specimen,1 Low specimen)**

6.2.4 Carryover is calculated and expressed as a percentage using the following formula:

6.2.5 Percent Carryover = $\frac{\text{(Low Target Value1-Low Target Value3)}}{\text{(High Target Value3-Low Target Value3)}} \times 100$

6.3 Linearity/Analytical Measurement Range (AMR):

6.3.1 The AMR is the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pre-treatment not part of the usual assay process. The analytical measurement range (AMR) specifications were determined by analyzing fresh human whole blood, supplemented with commercial linearity materials.

6.3.2 Display Range is set by the system software and reflects the defined limits of the screen display and printer output.

NOTE: Maximum display range results are flagged with a * to indicate that the value is higher or lower than the default display range.

6.3.3 Linearity material: We are using CBC line from R&D systems for linearity.

6.3.4 Stability and Storage:

6.3.4.1 Store CBC-Line upright at 2-8 ^{O}C when not in use.

6.3.4.2 Protect tubes from overheating and freezing.

6.3.4.3 Unopened tubes are stable through the expiration date.

6.3.5 Indications of Deterioration:

6.3.5.1 After mixing, CBC-Line RBC is similar in appearance to fresh whole blood.

6.3.5.2 In unmixed tubes, the supernatant may appear cloudy and reddish; this is normal and does not indicate deterioration.

6.3.5.3 Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration.

6.3.5.4 Do not use if deterioration is suspected.

6.3.6 CBC- Line RBC:

6.3.6.1 Remove tube from the refrigerator and allow to warm at room temperature for 15 minutes before mixing.

6.3.6.2 To mix, hold tube horizontally between the palms of the hands. Do not pre-mix on a mechanical mixer.

6.3.6.3 Roll the tube back and forth for 20-30 seconds; occasionally invert the tube. Mix vigorously but do not shake.

6.3.6.4 Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing.

6.3.6.5 Invert the tube 8-10 times immediately before each sampling.

6.3.7 CBC-Line WBC and CBC-Line PLT:

6.3.7.1.1 Remove tube from the refrigerator and allow to warm at room temperature for 15 minutes before mixing.

6.3.7.1.2 Mix using vortex mixer. Mix vigorously by vortexing the sample on a vortex mixer for 2 minutes.

6.3.7.1.3 Let sample sit undisturbed for 10 minutes to allow micro bubbles to dissipate before sampling.

6.3.7.1.4 Invert the tube 8-10 times immediately before ach sampling.

6.3.8. Analyze CBC-Line: Prepare CBC-Line for analysis exactly as a patient sample.

6.4. Imprecision (Reproducibility):

6.4.1. Imprecision is expressed as the standard deviation (SD) or coefficient of variation (CV) of analytic results in a set of replicate or duplicate measurements.

6.4.2. **NOTE:** Laboratories should confirm this imprecision performance using fresh whole blood specimens.

6.5. Comparability (Correlation):

6.5.1. The purpose of the study is to demonstrate that, when the same specimen is assayed on two instruments, the difference between the two measurements does not exceed an Allowable Total Error (TEa) defined by the laboratory.

6.5.2. Assay minimum of 20 samples (usually patient samples) on our instrument and other instrument performing same test. At minimum, samples should cover the range of values normally encountered. Ideally, they should cover the entire reportable range.

6.5.3. Sample Processed on both instruments same as the laboratory routinely analyzes specimens.

7. TYPE OF SAMPLE/CONTAINER/ADDITIVE

7.1. Sample Type:

7.1.1. Whole blood K2- EDTA specimens

7.1.2. Stability:

7.1.2.1. ≤ 3hrs at 20-25°C

7.1.2.2. 1 day at 2-8°C

7.1.2.3. Specimen stability: The RBC, white blood cell count (WBC), platelet count and red cell indices are usually stable for up to 8h after blood collection, When the blood is kept at 4°C the effects on the blood count are not usually significant for up to 24 hours.

