



Urgent Field Safety Notice Product Recall

Immediate Action Required

Date Issued November 16, 2012

Product

Product Name	List Number (LN)	Lot Number	Expiration Date
Clinical Chemistry Phenobarbital	1E08	52803UN12	EXPIRED 30 SEP 2012
		62299UN12	31 JAN 2013
		85773UN12	28 FEB 2013

Explanation

Abbott Diagnostics is recalling Clinical Chemistry Phenobarbital reagent lots 62299UN12 and 85773UN12 due to imprecision issues which increase with the age of the reagent lot. The imprecision of the Phenobarbital assay is $\leq 7\%$ Total CV%; however, internal testing confirmed CVs up to approximately 12% for in-date reagent lots over five months old. Although lot 52803UN12 is now expired, it exhibited similar imprecision issues. As a precaution, future replacement lots will have reduced dating until root cause is identified and preventive measures are implemented.

Patient Impact

This issue was identified internally and no customer reports of impacted results have been received. Patient management may be impacted as imprecision may lead to erroneous results.

Necessary Actions

1. Determine if you are using or have inventory of Clinical Chemistry Phenobarbital reagent lots 62299UN12 or 85773UN12.
2. Discontinue use and destroy any remaining inventory of those lots in accordance with your institution's policies and procedures.
3. Order replacement lot 27426UN12, which will expire 18 DEC 2012, and is the only lot currently available. Additional lots with reduced dating will be available in December and January. Please adjust your order accordingly.
4. Complete and return the enclosed Customer Reply Form.
5. Follow your laboratory protocol regarding the need for reviewing previously reported patient results for the three lots above.

If you have forwarded any of the lots above to another laboratory, please provide a copy of this letter to them.

Contact Information

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