



# Urgent Field Safety Notice Product Recall

Immediate Action Required

**Date Issued**

October 03, 2011

**Product**

Product Name	List Number (LN)	Lot Number	Expiration Date
Clinical Chemistry Urea Nitrogen	7D75-21	97642UN11	March 8, 2012
	7D75-31	97668UN11	March 8, 2012

**Explanation**

Abbott Diagnostics is recalling Clinical Chemistry Urea Nitrogen reagent lots 97642UN11 and 97668UN11 due to particulate matter in some reagent cartridges.

The particulate matter has been identified as an *Aureobasidium* species which alone does not represent a hazard, but generates visible matter within the reagent cartridge, and may cause discoloration over time.

As part of a recent investigation, we have been taking preventive steps throughout the manufacturing process at the facility where the lots above were manufactured. We are monitoring other Urea Nitrogen lots for this issue.

**Patient Impact**

We have received no reports of inaccurate Urea Nitrogen patient results due to this issue. Internal testing has observed atypical calibration curves, Quality Control (QC) results out of range, and "Unable to calculate results..." error codes. These data suggest that a 0.049% potential for inaccurate results exists.

**Necessary Actions**

- Determine if you are using or have inventory of Clinical Chemistry Urea Nitrogen:
  - LN 7D75-21 lot 97642UN11, or
  - LN 7D75-31 lot 97668UN11.
- Discontinue use and destroy any remaining inventory of these lots in accordance with your institution's policies and procedures.
- Order alternative lots of Clinical Chemistry Urea Nitrogen.
- Complete and return the enclosed Customer Reply form.

We have not received any reports of instrument contamination. However, if you are operating at ARCHITECT System Software version 7.00 or higher, you may wish to perform maintenance procedure **2183 Clean Wash Cups** as a precautionary measure. If you are not operating at version 7.00 and wish to perform a precautionary decontamination, please contact Customer Service for assistance.

If you have forwarded any Clinical Chemistry Urea Nitrogen 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.