7.1.2.4. If specimens cannot be processed within 3 hours, they should be refrigerated at 2 - 8°C. Before processing refrigerated specimens should be allowed to warm up to room temperature (minimum 15 minutes), then mixed, preferably by rotation, for at least 2 minutes

7.2. HANDLING OF SPECIMENS

7.2.1. Make sure the blood is sufficient and not excess anticoagulant

7.2.2. Adequate mixing of blood with anticoagulant

7.2.3. Error in patient and/or specimen identification

7.2.4. Adequate specimen storage conditions

7.2.5. Perform the test as soon as possible

7.3. SAMPLE ACCEPTANCE AND REJECTION CRITERIA

Samples are rejected in following conditions.

7.3.1. Frozen specimen

7.3.2. Clotted specimen

7.3.3. Hemolysed specimen (Partially hemolysed samples are processed with the comment regarding hemolysis on the report)

7.3.4. Samples collected in wrong tube or anticoagulant

7.3.5. Insufficient or excess amount of blood or EDTA

7.3.6. Centrifuged specimen

7.3.7. Specimen beyond stability

8. PATIENT PREPARATION

8.1. TYPE OF CONTAINER

8.1.1. K_2-EDTA Blood

8.2. REQUIRED EQUIPMENT AND REAGENT

8.2.1. Equipment:

8.2.1.1. Cell Dyn Emerald 22

8.2.1.2. Roller mixer

8.2.2. Reagents:

8.2.2.1. CELL-DYN Emerald 22 Diluent Reagent

8.2.2.2. CELL-DYN Emerald 22 Lyse Reagent

8.2.2.3. CELL-DYN Emerald 22 Easy Cleaner Reagent

8.2.2.4. Controls: CELL-DYN 22 PLUS Controls

8.2.2.5. Calibrator: CELL-DYN 22 Plus Calibrator

8.2.3. Supplies:

8.2.3.1. Disposable gloves

8.2.3.2. Containers for infectious materials

8.2.3.3. Printer paper

8.2.4. STORAGE AND STABILTY:

	Storage Temperature	**Maximum Storage Time**	**Additional Storage Instructions**
Reagents (Unopened)	2 to 10 °C	Until expiration date	Store in upright position.
Reagents (Opened)	2 to 10 °C	Until expiration date	*Store in upright position. *container can be used only for the number of days stated on the assay sheet *Avoid unnecessary cycles of warming and cooling *Avoid prolonged exposure to ambient room temperature or vigorous mixing
Calibrators	2 to 8 °C (unopened)	Until expiration date	Store in upright position. Protect vials from overheating and freezing. (Once opened, vial can be used for only one

			cycle provided that they are handled properly)
Controls	2 to 8 °C (unopened)	Until expiration date	Store in upright position. Protect vials from overheating and freezing; After opening, controls are stable for 7 days when stored at 2-8°C

9. ENVIRONMENT & SAFETY CONTROL

9.1. Humidity / Temperature

9.2. In vitro diagnostic use: Exercise the standard precautions required for handling all laboratory reagents

9.3. Exercise the normal precautions required for handling all laboratory reagents.

9.4. Disposal of all waste material in accordance with Procedure for Waste Management

9.5. Avoid the formation of foam with all reagents and sample types (specimens, calibrators, and controls).

9.6. Safety data sheet available in MSDS

10.CALIBRATION

10.1. Calibration Frequency:

10.1.1. The CELL-DYN Emerald 22 is calibrated with a commercial calibrator using CELL-DYN 22 Plus calibrator. CELL-DYN 22 Plus Calibrator is used to calibrate the WBC, RBC, HGB, MCV, and PLT parameters.

10.1.2. To determine if CELL-DYN Emerald may need to be calibrated, criteria include:

10.1.2.1. At least every six months

10.1.2.2. After any major part changed in the instrument.

10.1.2.3. A complete change of reagents, i.e., change in type of reagent from same vendor, or change to a different vendor.

