



Urgent Field Safety Notice Product Recall

Immediate Action Required

Date Issued

May 03, 2016

Product

Product Description	List Number	Lot Number	Expiration Date	UDI Number
CELL-DYN Emerald Cleaner	09H46-02	6991	30NOV2017	N/A
	09H46-02	7024	31DEC2017	N/A
	09H46-02	7027	31DEC2017	N/A

Explanation

The purpose of this letter is to inform you of a product recall for CELL-DYN Emerald Cleaner lots 6991, 7024 and 7027, 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, and 6953. Further investigation identified additional lots 6991, 7024, and 7027 as having similar occurrences. 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 6991, 7024 and 7027	
If....	Then...
You HAVE an alternate Cleaner Reagent lot available in inventory (other than 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) 6991, 7024 or 7027 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"> • 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.