SIEMENS

Urgent Field Safety Notice

DC17-01.A.OUS.DM

December 2016

Dimension® clinical chemistry system
Ammonia (AMM) Flex® Reagent Cartridge Reagent Instability

Our records indicate that your facility may have received the following product:

Table 1. Dimension® Affected Product

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date	1st Distribution Date
Ammonia AMM	DF119	10711991	FB7152	2017-06-01	2016-06-28
			EB7180	2017-06-29	2016-08-04
			BA7194	2017-07-13	2016-08-15
			EA7223	2017-08-11	2016-08-30
			BA7250	2017-09-07	2016-10-17

Reason for Correction

Siemens Healthcare Diagnostics has determined that Dimension® Ammonia (AMM) lots FB7152, EB7180, BA7194, EA7223, and BA7250 do not meet the 60-day calibration interval claim due to reagent instability and results may show an Abnormal Assay message. These lots may exhibit accuracy shifts for patient and/or Quality Control results (Table 2); which may cause laboratories to recalibrate more frequently than the of 60-day claim in the Instructions for Use (IFU).

Siemens and the reagent supplier are conducting additional testing to monitor stability for newer reagent lots to ensure no other lots are impacted.

Table 2. QC and patient bias observed during Siemens' investigation

Lot Number	Average % Bias	Range % Bias
FB7152/BA7194/EB7180[1]	-44	-35 to -81
EA7223/BA7250[2]	-13	-11 to -15

[1] Data for a period of 41 days without recalibration on lot EB7180 which represents the worst case scenario.

[2] Data for a period of 14 days without recalibration on lot EA7250 which was manufactured with same reagent as lot EA7223.

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Risk to Health

When this issue occurs, the remote potential exists for misinterpretation of ammonia levels, which may affect consideration of intervention. Clinical impact would be mitigated by correlation to clinical symptomology as well as to other laboratory testing such as liver function tests, electrolytes, and/or blood glucose ordered to determine the cause of a patient's symptoms. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

If using one of the lots listed in Table 1, please discard and use an alternate lot of Dimension AMM. Please check the acceptability of the calibration and QC.

- Discontinue use of and discard lots FB7152, EB7180, BA7194, EA7223, and BA7250
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to regulatory authorities.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.

Note: The supply of the Dimension AMM will be closely monitored. In order to ensure inventory for all customer's; allocation may be required thus delaying full replacement orders. **Until the lab has received their full replacement order, customers can conserve their Dimension AMM Flex reagent cartridge supply by limiting the Ammonia testing to one Dimension instrument in the laboratory.**

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Dimension and Flex are registered trademarks of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK
Dimension clinical chemistry system
Ammonia AMM Reagent Instability
Lots FB7152, EB7180, BA7194, EA7223, and BA7250

Complete and return this Field Correction Effectiveness Check Form within 30 days

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics UFSN DC-17-01.A.US dated Dec, 2016 regarding Dimension® Ammonia (AMM) Flex® Reagent Cartridge Reagent Instability. Please read each question and indicate the appropriate answer.

Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided below.

1. I have read and understood UFSN instructions provided in this letter. Yes ☐ No ☐

2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes ☐ No ☐

   If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Lot #	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
FB7152		
EB7180		
BA7194		
EA7223		
BA7250		

Name of person completing this form: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

Fax this completed form to the Customer Care Center – Technical Solution at XXX-XXX-XXXX. If you have any questions, contact your local Siemens technical support representative.

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