SIEMENS

Urgent Field Safety Notice

CHC17-06.A.OUS.SYC

June 2017

Syva® EMIT® 2000

Sulfasalazine and Sulfapyridine Interference with NADH and/or NADPH Reaction Assays

Our records indicate that your facility may have received the following product(s) listed in Table 1.

Reason for Correction

Table 1. Syva® EMIT® 2000 Products affected by Sulfasalazine and Sulfapyridine

Assay	Cat Number	Siemens Material Number (SMN)	Lot Number
Tacrolimus	8R019UL	10445397	All
Sirolimus	8S019UL	10445401	All

Siemens Healthcare Diagnostics has become aware of sulfasalazine and sulfapyridine drug interference in the assays listed in Table 1 which use NADH and/or NADPH to generate redox reactions which produce colorimetric signals. Other Syva® EMIT® assays were tested and did not show any interference.

Siemens has confirmed that erroneous results may occur on samples drawn from patients taking sulfasalazine and sulfapyridine as indicated in the Appendix. Sulfasalazine is an accepted treatment for inflammatory bowel disease, ulcerative colitis, Crohn's disease, rheumatoid arthritis, inflammatory arthritis, and uveitis. Sulfapyridine is used occasionally for dermatitis herpetiformis and related skin disorders when alternative treatment is unsuitable.

The Limitations of the Procedure section of the Instructions For Use (IFU) for the Syva® EMIT® 2000 Tacrolimus assay will be updated to indicate that: Venipuncture should occur prior to sulfasalazine and/or sulfapyridine administration due to the potential for falsely elevated results.

The Limitations of the Procedure section of the IFU for the Syva® EMIT® 2000 Sirolimus assay will be updated to indicate that: Venipuncture should occur prior to sulfasalazine administration due to the potential for falsely elevated results and sulfapyridine administration due to the potential for falsely depressed results.

See Appendix for Maximum % bias observed in the studies conducted by Siemens.

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Risk to Health

The clinical utility of either the Sirolimus or Tacrolimus assay is not impacted as a result of the bias observed due to sulfasalazine or sulfapyridine interference. Sirolimus and Tacrolimus values are not used in isolation to guide clinical decisions as therapeutic ranges for these drugs are dependent upon a number of variables including transplant type, time post-transplant, co-administration of other immunosuppressants, and clinical symptomology consistent with either rejection or toxicity. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer:

- Please review this letter with your Medical Director.
- Venipuncture should occur before drug administration of sulfasalazine or sulfapyridine as indicated above under Reason For Correction. Baseline assay values before administration of sulfasalazine or sulfapyridine therapy are not affected.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- 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.

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.

Appendix:

Maximum bias observed at 0.3 mg/mL (300 mg/L) of Sulfasalazine and Sulfapyridine

Assay	Mean Concentration of Analyte	Maximum% bias observed at 0.3 mg/mL Sulfasalazine	Maximum% bias observed at 0.3 mg/mL Sulfapyridine
Tacrolimus	4.9 ng/mL	17%	14%
Tacrolimus	10.8 ng/mL	13%	10%
Sirolimus	6.1 ng/mL	3%	-15%
Sirolimus	20.0 ng/mL	15%	5%

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FIELD CORRECTION EFFECTIVENESS CHECK

Sulfasalazine and Sulfapyridine Interference with NADH and/or NADPH reaction Assays

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CHC17-06.A.OUS.SYC dated June 2017 regarding Sulfasalazine and Sulfapyridine Interference with NADH and/or NADPH reaction Assays. Please read the question and indicate the appropriate answer. Email this completed form to Siemens Healthcare Diagnostics at the email address provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: Postcode:

Phone: Country:

Customer Sold To #: Customer Ship To #:

Please emailthis completed form to eric.donnachie@siemens-healthineers.com

If you have any questions, contact your local Siemens technical support representative in the Customer Care Center at 0845 600 1955.

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