



Urgent Field Safety Notice Product Correction

Immediate Action Required

Date Issued

July 22, 2014

Product

Product Name	List Number (LN)	Lot Number	Expiration Date
Clinical Chemistry ICT Serum Calibrator	1E46-03	21399UN13	5 AUG 2014
		67873UN13	12 NOV 2014
		74710UN13	8 DEC 2014
		82008UN13	14 JAN 2015
		88884UN13	4 FEB 2015

Explanation

An Abbott investigation has identified that the ICT Serum Calibrator lots above may generate lower than expected Potassium Quality Control (QC) and patient results.

A potential cause of this issue is increased ammonia content over the shelf life of the calibrator. Elevated ammonia concentration may impact the Potassium calibration and potentially cause a calibration curve to generate the lower results. Your QC and patient results recovery could vary due to individual laboratory differences.

The lots above demonstrated acceptable performance at release and at internal testing intervals. However, internal testing in June 2014 has shown that product performance has changed over time. These lots were compared to flame photometry (reference method) and either have exceeded or have the potential to exceed the acceptable performance ($\leq 3\%$ average bias) for samples with values between 3.0 and 6.0 mmol/L.

While our investigation continues, revised manufacturing procedures have been implemented to minimize the potential for a recurrence of this issue.

Patient Impact

Patient results may have shifted down by 1-3% beyond the acceptable performance of the assay.

Necessary Actions

If you are currently using or have inventory of the ICT Serum Calibrator lots above, follow the instructions below:

IF	THEN
The calibration curve for Potassium is verified with at least two levels of controls according to established quality control requirements for your laboratory	You may continue to use the lot until you receive a new lot through your normal ordering processes.
QC results for Potassium are not within established quality control requirements for your laboratory	Recalibrate using a different calibrator lot. New lots are available.

Note: You may observe a shift in QC performance when implementing a new calibrator lot. Follow the established quality control procedures for your laboratory.

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- Place orders for replenishment product if needed through your normal ordering process.
 - Follow your laboratory protocol regarding the need to review previously reported patient results.
 - Complete and return the customer reply form.

Please retain this communication for future reference. If you have forwarded any of the Clinical Chemistry ICT Serum Calibrator of the lots above to another laboratory, please provide it with a copy of this letter.

**Contact
Information**

We recognize the disruption this may cause your laboratory and sincerely apologize for any inconvenience. 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.