10.1.2.4. When indicated by quality control data.

10.1.2.5. As directed by the regulatory agencies governing the laboratory

10.1.2.6. *Always consider calibration as the last step in a troubleshooting sequence. Frequent unnecessary calibration can mask an underlying problem with instrument*.

10.1.2.7. Calibration for cell Dyn emerald 22 AL is performed only by engineer

10.2. TRACEABILITY:

10.2.1. The calibrator is value assigned using instruments calibrated to whole blood. The calibrator parameters are traceable back to the following standard methods.

PARAMETER	REFERENCE METHOD/MATERIAL
WBC & RBC	Single channel particle calculator
HGB	Cyanide meth hemoglobin method
HCT	Mircoblood sedimentation method
PLT	Phase contrast microscope counting method

10.2.2. The relative uncertainty of measured results of the reference method fall within following percentage. WBC ≤4% , RBC ≤ 2%, HGB ≤2%, PLT ≤9%

10.2.3. MCV is calculated parameter traceable to the methods for RBC & HCT

10.3. CONTENTS: CELL-DYN calibrator is a stable whole blood preparation that contain any or all of the following

10.3.1. Stabilized human or mammalian red blood cells

10.3.2. Human, mammalian or simulated WBSs and platelets

10.4. CALIBRATOR STORAGE & STABILITY

10.4.1. Unopened calibrators are stable until the expiry date when stored at 2- 8°C

10.4.2. Once opened, vial can be used for only one cycle provided that they are handled properly:

11.QUALITY CONTROL

11.1. QC MATERIALS: We are using CELL-DYN 22 PLUS Controls three levels of Hematology controls Low, Medium and High are available.

11.2. FREQUENCY OF RUNNING INTERNAL QC

11.2.1. Every 24 hours when the test is in use.

11.2.2. After every calibration.

11.2.3. After maintenance, component replacement, or a field service action

11.2.4. Don't run Patient samples unless IQC result is acceptable

11.3. EXTERNAL QC:

11.3.1. We participate in CAP PT program

11.3.2. Number of cycle 3/year

11.3.3. Perform the test as instructed by CAP.

12.PROCEDURE

12.1. Operator Log In and Log Out:

12.1.1. Each operator should log in to the CELL-DYN Emerald 22 when operating the instrument.

12.1.2. Upon log in, the date is recorded and compared to last time an operator logged into the system.

12.2. Daily Start Up Procedures:

12.2.1. Running the Start Up Cycle and confirming that Background Counts are within acceptable limits

12.2.2. Performing daily Quality Control checks

12.2.3. Check all reagents needed before processing the sample.

12.3. Loading or Replacing Reagents:

12.3.1. There are 3 reagents: CELL-DYN Emerald 22 Diluent Reagent, CELL-DYN Emerald 22 Lyse Reagent, and CELL-DYN Emerald 22 Easy Cleaner Reagent

12.3.2. From the **MAIN** menu, touch **[REAGENTS],** followed by **[DILUENT]** to access the Diluent screen.

12.3.3. Scan the two barcodes on the label of the new reagent container to automatically populate all empty fields.

12.3.4. Verify that all fields are complete. If not, repeat the scan of both barcode labels.

12.3.5. Touch **[CONFIRM].** If the information entry is successful, the **[PRIME DILUENT]** key turns green.

12.3.6. Touch **[PRIME DILUENT]**.

12.3.7. To replace the CELL-DYN Emerald 22 Lyse Reagent or CELL-DYN Emerald 22 Diluent Reagent, touch **[ESC]** to return to the **REAGENTS** menu and repeat the above steps for the desired reagent

12.4. Replacing or Emptying the Waste Container:

12.4.1. From the **MAIN** menu, touch **[REAGENTS]**, followed by **[WASTE]**.

12.4.2. Remove the full container and replace it with an empty one.

12.4.3. Touch the box below and to the right of **<CAPACITY>** and enter the volume of the waste container.

12.4.4. Touch **[RESET]** or **[CONFIRM]** to enter the container capacity into the system memory.

12.4.5. Touch **[YES]** to save and return to the **REAGENTS** screen or touch **[NO]** to return to the **WASTE** screen.

