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Urgent Field Safety Notice:

Dimension® clinical chemistry system and Dimension Vista® System

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

Dear Sirs,

Our records indicate that your facility may have received the following products listed in Table1:

Table 1. Dimension/Dimension Vista Products affected by Sulfasalazine and/or Sulfapyridine

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
Ammonia	AMM	DF119/ K3119	10711991/10 711992	All
Alanine Aminotransferase	ALTI	DF143/ K2143	10475530/10 635565	All
Aspartate Aminotransferase	AST	DF41A/ K2041	10444959/10 445148	All
Glucose	GLUC/GLU	DF40/ K1039	10444971/10 445162	All
Creatine Kinase MB	MBI	DF32/ K3032	10464510/10 464339	All
Thyroxine	T4	DF65/ K6065	10444908/10 445101	All

Reason for Correction

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 reduction oxidation reactions which produce colorimetric signals. No other Dimension/Dimension Vista assays exhibited any interference.

Siemens has confirmed that falsely depressed or falsely elevated results may occur on samples drawn from patients taking Sulfasalazine and Sulfapyridine as indicated in the Appendix. Sulfasalazine is the 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 Dimension and Dimension Vista assays listed in Table 1 will be updated as follows:

Dimension Ammonia: Venipuncture should occur prior to sulfapyridine administration due to the potential for falsely depressed results.

Dimension Vista Ammonia: Venipuncture should occur prior to sulfasalazine administration due to the potential for falsely elevated results. Venipuncture should occur prior to sulfapyridine administration due to the potential for falsely depressed results.

Dimension Alanine Aminotransferase: Venipuncture should occur prior to sulfasalazine administration due to the potential for falsely depressed results.

Dimension Vista Alanine Aminotransferase: Venipuncture should occur prior to sulfasalazine and/or sulfapyridine administration due to the potential for falsely depressed results.

Dimension Aspartate Aminotransferase: Venipuncture should occur prior to sulfasalazine administration due to the potential for falsely depressed results.

Dimension Vista Aspartate Aminotransferase: Venipuncture should occur prior to sulfasalazine and/or sulfapyridine administration due to the potential for falsely depressed results.

Dimension & Dimension Vista Glucose: Venipuncture should occur prior to sulfasalazine administration due to the potential for falsely depressed results. Venipuncture should occur prior to sulfapyridine administration due to the potential for falsely elevated results.

Dimension Creatine Kinase MB: Venipuncture should occur prior to sulfapyridine administration due to the potential for falsely depressed results.

Dimension Vista Creatine Kinase MB: Venipuncture should occur prior to sulfasalazine administration due to the potential for falsely elevated results.

Dimension & Dimension Vista Thyroxine: Venipuncture should occur prior to sulfasalazine administration due to the potential for falsely elevated results.

Baseline assay values before administration of Sulfasalazine or Sulfapyridine therapy would not be affected.

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

Risk to Health

The probability of misinterpretation of results for the assays described in Table 1 due to this interference is remote and would be limited to scenarios where a patient has taken sulfasalazine or sulfapyridine and had a blood sample drawn before clearance of the drug to a level that does not interfere with laboratory testing. Mitigations include correlation to clinical history and presentation as well as to other diagnostic laboratory testing, serial testing, and/or more vigilant clinical monitoring depending on the analyte. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer:

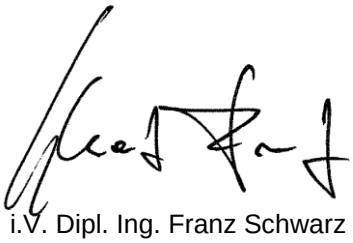
- Please review this letter with your Medical Director.
- Venipuncture should occur before drug administration of sulfasalazine or sulfapyridine as indicated above under Reason For Correction. Baseline assay values before administration of Sulfasalazine or Sulfapyridine therapy would not be affected.
- 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.

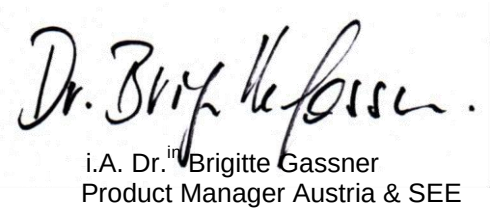
We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH



i.V. Dipl. Ing. Franz Schwarz
Head of RAQS Austria & SEE



i.A. Dr.in Brigitte Gassner
Product Manager Austria & SEE

Attachement I: Appendix

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Maximum bias observed for sulfasalazine and sulfapyridine with Dimension Assays

Assay	**Concentration of analyte**	**Maximum% bias observed at 300 mg/L [0.75 mmol/L] Sulfasalazine**	**Maximum% bias observed at 300 mg/L [1.2 mmol/L] Sulfapyridine**
Ammonia (AMM)	~426 µg/dL [~250 µmol/L]	<10%	-19%
Alanine Aminotransferase (ALTI)	~55 U/L [~0.92 µkat/L]	-29%	<10%
Aspartate Aminotransferase (AST)	~37 U/L	-10%	<10%
Glucose (GLUC)	~126 mg/dL [~7.0 mmol/L]	-17%	11%
Creatine Kinase MB (MBI)	~20 U/L [0.33 µkat/L]	<10%	-11%
Thyroxine (T4)	~8 µg/dL [~103 nmol/L]	15%	<10%

Maximum bias observed for sulfasalazine and sulfapyridine with Dimension Vista Assays

Assay	**Concentration of analyte**	**Maximum% bias observed at 300 mg/L [0.75 mmol/L] Sulfasalazine**	**Maximum% bias observed at 300 mg/L [1.2 mmol/L] Sulfapyridine**
Ammonia (AMM)	~426 µg/dL [~250 µmol/L]	66%	-19%
Alanine Aminotransferase (ALTI)	~55 U/L [~0.92 µkat/L]	-72%	-19%
Aspartate Aminotransferase (AST)	~37 U/L	-19%	-12%
Glucose (GLU)	~126 mg/dL [~7.0 mmol/L]	-21%	11%
Creatine Kinase MB (MBI)	~20 U/L [0.33 µkat/L]	22%	<10%
Thyroxine (T4)	~8 µg/dL [~103 nmol/L]	18%	<10%