

Dimension® Integrated Chemistry Systems

Dilution Check Failure

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

Table 1. Affected Product

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number
QuikLYTE® Dilution Check	S640	10444872	4MD707

Reason for Recall

Siemens Healthcare Diagnostics has confirmed complaints of failing dilution checks when using QuikLYTE Dilution Check lot 4MD707. This lot may exhibit a positive bias possibly beyond 5% that can result in a dilution check failure or may result in an unnecessary correction if the bias is between 1 – 5%. A dilution check failure prevents complete installation of the QuikLYTE Integrated Multisensor as described in the Dimension Operator's Guide.

The root cause is under investigation.

Risk to Health

The overall risk to health is related to a potential Sodium correction up to 5% that may result in a depressed value which is likely to be detected by Quality Control. A laboratory look back is not recommended.

Actions to be Taken by the Customer

- Discontinue use of and discard the lot listed in Table 1.
- Please review this letter with your Medical Director.
- Review your inventory of this product to determine your laboratory's replacement needs.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

Dimension® Integrated Chemistry Systems: Dilution Check Failure

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® is a trademark of Siemens Healthcare Diagnostics.

URGENT FIELD SAFETY NOTICE EFFECTIVENESS CHECK

Dimension® Integrated Chemistry Systems

Dilution Check Failure

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated February 2015 regarding Dilution Check Failure. Please read each question and indicate the appropriate answer. Fax this completed form to your local Siemens Technical Support representative.

1. I have read and understood the Urgent Field Safety Notice 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 Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
QuikLYTE Dilution Check S640/SMN 10444872 Lot 4MD707		

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

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

Please fax this completed form to your local Siemens Technical Support representative. If you have any questions, contact your local Siemens Technical Support representative.