12.4.6. Container capacity into the system memory.

12.4.7. Touch the **HOME** icon to return to the **MAIN** menu.

12.5. Processing Quality Control:

12.5.1. Six QC files are available on the CELL-DYN Emerald 22.

12.5.2. Each file stores 100 results and the instrument automatically calculates the Mean, Standard Deviation and Coefficient of Variation % for those results.

12.5.3. QC File Setup:

12.5.3.1. QC files are accessed from the **MAIN** menu by touching **[QUALITY CONTROL]**.

12.5.3.2. Touch the lot number to select a file.

12.5.3.3. Touch **[EDIT]** to enter new Assay Values and Limits.

12.5.3.4. Touch **[RUN AND RESULTS]** to view file data.

12.5.3.5. Touch the **TOOLS** icon to Print Targets, Results or Graphics (LJ Graphs)

12.5.3.6. Touch **[SEND]** to send results to the LIS.

12.5.3.7. Touch **[SAVE]** to save the results to a USB drive.

12.5.3.8. **[EXIT]** to return to the previous screen.

12.5.3.9. Touch the file location followed by **[EDIT]** to display the entry screen.

12.5.3.10. Touch the **<LOT>** entry, enter the lot number and touch **[CONFIRM]** to save. Press the **ENTER**.

12.5.3.11. Touch **<EXPIRATION>** entry fields enter the expiration date and press the **ENTER.**

12.5.3.12. Select the radio button (L for low, N for normal, or H for high) corresponding to the level of control for this QC file.

12.5.3.13. After selecting the QC level, touch the **<WBC>** entry field, enter the **ASSAYS** (Target or Assay Values) and **LIMITS** (+/- Mean Range or your calculated range), then press the **ENTER** key to save each entry and advance the cursor to the next field. Alternatively, you may touch **[LOAD]** to upload control assay values from a removable storage device for this Select **[EDIT]**. And then **[LOAD]**.

12.5.3.14. When all entries are complete, touch the **TOOLS** icon, then **[PRINT]** to generate a permanent record of our settings.

12.5.3.15. When entries have been verified to be correct, touch **[CONFIRM]**. A window displays asking if you want to save the modifications. Touch **[YES]** to save the entries or **[NO]** to return to the entry screen.

12.5.3.16. When **[YES]** is touched, a second window displays. If the selected file already contains data, the window notifies that all results will be deleted for the previous lot. Touch **[YES]** to continue or **[NO]** to return to the entry screen.

12.5.3.17. Set up additional files as directed above.

12.5.4. Daily QC procedure:

12.5.4.1. Remove the cap from the well-mixed control vial.

12.5.4.2. Immerse the aspiration probe in the control vial and press the start switch.

12.5.4.3. When the cycle LED turns red, the probe retracts

12.5.4.4. Results are displayed in the upper part of the screen.

12.5.4.5. The results are displayed with the most current run in the last row of the table. Numbers displayed in bold text are outside of the defined range for that parameter. Statistics are automatically calculated and shown at the bottom of the screen.

12.5.4.6. Touch the **[QC LOT]** dropdown menu to select another file. Run the control as described above

12.5.4.7. Touch **[LJ]** to display the Levey-Jennings graphs.

12.5.5. Printing QC Results:

12.5.5.1. After running the QC Machine automatically print the QC report (if not Touch the **TOOLS** icon then **PRINT** to print the result).

