



Urgent Field Safety Notice Product Recall

Immediate Action Required

Date Issued May 11, 2015

Product

Product Name	List Number (LN)	Lot Number	Expiration Date	UDI
Alkaline Wash	9D31-20	49059UN14	04-MAR-2016	N/A

Explanation

We regret to inform you that Abbott Diagnostics is recalling Alkaline Wash lot number 49059UN14 due to leaking product and/or material received with loose bottle caps that may have leaked during shipment. Alkaline solution is corrosive and the operator can be exposed when the bottle is leaking.

Patient Impact

Patient results are not impacted.

Necessary Actions

1. Determine if you are using or have inventory of Alkaline Wash LN 9D31-20, lot number 49059UN14.
2. While wearing the appropriate Personal Protective Equipment (PPE), **visually inspect** your inventory. To ensure your safety, review the product Safety Data Sheet, available at www.abbottdiagnostics.com, or contact your local representative. For a detailed discussion of safety precautions, refer to the ARCHITECT System Operations Manual.

If...	Then...
You observe any signs of leakage or loose caps	Discontinue use and dispose of any remaining inventory of those kits in accordance with your institution's policies and procedures.
You DO NOT observe any signs of leakage or loose caps	You may continue to use the product following the precautions per the ARCHITECT System Operations Manual and the Safety Data Sheet.

3. Complete and return the enclosed Customer Reply form.

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. Abbott is committed to providing you with the highest quality diagnostic products and support services to meet the needs of your laboratory and the providers and patients you serve.

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.