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Urgent Field Safety Notice:

Dimension® Clinical Chemistry System

Dimension® Tacrolimus (TAC) Flex® Reagent Cartridge Imprecision with lots GA2286, GA3047 and GA3171

To whom it may concern,

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

Table 1. Dimension® Affected Product

Product	Siemens Material Number (SMN)/REF (Catalog Number)	Unique Device Identification (UDI)	Lot Number	1st Distribution Date (YYYY-MM-DD)	Expiration Date (YYYY-MM-DD)
TAC	10700795 (DF207)	00842768035425GA2286221013107007958 40 00842768035425GA3047230216107007958 40 00842768035425GA3171230620107007958 40	GA2286 GA3047 GA3171	2021-11-01 2022-03-22 2022-06-23	2022-10-13 2023-02-16 2023-06-20

Reason for Urgent Field Safety Notice

Siemens Healthineers has received customer complaints and confirmed imprecision for Quality Control (QC) and patient samples with Dimension Tacrolimus (TAC) lots GA2286, GA3047 and GA3171. Siemens internal investigation of the Dimension TAC assay showed the worst case imprecision with patient samples at the low end of the Analytical Measurement Range (AMR). A patient sample at 2.0 ng/mL (2.6 nmol/L) recovered as 0.0 ng/mL (0.0 nmol/L) (100% negative bias), another patient sample at 2.1 ng/mL (2.7 nmol/L) recovered at 4.3 ng/mL (5.6 nmol/L) (103% positive bias).

Risk to Health

Worst case, erroneous results could affect tacrolimus monitoring after organ transplant. Mitigations include correlation of test results with patients' clinical information, serial testing and monitoring of clinical symptoms. A review of previously generated results is not recommended as tacrolimus measurements are part of serial assessments and used for immediate patient management.

Actions to be Taken by the Customer

For the products listed in Table 1, please perform the following steps:

- Discontinue use and discard the lots listed in Table 1 and complete the attached Product Replacement form for no-charge product replacement. Please note, lot GA2286 is expired.
- Review your inventory to determine possible replacement needs and provide information to Siemens for reporting to the Authorities.
- Please review this letter with your Medical Director and the decision on a review of previously generated results.
- If you receive any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Remote Services Center or your local Siemens Technical Support Representative.
- Complete and return the Field Correction Effectiveness Check/Product Replacement Form attached to this letter within 30 days to Siemens Healthineers for reporting to the Authorities.

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

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Electronically signed by: Roland Ertl
Reason: I am approving this document
Date: Jan 31, 2023 11:42 GMT+1

i.A. Roland Ertl, MA
Quality Management CEECA

Electronically signed by: Carina Marie Viehboeck
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