



Urgent Field Safety Notice Product Recall Immediate Action Required

Date Issued

June 27, 2016

Product

Product Description	List Number	Lot Number	Expiration Date	UDI Number
CELL-DYN Emerald Cleaner	09H46-02	7044	31JAN2018	N/A
	09H46-02	7082	28FEB2018	N/A
	09H46-02	7110	31MAR2018	N/A
	09H46-02	7119	30APR2018	N/A

Explanation

The purpose of this letter is to inform you of a product recall for CELL-DYN Emerald Cleaner lots 7044, 7082, 7110, and 7119, and to provide you with instructions on what actions your laboratory must take.

Abbott previously identified occurrences where the CELL-DYN Emerald Analyzer generates Quality Control (QC) Out Of Range Low for parameters RBC and PLT when using Emerald Cleaner lots 6853, 6901, 6953, 6991, 7024 and 7027. Testing of cleaner lots 7044, 7082, 7110 and 7119 confirmed RBC and PLT controls out of range. Cause for the QC material out-of-range low issue has been traced to the manufacturing process for a raw material used in the CELL-DYN Emerald Cleaner. Actions have been taken to help verify acceptable performance of replacement product. In the interim, immediate action is 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 7044, 7082, 7110 and 7119	
If....	Then...
You HAVE an alternate Cleaner Reagent lot available in inventory (other than 6853, 6901, 6953, 6991, 7024, or 7027)	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.

**Necessary
Actions Cont.**

If you do not have an alternate lot available,	
<p>And are not experiencing QC Out Of Range Low for parameters RBC and PLT</p>	<p>Immediately order a replacement Cleaner lot.</p> <p>Ensure you are meeting your internal QC requirements. You can continue to use until replacement arrives.</p> <p>Once you receive the replacement Cleaner lot, perform steps 1 -3:</p> <ol style="list-style-type: none"> 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 <p>Destroy any remaining inventory of Cleaner lot(s) 7044, 7082, 7110 or 7119 according to your laboratory procedures.</p>
<p>And you have QC Out Of Range Low for parameters RBC and PLT and Troubleshooting does not resolve the issue...</p>	<p>Contact Customer Support.</p>

Additionally, please ensure the following actions are completed...
<ul style="list-style-type: none"> • 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).
<ul style="list-style-type: none"> • Please ensure routine bleach cleaning is performed as prescribed in the Service and Maintenance section of the CELL-DYN Emerald Instrument Operator’s Manual (pages 9-1 and 9-11).
<ul style="list-style-type: none"> • Complete and return the Customer Reply Form. Your local Customer Support will provide you with replacement product and/or credit.
<ul style="list-style-type: none"> • 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.
<ul style="list-style-type: none"> • 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.