



## Urgent Field Safety Notice Product Recall

Immediate Action Required

**Date Issued**

October 29, 2013

**Product**

Product Name	List Number	Lot Number
AxSYM Valproic Acid Reagent	07A71-20	18439M503

**Explanation**

- The purpose of this communication is to inform you of a lot specific issue with AxSYM Valproic Acid Reagent lot 18439M503 and provide instructions on actions your laboratory must take.
- Abbott has confirmed that some kits of AxSYM Valproic Acid Reagent lot 18439M503 have the potential to generate invalid calibration, control or sample runs due to Net Intensity Too Low, resulting in AxSYM instrument Error Code 1072.
- We have determined that this issue is linked to the Valproic Acid Fluorescein Tracer component in reagent lot 18439M503.
  - If a reagent kit of lot 18439M503 is impacted, Error Code 1072 will occur and prevent completion of calibration and/or reporting results.
  - A reagent kit of lot 18439M503 that is not impacted will run successfully with no error code.
- There is no impact to other AxSYM Valproic Acid Reagent lots.

**Patient Impact**

When a valid calibration and/or control/sample run is obtained, patient results generated with reagent lot 18439M503 are acceptable.

**Necessary Actions**

Please follow these necessary steps:

1. Contact Abbott Customer Service to order AxSYM Valproic Acid Reagent kits to replace your inventory of lot 18439M503.
2. If a valid calibration and/or control/sample run is obtained, you may continue to use AxSYM Valproic Acid Reagent lot 18439M503 until your replacement lot is received.
3. Immediately, upon receipt of your replacement material, please destroy all remaining inventory of lot 18439M503.

If you have forwarded AxSYM Valproic Acid Reagent lot 18439M503 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 apologize for any inconvenience this 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, please contact your local Customer Service representative.



## Customer Reply

Immediate Action Required

**Instructions:** Please provide a copy of the accompanying Product Recall Letter to the laboratory manager/supervisor responsible for AxSYM Valproic Acid.

The laboratory manager/supervisor should complete the information below acknowledging receipt of the Product Recall Letter and fax the Customer Reply Form, prior to **November 12, 2013** via FAX #: 1-800-777-0051 or e-mail to [QAGCO@abbott.com](mailto:QAGCO@abbott.com). Even if you no longer have the instrument(s), please return the completed Customer Reply Form so that we can appropriately update our customer database.

Thank you for your cooperation,  
Abbott Diagnostics - Quality Assurance for Global Commercial Operations

Product Name	List Number	Lot Number
AxSYM Valproic Acid Reagent	07A71-20	18439M503

**Abbott Diagnostics Product Recall letter dated October 29, 2013.**

**Were the Necessary Actions, as stated in the Product Recall Letter, understood and completed?**

☐ **Yes**      Lot Number      # of Kits  
                    18439M503      \_\_\_\_\_  
**Note:** Credit will be based upon the number of kits destroyed.

☐ **No** (If answered No, an Abbott Representative will contact you.)

☐ **Action is not applicable. No longer have instrument.**

\_\_\_\_\_  
Customer Number

\_\_\_\_\_  
Serial Number(s)

\_\_\_\_\_  
Name of Institution

\_\_\_\_\_  
Address

\_\_\_\_\_  
Phone Number

\_\_\_\_\_  
City

\_\_\_\_\_  
State

\_\_\_\_\_  
Zip Code

\_\_\_\_\_  
Name (print)

\_\_\_\_\_  
Title/Position

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date