SIEMENS Healthineers

Urgent Field Safety Notice

CHC23-02.A.OUS

August 2023

ADVIA® 1800 Chemistry System
ADVIA® 2400 Chemistry System
ADVIA® Chemistry XPT

Potential for Positive Bias with Some IRON_2 Reagent Wedges

Our records indicate that your facility has received the following product:

Table 1. ADVIA Chemistry Affected Product(s)

Assay	Test Code	Siemens Material Number (SMN) / Catalog Number	Unique Device Identification (UDI)	Lot Number
Iron_2	IRON_2	SMN: 10377510 (6 x 350 tests) SMN: 10341118 / 02194838 (7 x 145 tests)	00630414561974 00630414513157	All lots

Reason for Correction

The purpose of this communication is to inform you of an issue with the products indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed, through investigation of customer complaints, the potential for a positive bias on Quality Control (QC) and patient sample results when using some IRON_2 reagent wedge pairs. When the issue occurs, the observed bias will vary wedge to wedge. However, within an impacted wedge, the level of bias remains consistent.

The frequency of a reagent wedge pair exhibiting a positive bias is estimated to be less than 1%. Instructions are provided below in the “Actions to be Taken by the Customer” section to help determine if the IRON_2 reagent wedges in your inventory are impacted.

See Table 2 for biases observed with QC samples tested with affected wedges from lot 601757. Similar biases are expected for affected wedges from all in date and future lots until the issue is resolved. A similar bias can be expected for patient samples across the entire analytical measuring range as IRON_2 is a linear method and QC samples are designed to mimic patient sample performance.

Siemens Healthcare Diagnostics is currently investigating the root cause of this issue.

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Table 2. Quality Control Results for Three Affected Reagent Wedge Pairs

	QC Level	2SD ranges µg/dL (µmol/L)	Affected wedge µg/dL (µmol/L)	Unaffected wedge µg/dL (µmol/L)	Absolute Bias µg/dL (µmol/L)
Set 1	1	53 – 65 (9.49 – 11.6)	76 (13.6)	57 (10.2)	19 (3.4)
	2	144 – 160 (25.8 – 28.6)	165 (29.5)	145 (26.0)	20 (3.5)
Set 2	1	53 – 65 (9.49 – 11.6)	84 (15.0)	59 (10.6)	25 (4.4)
	2	144 – 160 (25.8 – 28.6)	175 (31.3)	150 (26.9)	25 (4.4)
	3	224 – 260 (40.1 – 46.5)	265 (47.4)	245 (43.9)	20 (3.5)
Set 3	1	53 – 65 (9.49 – 11.6)	182 (32.6)	57 (10.2)	125 (22.4)
	2	144 – 160 (25.8 – 28.6)	269 (48.2)	145 (26.0)	124 (22.2)
	3	224 - 260 (40.1 – 46.5)	359 (64.3)	235 (42.1)	124 (22.2)

Risk to Health

If an affected reagent wedge pair is encountered, this issue may cause failed QC or erroneous patient results. Failed QC will cause an apparent delay in testing with negligible potential for injury. The impact is mitigated by availability of unaffected reagent wedge pairs and use of standard laboratory procedures to enable uninterrupted generation of results to help guide patient care, as required by the clinical setting.

If QC is not run on an affected reagent wedge pair prior to patient testing, erroneously elevated iron results for patients may be generated. Depending on the bias observed, this may confound interpretation during investigation of or treatment for iron overload or deficiency. Mitigations include correlation with patient clinical presentation and history, along with use of imaging and/or other laboratory testing appropriate for the clinical context, including an iron panel, complete blood count and differential, and metabolic panel.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Perform the instructions provided in Additional Information.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 10 working 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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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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 Healthineers Customer Care Center 1800-815-508 or your local Siemens Healthineers technical support representative.

Additional Information

Please complete these instructions **with each wedge set** in your inventory prior to processing patient samples.

1. Ensure only one R1 and one R2 is onboard the system.
2. Run each level of QC that your laboratory has identified for use with IRON_2 on that reagent wedge set and determine if your QC criteria are met.
3. If acceptance criteria **IS** met, proceed using the R1/R2 wedge to generate patient results.
4. If the acceptance criteria **IS NOT** met, discard the reagent wedge set. If you have another set of IRON_2 reagent, repeat steps 1 – 3 and assess acceptance.

ADVIA is a trademark of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

Potential for Positive Bias with Some IRON_2 Reagent Wedges

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CHC23-02.A.OUS dated August 2023, regarding Potential for Positive Bias with Some IRON_2 Reagent Wedges on ADVIA Chemistry systems. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Sdn Bhd as per the instructions 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 ☐

2. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes ☐ No ☐

   If the answer to the question 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 SMN/Catalog #**	**Quantity of Affected Product in inventory Returned/ Replacement Quantity Required**
IRON_2 SMN: 10377510 (6 x 350 tests)	
IRON_2 SMN: 10341118 / 02194838 (7 x 145 tests)	

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

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

If you have any questions, contact your local Siemens Healthineers technical support representative.

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