



Urgent Field Safety Notice Product Recall Immediate Action Required

Date Issued

January 11, 2008

Product

CELL-DYN Sapphire Hemoglobin Reagent Syringe

List Number: 08H49-02

Syringes Affected Syringes with packaged dates 08 May 2007 to 29 November 2007

The CELL-DYN Sapphire Hemoglobin Reagent Syringe is packaged in a white box and sealed with a label wrapped around the center of the box. Printed on the label is the list number and date the syringe was packaged. If removed from the shipping package, the CELL-DYN Sapphire Hemoglobin Reagent Syringes are indistinguishable.

Explanation

We have recently identified an issue concerning some CELL-DYN Sapphire Hemoglobin Reagent Syringes that were improperly lubricated during the manufacturing process. Due to the inappropriate lubrication of the plunger, the syringes may cause hemoglobin background to be out of specification upon installation.

The potentially affected CELL-DYN Sapphire Hemoglobin Reagent Syringes have been isolated to those with package dates of 08 May 2007 through 29 November 2007. Syringes with packaged dates of **07 May 2007 and earlier** or **30 November 2007 and later** are not affected by this issue.

Patient Impact

Background readings have been observed to be < 0.7 g/dL (specification is ≤ 0.1 g/dL). As instructed in the *CELL-DYN Sapphire System Operator's Manual*, hemoglobin background should be verified to be ≤ 0.1 g/dL upon installation of a new CELL-DYN Sapphire Hemoglobin Reagent Syringe. If the Operator's Manual instructions are not followed, analytical results may be affected.

Necessary Actions

Verify the packaged date for any replacement syringe(s) that you may have in your laboratory. If the packaged date(s) is not in the range of 08 May 2007 to 29 November 2007, no further action is required.

Not all syringes within the range of 08 May 2007 to 29 November 2007 are affected.

Upon installation of a new CELL-DYN Sapphire Hemoglobin Reagent Syringe, if the **hemoglobin background is within specification (≤ 0.1 g/dL)**

- No further action is required.

Upon installation of a new CELL-DYN Sapphire Hemoglobin Reagent Syringe, if the **hemoglobin background is not within specification (> 0.1 g/dL)**

- Clean the syringe as instructed in the system operator's manual and repeat the background verification.
- If elevated hemoglobin background persists (> 0.1 g/dL), contact your local Customer Support representative.

**Necessary
Actions(cont.)**

- Please complete the Customer Reply Form and return to Abbott as requested.
- Please retain this communication for future reference.

**Contact
Information**

If you or any of the health care providers you serve have any questions regarding this information, U.S. customers should call Customer Support at 1-877-4ABBOTT. Customers outside the U.S., please contact your local hematology customer support representative.