12.5.5.2. For a Levey-Jennings report, touch the **[LJ]** button from the QC file, select **[TOOLS]**, then **[PRINT]**.

12.6. Processing a Patient Sample:

12.6.1. The CELL-DYN Emerald 22 provides the option of testing samples in one of two modes, CBC or DIF. In DIF mode the results include all CBC parameters (WBC, RBC, HGB, PLT, HCT, MCV, MCH, MCHC, RDW, and MPV) as well as the WBC differential cell types (LYM % and #, MON % and #, NEU % and #, EOS% and #, BAS % and #).

12.6.2. If **[DIF]** is shown in the **[RUN SAMPLE]** screen, this is the mode the last sample was run.

12.6.3. In CBC mode the results include all CBC parameters but the WBC differential results are not measured or reported. To select this mode, touch the **[DIF]** button, sample mode will change to **[CBC]**.

12.6.4. To select this mode, touch the **[DIF]** button, sample mode will change to **[CBC]**.

12.6.5. Open mode:

12.6.5.1. From the **MAIN** menu, touch **[RUN SAMPLE]**. To enter NAME, PID, or/and SID press the **[NEXT SAMPLE]** at the bottom of screen.

12.6.5.2. If the Aspiration Probe is not visible, press the Start Switch (located directly behind the probe) and wait for it to descend.

12.6.5.3. Select DIF or CBC mode

12.6.5.4. Remove the cap from the well-mixed Specimen tube.

12.6.5.5. Immerse the probe in the specimen and press the Start Switch.

12.6.5.6. The Cycle LED (located directly above the Aspiration Probe) turns Red and flashes.

12.6.5.7. Remove the tube and re-cap it.

12.6.5.8. Results will be automatically sent to the LIS when the analysis is complete

12.6.5.9. Review Results: When the cycle is finished the results posted to the Data log and are displayed in the Run View.

12.6.5.10. Graphs are displayed on the right side of the screen

12.6.5.11. Display the Flags region (located below the results), touch the **[FLAGS ALERT]** box on the screen. The popup window displays analytical alarms and flags. To close the pop-up window, touch **[ESC]**

12.6.6. Closed Mode

12.6.6.1. Barcoded samples can be processed by loading the sample on sample loader rack. Place the racks on the loader and press [RUN LOADER**]**

12.6.7. DATALOG: The CELL-DYN Emerald 22 DATALOG stores 1000 (internal memory) CBC or DIF records, including demographics, results and graphs. For increasing storage capacity use a USB drive.

12.6.8. To print, send, delete or save results from the DATALOG.

12.6.8.1.1. Touch the **Tools** icon to print, send, delete or save the record.

12.6.8.1.2. Touch **[PRINT]** to print the selection(s).

12.6.8.1.3. Touch **[SEND]** to send the selection(s) to the LIS.

12.6.8.1.4. Touch **[DELETE]** to delete the selected results from DATALOG.

12.6.8.1.5. Touch **[SAVE]** to save the selected results on a USB drive

12.6.8.1.6. Touch **[EXIT]** to return to the record.

12.7. Maintenance:

Refer maintenance policy

12.8. Calibration procedure steps:

12.8.1.1. From the **MAIN** menu, touch **[CALIBRATION]** to display the Calibration screen

12.8.1.2. Touch **[EDIT]**.

12.8.1.3. Touch the **<LOT> &<EXPIRATION> and enter the details**

12.8.1.4. Touch the **<ASSAYS>** and **<LIMITS>** and type in the assay value and limits from the calibrator's assay sheet.

12.8.1.5. Touch **[CONFIRM]** to save the information and return to the previous screen, which shows the newly entered information.

12.8.1.6. You will be prompted: "**DO YOU WANT TO SAVE MODIFICATIONS?**" Touch **[YES]** to save or **[NO]** to return to the Calibration Entry Screen. You will be prompted: "**YOU ARE GOING TO DELETE ALLASSOCIATED RESULTS. DO YOU WANT TOCONTINUE?**" Touch **[YES]** to delete all results or touch **[NO]** to exit the screen without saving modifications.

