Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-6081

Urgent Field Safety Notice
Product Recall
Immediate Action Required

Date Issued March 24, 2016

Product

Product Description	List Number	Lot Number	Expiration Date	UDI Number
CELL-DYN Emerald Cleaner	09H46-02	6853	31JUL2017	N/A
	09H46-02	6901	31JUL2017	N/A
	09H46-02	6953	30SEP2017	N/A

Explanation

The purpose of this letter is to inform you of a product recall for CELL-DYN Emerald Cleaner lots 6853, 6901, 6953 and to provide you with instructions on what actions your laboratory must take.

Abbott has identified occurrences where the CELL-DYN Emerald analyzer generates Quality Control (QC) Out Of Range Low for parameters RBC and PLT. Abbott is continuing to investigate but immediate actions are necessary.

Patient Impact

Abbott has no evidence that there is impact to generated patient results. There is a potential for delay in results due to QC out of range.

Necessary Actions

For Emerald Cleaner lots 6853, 6901, and 6953	
If…	**Then…**
You **HAVE an alternate Cleaner Reagent lot available** in inventory (other than 6853, 6901, or 6953)	Immediately discontinue use of impacted Cleaner lot(s) 1. Switch to the alternate lot of Cleaner Reagent. 2. Run the Decontamination Procedure per CELL-DYN Emerald Operator's Manual (9140859 version H) page 9-16 steps 1 -3. (see attachment 1) This will take 15 – 30 minutes. 3. Check the QC and follow any additional laboratory procedures **Destroy any remaining inventory** of impacted Cleaner lot(s) according to your laboratory procedures.

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If you do not have an alternate lot available,	
And are **not** experiencing QC Out Of Range Low for parameters RBC and PLT	Immediately order a replacement Cleaner lot. Ensure you are meeting your internal QC requirements. You can continue to use until replacement arrives. Once you receive the replacement Cleaner lot, perform steps 1 -3: 1. Switch to the alternate Cleaner lot. 2. Run the Decontamination Procedure per CELL-DYN Emerald Operator's Manual (9140859 version H) page 9-16 steps 1-3. (see attachment 1) This will take 15 – 30 minutes. 3. Check the QC and follow any additional laboratory procedures **Destroy any remaining inventory** of Cleaner lot(s) 6853, 6901, or 6953 according to your laboratory procedures.
And you have QC Out Of Range Low for parameters RBC and PLT and Troubleshooting does not resolve the issue…	Contact Customer Support.

Additionally, please ensure the following actions are completed…
• Follow directions in CELL-DYN Emerald Operator's Manual (9140859 version H) page 2-36 step 3 (see attachment 2) to ensure that AUTOCLEAN is checked and CLEAN INTERVAL (CYCLES) is set to your chosen value, (the default value is 80).
• Complete and return the Customer Reply Form. Your local Customer Support will provide you with replacement product and/or credit.
• If you have forwarded the product listed above to other laboratories, please inform them of this Product Recall and provide to them a copy of this letter.
• Please retain this letter for your laboratory records.

Contact Information

We sincerely regret any inconvenience this issue may cause. If you or any of the health care providers you serve have any questions regarding this information, U.S. Customers please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.

ATTACHMENT 1
Decontamination

Materials Required

- Cotton gauze pads
- Three beakers, each filled with about 150 mL of deionized water (one for each reagent line)
- 0.5% sodium hypochlorite (bleach) cleaning solution (Refer to **Appendix C**)
- 3.6% sodium hypochlorite (bleach), for Clean Out cycle (Refer to **Appendix C**)
- Warm tap water
- Plastic bags – one each for diluent and waste tubing
- Packaging or cellophane tape
- Clean paper towels

Decontamination Procedure

1. Touch **[RUN SAMPLE].** Place 1 mL of the 0.5% sodium hypochlorite solution in a clean test tube. Immerse the tip of the aspiration probe in the bleach solution. Press start switch to decontaminate the fluidics.
2. When the instrument is ready for the next cycle, dampen a gauze pad with the 0.5% sodium hypochlorite solution and wipe the outside of the Aspiration Probe.
3. Initiate a **SYSTEM CLEAN** cycle as follows:

