# Clinical Diagnostic Solutions, Inc.

a Boule Diagnostics, AB company

# **Beginning of Day**

If instrument is in Standby Mode (screen dark):

- Touch the screen to activate system and press **IEXIT STANDBY1.**
- Enter Operator ID (Optional) and press [OK] or press [CANCEL] to exit.
- The instrument is now preparing itself for the day.

# **Daily Startup Sequence**

#### 1. Perform Background Check

a. System may perform an automatic background check (instrument dependent):

Check that results are within the following limits:

WBC	≤ 0.1
RBC	≤ 0.01
HGB	≤ 0.2
PLT	≤ 10

- Perform manual background check if unacceptable.
- b. If instrument does not perform automatic background check, then perform a manual background check:
  - Press [NEW SAMPLE], Press [NEXT PROFILE] (should change to "Background" profile), Press Start plate (1:1 behind left probe) to initiate background check.
  - Check that results are within the limits above.

#### 2. Perform a Quality Control Check

- a. Prepare controls in accordance to the control package insert. Allow controls to reach room temperature for 30 minutes. Manually mix controls by gently rolling between hands and by gentle inversion.
- b. If opening a new Lot, scan in control information from supplied barcode sheet (see page 2 for details). If not, go to next step.
- c. Scan in Low control vial barcode label.
- d. Aspirate control material in either Open Tube. Cap Pierce, or Micropipette Adapter mode. If using Open Tube, wipe sample probe with clean absorbent cloth prior to analyzing control. (If using Autoloader, see instructions in Section 5.9 of User's Manual.)
- e. Repeat steps c d for Normal and High control levels.
- When control results are acceptable, the daily f. startup sequence is complete.
- g. Print and file Control Results.

# **Medonic M-Series**

Hematology Analyzer



# **Control Review / Analysis**

- 1. Exclude Controls from QC Reports:
  - Press [QC] from Main Menu, Press [VIEW CON/CAL], input search criteria to be used.
  - Press [SAMPLE] or [LIST] buttons to display • selected samples.
  - Scroll to the control sample to be excluded using [PREV] and [NEXT] buttons.
  - Press [EXCLUDE/INCLUDE] button. An "X" will be placed next to the excluded sample.
  - To include the sample press [EXCLUDE/INCLUDE] button again.
- 2. Review Control runs and Statistical Data
  - Refer to User's Manual Section 6.1
    - Refer to Monthly QC Report Flowchart supplement
- 3. Review Control Levy-Jennings Plots.
  - Refer to User's Manual Section 6.2
  - Refer to Monthly QC Report Flowchart . supplement.

# Patient Sample Run

- Choose [NEW SAMPLE] from List. Sample. or Main menu to begin sample analysis.
- Press alpha numerical keys to enter sample ID or scan in the ID barcode from the sample vial.
- Choose sample aspiration mode (See 1-5 below) and analyze sample.
- . After 45 seconds, results will be displayed on List or Sample menu.
- When [NEW SAMPLE] button returns to green, operator can begin next sample analysis.
- Continue to Page 2.

#### 1. Open Tube (OT) Mode

- a. Place sample probe into well mixed sample vial.
- b. Press the 1:1 Start plate to analyze the sample.
- c. Follow the instruction on the display when to remove the sample vial.

#### 2. Cap Pierce (CP) Mode

- a. Open door to Cap Pierce device and insert vacuum tube upside down, pressing the tube in place.
- b. Close door to Cap Pierce and sample cycle will automatically begin.

#### 3. Micropipette Adapter (MPA) Mode

- a. Remove MPA device from instrument.
- b. Fill micropipette completely with fresh whole blood. Ensure that there are no bubbles.
- c. Carefully wipe excess blood from outside surfaces of micropipette. Do not touch open ends of micropipette.
- d. Insert the micropipette into the MPA device.
- e. Insert MPA device into analyzer. The sample cycle will automatically begin.

#### 4. Autoloader (AL) Mode

 Refer to detailed instructions in User Manual Section 5.9

#### 5. Pre-Dilute (PD) Mode

 Refer to detailed instructions in User Manual Section 5.6

#### Sample Review

 If Parameter or System Information messages are generated, refer to User Manual Section 9.

# End of Day

- 1. Wipe OT sample probe and Pre-dilute probe with alcohol swab.
- 2. Remove possible traces of salt crystals or blood at the top of the Open Tube probe, Pre-dilute probe, probe rinse cup, and around the top of the Cap Pierce or Autoloader using a paper tissue with a disinfecting solution.
- 3. Clean outside of instrument with soft cloth and DI water if needed.

#### New Control Lot Input

This procedure enters all control assay value ranges for the new lot of control. After entering the new lot information, the system automatically recognizes the control tube when it is scanned and analyzed each day.

- From the Main Menu go to [Q/C MENU] [ENTER CON/CAL] [CONTROL/CALIBRATOR ASSAY VALUE INPUT]
- 2. If insufficient space message is displayed, follow screen instruction to delete oldest lot.
- 3. Scan barcodes in order from 1 to 9 from the left most column do not skip a barcode.
- 4. Once complete, exit the Control / Calibrator Assay Value Input screen and return to sample run screen.
- 5. Scan Low level blood control vial barcode and analyze control as per User Manual.
- 6. Repeat steps 1-4 using barcodes from center column.
- 7. Repeat step 5 using Normal level blood control.
- 8. Repeat steps 1-4 using barcodes from right most column.
- 9. Repeat step 5 using High level blood control.

#### **Changing of Reagents**

The interlocked reagent system displays indicator and warning messages to alert the operator when reagents are running low and need to be changed. When this occurs, perform the following:

- 1. Press [MENU] to access the Main menu and then press [REAGENT SETUP].
- 2. Press [ENTER NEW REAGENT].
- 3. Scan Barcode 1 and then Barcode 2 on the reagent container.
- 4. When all barcodes are entered, a screen will display that reagent barcodes have been accepted.
- 5. Press [EXIT] to return to the Main menu.
- 6. Remove the cap and seal on the new reagent container.
- 7. Transfer the reagent level sensor and clear protective cap from the used container to the new reagent container. It is <u>important</u> when transferring the reagent level sensor that it is kept clean and inserted into the correct reagent container.
- 8. The analyzer is now ready to resume operation or analyze samples.