12.8.1.7. Touch **[RUN AND RESULTS]** to initiate a calibration

12.8.1.8. Be certain that the calibrator is at room temperature and has been mixed according to the instructions in the package insert before proceeding with the Automated Calibration Procedure.

12.8.1.9. Immerse the Aspiration Probe in a well-mixed calibrator and press the Start switch.

12.8.1.10. The Cycle LED flashes during aspiration. The probe retracts when aspiration is complete

12.8.1.11. Re-cap the calibrator vial and gently mix until the Cycle LED turns green and the probe extends

12.8.1.12. Repeat the previous three steps to run the calibrator a minimum of five times. (Maximum 10 runs.)

12.8.1.13. Statistical calculations are done automatically with each run.

12.8.1.14. The **SEL** column is used to select or deselect individual runs from the calculations.

12.8.1.15. All results with " " in the SEL column are included in the calculation table at the bottom of the calibration screen.

12.8.1.16. To deselect one or more calibration runs from the Factor, Mean, SD, and %CV calculations, touch the " " to the left of the set of results you wish to exclude

12.8.1.17. Values displayed in bold text are outside of the defined target range if the **LIMITS HIGH** and **LIMITS LOW** in the **CALIBRATION - EDIT** menu have been configured

12.8.1.18. Make a copy of the completed Calibration Worksheet and save for your records.

12.8.1.19. Calibration Verification Procedure*:*

12.8.1.19.1. Calibration Verification is done to verify the accuracy of the calibration. It is accomplished by running the second tube of calibrator in the same manner as the first and comparing the results to the Assay Values.

12.8.1.19.2. Run the calibrator two times in the precision file.

12.8.1.19.3. Using the Calibration Verification Worksheet from, enter the assay value from the assay sheet into the first column and the mean of the two runs from the result file into the second column. Verify the difference between the two columns is within the +/- tolerance limits as shown on the Calibrator Assay Sheet; if not, troubleshoot; if it is within the limits, complete the Calibration Verification Worksheet and make a copy.

12.8.1.19.4. When calibration is complete and all required information has been printed, touch **[HOME]** followed by **[MAINTENANCE]**, **[SYSTEM CHECKS]**

12.9. Linearity procedure:

12.9.1. Touch **[MAINTENANCE]**, **[SYSTEM CHECKS]**, then **[LINEARITY]**.

12.9.2. Enter additional information about the sample in the **<NEXT SID>** field.

12.9.3. Touch **[CONFIRM]** to save entries or **[ESC]** to exit without saving.

12.9.4. At the Linearity Run screen, aspirate the sample. All results of linearity testing are stored in the **Datalog**.

12.10. Running precision:

12.10.1. The **Precision** Button in the **[MAINTENANCE]**, allows an operator to perform a precision test consisting of up to 33 runs. The mean(+/-), SD (Standard Deviation) and CV% are calculated automatically for each parameter.

12.10.2. When the sample probe descends, present a well-mixed sample and touch the start switch. Repeat until the number of desired precision replicates is reached. The mean, SD, and CV% ill update with each run.

12.10.3. Precision test results are not stored in the **DATALOG** and are accessible only through the **PRECISION** Button.

13.INTERFERENCE

Parameter	Causes of Spurious Increase	Causes of Spurious Decrease
White Cell Count (WBC)	Cryoglobulin, cryofibrinogen Heparin Monoclonal proteins Nucleated red cells Platelet clumping Unlysed red cells	Clotting Smudge cells Uremia immune suppresants
Red Cell Count (RBC)	Cryoglobulin, Cryofibrinogen Giant platelets High white cell count (>50,000 K/µL)	Autoagglutination Clotting Hemolysis (in vitro) Microcytic red cells

