



Product Recall

Immediate Action Required

Date Issued August 26, 2011

Product

Product Name	List Number (LN)	Lot Number	Expiration Date
Clinical Chemistry Alkaline Phosphatase	7D55-21	71628UN10	November 19, 2011
	7D55-31	62474UN10	November 19, 2011
		08145UN11	February 15, 2012

Explanation

Abbott Diagnostics is recalling Clinical Chemistry Alkaline Phosphatase reagent lots 71628UN10, 62474UN10, and 08145UN11 due to particulate matter in some reagent cartridges.

The particulate matter has been identified as a Cladosporium fungal species. This fungus is a widespread mold that alone does not represent a hazard, but appears to generate visible clumps within the reagent cartridge, and may cause discoloration over time. An analysis of this issue is in progress to identify corrective actions and prevent recurrence in future reagent lots.

Patient Impact

We have received no reports of inaccurate Alkaline Phosphatase results due to this issue, nor has internal testing demonstrated any impact to results; however, having confirmed "Unable to calculate result..." error codes on calibration and sample runs, internal data suggests a rare (0.00636%) potential for inaccurate results to exist.

Necessary Actions

- Determine if you are using or have inventory of Clinical Chemistry Alkaline Phosphatase
 - LN 7D55-21 lot 71628UN10, or
 - LN 7D55-31 lot 62474UN10 and/or lot 08145UN11.
- Discontinue use and destroy any remaining inventory of those lots in accordance with your institution's policies and procedures.
- Order alternative lots of Clinical Chemistry Alkaline Phosphatase.
- Complete and return the enclosed Customer Reply form.
- We have not received any reports of system contamination. However, if you have not recently decontaminated your system, you may wish to perform the decontamination steps in Attachment A.

If you have forwarded any Clinical Chemistry Alkaline Phosphatase lots above to other laboratories, please provide a copy of this letter to them. Retain this letter for your records.

Contact Information

We sincerely regret any inconvenience this may cause your laboratory. If you have any questions regarding this information, U.S. Customers should contact Customer Service at 1-877-4ABBOTT. Customers outside the U.S., please contact your local area Customer Service.