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Urgent Field Safety Notice:

Dimension Clinical Chemistry System
Dimension Tacrolimus (TAC) Open Well Stability Positive Bias with Lot Numbers FA6254, FA6260, and FA6286

To whom it may concern,

Our records indicate that you have received:

Assay	Siemens Material Number/ Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date
Dimension Tacrolimus (TAC)	10700795/ 842768035425	FA6254	11-Sep-2025	11-Sep-2026
		FA6260	17-Sep-2025	17-Sep-2026
		FA6286	13-Oct-2025	13-Oct-2026

Siemens Healthineers has confirmed, through investigation of customer complaints, the potential for a positive bias in quality control (QC) and patient sample results when using Dimension Tacrolimus (TAC) lot numbers FA6254, FA6260, FA6286 on the Dimension System.

The internal investigation confirmed that the 48-hour open well stability stated in the Instructions for Use may not be met at lower analyte concentrations. The worst-case scenario observed was a positive bias of up to 59% at a concentration of 3.5 ng/mL [4.6 nmol/L] at 48 hours post-hydration.

Based on investigation data:

- Low level QC remains within expected performance through hour 18 of the opened reagent well. Mid and high-level QC remain within expected performance of 120% (see Table 1 in the Appendix).
- Per the assay Instructions for Use, QC should be processed every 24 hours. Depending on laboratory established QC ranges, QC failures can alert customers to the issue before patient samples are processed.
- Observed QC behavior is consistent with impact to patient sample results.
- Syva Emit 2000 and Atellica CH Tacrolimus Assays are not impacted.

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

Impact to Results

Erroneously elevated Tacrolimus QC and patient results may be observed as a positive bias post-hydration, with the greatest impact occurring at lower concentrations. Representative data is shown in Table 1 in the Appendix. Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Customer Actions

- Immediately discontinue use of and discard the affected 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.
- 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 (30) 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, non-affected lot numbers of this product are available.

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

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Electronically signed by: Gudrun Kapl
Reason: I have reviewed this document
Date: May 26, 2026 09:37:22 GMT+2

i.V. Dipl.-Ing. Gudrun Kapl

Electronically signed by: Carina Marie Viehboeck
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Date: May 26, 2026 09:18:03 GMT+2

i.A. Dipl.-Ing. Carina Viehböck

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Appendix

Table 1: Quality Control bias relative to time post-hydration

QC Recovery ng/mL [nmol/L]	0 hours	18 hours	24 hours	48 hours
QC1	3.6 [4.7]	4.0 [5.2]	5.0 [6.5]	5.8 [7.5]
QC2	10.9 [14.2]	10.2 [13.3]	11.8 [15.32]	13.0 [16.9]
QC3	20.8 [27.0]	20.6 [26.8]	22.3 [29.0]	22.9 [29.8]

QC Recovery Post-Hydration Time [%]	0 hours	18 hours	24 hours	48 hours
QC1	100%	110%	137%	159%
QC2	100%	93%	108%	120%
QC3	100%	99%	107%	110%