Hemoglobin (HGB)	Carboxyhemoglobin (>10%) Cryoglobulin, cryofibrinogen Hemolysis (in vivo) Heparin High white cell count (>50,000 K/µL) Hyperbilirubinemia Lipemia Monoclonal proteins	Clotting
Hematocrit (Automated) (HCT)	Cryoglobulin, Cryofibrinogen Giant platelets High white cell count (>50,000 K/µL) Hyperglycemia (>600 mg/dL)	Autoagglutination Clotting Hemolysis (in vitro) Microcytic red cells
Hematocrit (HCT) (Microhematocrit)	Hyponatremia Plasma trapping	Excess EDTA Hemolysis (in vitro) Hypernatremia
Mean Cell Volume (MCV)	Autoagglutination High white cell count (>50,000 K/µL) Hyperglycemia Reduced red cell deformability Swollen red cells	Cryoglobulin, cryofibrinogen Giant platelets Hemolysis (in vitro) Microcytic red cells
Mean Cell Hemoglobin (MCH)	High white cell count (>50,000 K/µL) Spuriously high hemoglobin Spuriously low red cell count	Spuriously low hemoglobin Spuriously high red cell count

Mean Cell Hemoglobin Concentration (MCHC)	Autoagglutination Clotting Hemolysis (in vivo and in vitro) Spuriously high hemoglobin Spuriously low hematocrit	High white cell count (>50,000 K/µL) Spuriously low hemoglobin Spuriously high hematocrit
Platelets (PLT)	Cryoglobulin, cryofibrinogen Hemolysis (in vivo and in vitro) Microcytic red cells Red cell inclusions White cell fragments	Clotting Giant platelets Heparin Platelet clumping Platelet satellitosis

14.CALCULATION

14.1. The analyzer automatically calculates the results:

14.2. The Hematocrit (HCT) is the ratio of red blood cells to plasma and is expressed as a percentage of the whole blood volume. It is derived from the volume of the RBCs that are counted during the measurement cycle.

14.3. The mean cell volume (MCV) is the average volume of individual RBCs.

14.4. MCV = HCT x 10/100

14.5. MCH = HGB x 10/RBC

14.6. MCHC = HGB x 100/HCT

15.BIOLOGICAL REFERENCE INTERVALS:

	Hgb	***HCT***	***RBC***	***MCV***	***MCH***	***MCHC***	***PLT***
Age/Unit	**g/dl**	**%**	**10^6µl**	**fl**	**pg**	**g/dl**	**10^3 µl**
0-14 days Female	12.5 - 20.5	31-71	3.6 - 6.2	86-124	31 - 37	28 - 38	170 - 500
0-14 days Male	12.5 – 20.5	31-71	3.6-6.2	86-124	31-37	28-38	170-500

15days-30 days Female	11.5 - 16.5	33-53	3.0-5.4	92 - 116	30 - 36	29 - 37	200 - 500
15days-30 days Male	11.5 - 16.5	33-53	3.0-5.4	92-116	30-36	29-37	200-500
30days-60days Female	9.4 - 13.0	28-42	3.1-4.3	87 - 103	27 - 33	29 - 36	210 - 650
30days-60days Male	9.4 - 13.0	28-42	3.1-4.3	87-103	27-33	28.5-35.5	210-650
61days-180days Female	11.1 - 14.1	30 -40	4.1 - 5.3	68 - 84	24 - 30	28.5-35.5	200 - 550
61days-180days Male	11.1 - 14.1	30-40	4.1-5.3	68-84	24-30	30-36	200-550
181days- 1Year Female	11.1 - 14.1	30 -38	3.9 - 5.1	72 - 84	25 - 29	30 - 36	200 - 550
181days- 1Year Male	11.1 - 14.1	30-38	3.9-5.1	72-84	25-29	32-36	200-550
1.01Year-6Year Female	11.0 - 14.0	34 -40	4.0 - 5.2	75 - 87	24 - 30	32-36	200 - 490
1.01Year-6Year Male	11.0 - 14.0	34-40	4.0-5.2	75-87	24-30	31-37	200-490
6.01Year-12Year Female	11.5 - 15.5	35 -45	4.0 - 5.2	77 - 95	25 - 33	31 - 37	170 - 450
6.01Year-12Year Male	11.5 - 15.5	35-45	4.0-5.2	77-95	25-33	31-37	170-450
12-150 years Female	12.0 – 15.0	36-45	3.8-4.8	83 - 101	27 - 32	31.5-34.5	150 - 410
12-150 Male	13.0 -17.0	40-50	4.5-5.5	83 - 101	27 - 32	31.5-34.5	150 - 410