NOTE: Use the 3.6% sodium hypochlorite (bleach) for these steps.

   a. From the **MAIN** menu touch **[MAINTENANCE]**
   b. Touch **[SYS CLEAN]** and follow the instructions step-by-step as displayed

4. When the cleaning procedure is completed, power off the instrument by pressing and holding the Power On/Off button until the display turns dark.
5. Remove the power cord from the rear of the instrument and then disconnect it from the power outlet.
6. Disconnect the AC Adapter from the power cord.
7. Disconnect the printer according to manufacturer's directions.
8. Disconnect the Diluent line from the rear of the instrument and allow any reagent in the line to drain into the container. Remove the cap from the container and remove the tubing. If necessary, wipe the outside of the tubing with a clean paper towel and then place the tubing in a plastic bag and close it.
9. Disconnect the waste line from the rear of the instrument and allow any waste in the line to drain into the container. Dispense 0.5% sodium hypochlorite solution into the tubing and allow it to drain into the waste container. Remove the cap from the container and remove the tubing. Rinse the tubing inside and out with warm running tap water. Wipe the outside with a clean paper towel, place the tubing in a plastic bag and close the bag.

Other Settings

The **Other Settings** Button displays the following screen.

The Delay Box is used to configure the following options:

1. **PROBE UP** – Sets the time in minutes to retract the probe when the instrument is not in use.
   a. Touch the entry field and use the numeric keypad to enter the time in minutes. The default value is 5 minutes and the range is 1 to 60 minutes.
2. **SHUT DOWN** – Sets the time in minutes between automatic shut down cycles.
   a. Touch the entry field and use the numeric keypad to enter the time in minutes. The default value is 180 and the range is 30-720 minutes
3. **SET AUTOCLEAN** – Configures the system to automatically run an Auto-clean cycle when the specified number of cycles is reached.
   a. Touch the entry field next to **<SET AUTOCLEAN>** to select the option.
   b. Touch the entry field next to **<CLEAN INTERVAL>** and use the numeric keypad to enter the number of cycles. The default value is 80 cycles and the range is 10 to 5000 cycles.

NOTE: The maximum number of runs recommended between Autoclean cycles is 80.

NOTE: Automatic autoclean occurs only when the number of samples run since Start Up on a single day exceeds the number entered at **<CLEAN INTERVAL (CYCLES)>**.

4. **WAKE UP** – Configures the system to automatically power up and execute a Start Up Cycle on the day(s) and time specified.
   a. Touch the entry field next to **<AUTO.>** to select the option.
   b. Touch the entry field next to **<TIME>** and use the numeric keypad to enter the time that the system will execute the **WAKE UP** option. Touch the entry field next to **<PM>** to designate either PM (selected) or AM (not selected).
   c. Touch the entry field next to the day(s) that the system will execute the **WAKE UP** option.

NOTE: The system will execute an automatic shut down cycle when the Shut Down minutes of non-use have elapsed following an auto Wake Up.

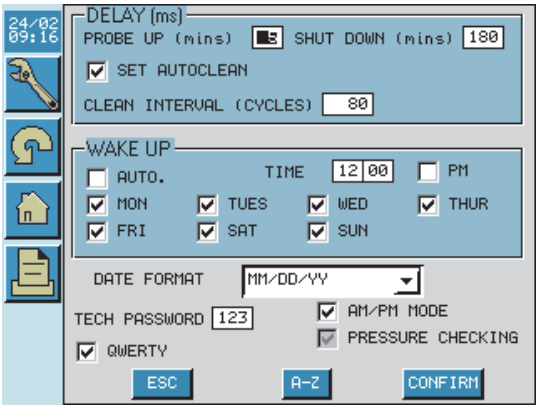

Figure 2.23 Other Settings Set Up