Urgent Field Safety Notice

DC26-01.A.OUS

Dimension Clinical Chemistry System

Title Imprecision with Quality Control and Patient Results for Dimension Creatinine Lot Numbers GA6307 and BA7005

Date Issued MAR-2026

Products

Assay	Siemens Material Number/ Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date
Dimension Creatinine (CRE2)	10872079/ 630414595009	GA6307	03-Nov-2025	03-Nov-2026
		BA7005	05-Jan-2026	05-Jan-2027

Issue Description

Siemens Healthineers has confirmed, through investigation of customer complaints, a potential for imprecision in Dimension Creatinine (CRE2) quality control (QC) and patient sample results when using lot numbers GA6307 and BA7005 on the Dimension System.

Based on investigation data:

- Within-lab precision for serum/plasma samples may not perform as intended at lower concentrations, while serum/plasma repeatability and urine sample precision remain within expected performance.
- Depending on the QC ranges established by the laboratory, QC failures can alert customers to the issue before patient samples are processed.
- This issue is isolated to Dimension CRE2 assay and the two lot numbers referenced above.
- Dimension Vista and Atellica Creatinine Assays are not impacted.
- Other Siemens Healthineers systems that utilize the Dimension Creatinine (CRE2) formulation, for example the Dimension Vista, are not impacted.

Siemens Healthineers is actively investigating the root cause of this issue.

Impact to Results

Erroneously decreased or increased creatinine patient results may occur. Results from internal studies are shown in Appendix, Table 1 and 2. Imprecision could result in differences of up to 0.29 mg/dL (26.05 µmol/L) at creatinine concentrations less than 1.00 mg/dL (less than 88.42 µmol/L) and differences of up 0.23 mg/dL (18.75 µmol/L) at creatinine concentrations between 1.00-2.00 mg/dL (88.42 - 176.84 µmol/L). Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Customer Actions

- Immediately discontinue use and discard the kit lot numbers listed in the Products section above.
- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.

SIEMENS Healthineers

- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens Healthineers for required regulatory reporting.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within (10) days.
- Please retain this letter with your laboratory records and forward it to anyone who may have received or used this product.

Single Registration Number (SRN) US-MF-000016336

Resolution Alternate lot numbers of this product that are not impacted are available.

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

Appendix Table 1:

Representative Data for Serum QC1 and Patient Pool imprecision (Standard Deviation)

Material	Mean mg/dL(µmol/L)	Within-Lab Precision Expected Standard Deviation mg/dL(µmol/L)	Within-Lab Precision Observed Standard Deviation mg/dL (µmol/L)
Serum Pool	0.80 (70.36)	≤ 0.067 (5.924)	0.105 (9.284)
Serum QC1	0.87 (76.92	≤ 0.067 (5.924)	0.103 (9.107)

Table 2:

Representative Data for Serum QC2 and QC3 imprecision (% Coefficient of Variation)

Material	Mean mg/dL(µmol/L)	Within-Lab Precision Expected % Coefficient of Variation	Within-Lab Precision Observed % Coefficient of Variation
Serum QC2	1.97 (174.19)	≤ 4.288	5.63
Serum QC3	6.54 (578.27)	≤ 4.288	1.63

Siemens Healthcare Sdn. Bhd.
Registration No: 201501001338 (1126670-U)

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice **DC26-01.A.OUS** dated MAR-2026. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

1. Have you read and understood the instructions provided in this letter? Yes ☐ No ☐
2. Do you have the affected product(s) on hand? Please check inventories before answering. Yes ☐ No ☐
3. Were affected Site Personnel notified? Yes ☐ No ☐
4. Was a copy of the letter retained and posted with the current product labeling? Yes ☐ No ☐

If the answer to the question #2 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** **Discarded/Replacement Quantity Required**	
Dimension Creatinine (CRE2) lot GA6307		
Dimension Creatinine (CRE2) lot BA7005		
Name of person completing questionnaire:		
Title:		
Institution:		
Street:		
City:	**State:**	**Zip Code:**
Phone:	**Country:**	
Customer Sold To #	**Customer Ship To #**	

Please send a scanned copy of the completed form via email to fscareportingunit.my@siemens-healthineers.com.

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