	Hgb	***HCT***	***RBC***	***MCV***	***MCH***	***MCHC***	***PLT***
Age/Unit	**g/dl**	**%**	**10^6µl**	**fl**	**pg**	**g/dl**	**10^3 µl**
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12-150 Male	13.0 -17.0	40-50	4.5-5.5	83 - 101	27 - 32	31.5-34.5	150 - 410

16.DILUTIONS:

N/A

17.CRITICAL VALUE

Parameter	Less than	Greater than
WBC Count	**2.0 x 10^3 /µl**	**40.0 x10^3 /µl**
Hemoglobin (HGB)	**7.0 g/dl**	**20.0 g/dl**
Hematocrit (HCT)	**20 %**	**60 %**
Platelet Count (PLT)	**40 x10^3/µl**	**1000 x10^3/µl**
Blasts	**--**	**First Observation**
Organisms/ Parasites detected on Smear review or Rapid kit	**--**	**First Observation**
PEDIATRIC-SPECIFIC RANGES		
Hemoglobin, Neonatal	**10 g/dl**	**22 g/dl**
Hematocrit, Neonatal	**33 %**	**71 %**
Platelet Count (PLT)	**50 x10^3/µl**	**900 x10^3/µl**
*** These values are according to American Society for Clinical Pathology ASCP** (Am J Pathol2011; 135:505-513)		

18.LABORATORY CLINICAL INTERPRETATION

18.1. Result evaluation:

18.1.1. Review the flags on the results and take the corrective action accordingly. Result of the patient evaluated according to provisional diagnosis of the patient and the type of the sample and if its value is critical.

18.2. Result confirmation:

18.2.1. If any result shows (*) it should be check for hemolysis, lipemia or it need rerun.

18.2.2. Result is confirmed by revising the patient identification from the request with the sticker on the sample.

18.2.3. The laboratory technical staff confirms the acceptability of quality control results prior to reporting patient results.

18.2.4. Patients with previous Laboratory records, check first the latest result before releasing the current results.

18.2.5. Confirm and repeat any High / low Critical value result.

18.2.6. Review the print out results for any Flags or Remarks.

18.2.7. If result of **Total Leukocyte Count less than 2.000** X 10^3 µl and **more than 30.000** X 10^3 µl correlate with blood smear.

18.2.8. If **Platelet less than 100** 10^3 µl and **more than 600** 10^3 µl correlate with blood smear.

18.2.9. If **Hemoglobin less than 7**g/dl **blood film** immediately report the critical values to referring Physician.

18.2.10. In the case of Lipemic samples **RBC count, MCV, HCT and Platelet** can be reported. Hemoglobin result cannot be reported as hemoglobin is falsely increased. Ask the patient to repeat after fasting for 12 hrs.

18.2.11. In case of Hemolysed sample **Hemoglobin** and **WBC count** can be reported. If sample is slightly hemolysed release the result with a comment if sample is grossly hemolysed reject the sample and ask for repeat collection.

19.POTENTIAL SOURCES OF VARIATION

Refer to 13. Interference

20.REFERENCES

20.1. Cell Dyn Emerald 22 Operator's Manual

20.2. Practical Haematology By Dacie and Lewis

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Thank You