SIEMENS Healthineers

Urgent Field Safety Notice

ACHC22-05.A.OUS

June 2022

Randox Laboratories Soluble Transferrin Receptors – Atypical Calibration Curves and Poor Low-End Accuracy

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

Table 1. Randox Affected Product(s)

Assay	Randox Catalog Number	Siemens Material Number (SMN)	GTIN/UDI	Lot Number
Soluble Transferrin Receptors (STFR)	TF10159	11318376	05055273215564	All lots
Soluble Transferrin Receptors Calibrator Series (STFR CAL)	TF10161	11306493	05055273215557	All lots

Reason for Correction

The purpose of this communication is to inform you of an issue with the products indicated in Table1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has received an Urgent Field Safety Notice (UFSN) REC597 from Randox Laboratories, dated May 26, 2022, on May 31, 2022, for the above noted products. As the distributor of the products, Siemens is informing our customers that per the attached UFSN, complaints were received for atypical calibration curves that can result in a non-numerical result at a concentration in alignment with the Randox STFR Level 1 Control, or below.

This correction is relevant to testing performed only on the Siemens Atellica® CH 930 analyzer, software versions 1.25.2 or lower, when the assay parameters specified in the instrument software are utilized.

Per Randox, further internal investigations have confirmed poor low-end accuracy. Randox has confirmed that results reported can be underestimated by up to 30% and outside of assigned ranges. Greater deviations for concentrations lower that 1.7 mg/L can be expected.

The issue will be resolved in Atellica Solution Software (SW) version 1.25.3.

511 Benedict Avenue
Tarrytown, N.Y. 10591

Risk to Health

The STFR assay is not intended to be used as a standalone assay and borderline results will be interpreted in conjunction with other diagnostic tests such as ferritin. The (STFR/logFER) is used as an index for the diagnosis of IDDA (Iron Deficiency Anaemia) and ACD (Anaemia of Chronic disease).

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Perform the instructions provided in Additional Information.
- 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 Healthineers Customer Care Center or your local Siemens Healthineers 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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Additional Information

- Until all Atellica CH analyzers in the laboratory are updated to SW 1.25.3, the assay can be run by Open Channel. Please contact applications@randox.com for an Atellica CH Open Channel application sheet.
- Following installation of SW version 1.25.3, the assay must be re-calibrated.
- Review results generated with the affected products in line with the clinical profile of the patient.

Atellica is a trademark of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

Randox Laboratories Soluble Transferrin Receptors – Atypical Calibration Curves and Poor Low-End Accuracy

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ACHC22.05-A.OUS dated June 2022 regarding Randox Laboratories Soluble Transferrin Receptors – Atypical Calibration Curves and Poor Low-End Accuracy. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the UFSN instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Please send a scanned copy of the completed form via email to XXXX@XXXX

Or to fax this completed form to the Customer Care Center at XXXXXX

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

511 Benedict Avenue
Tarrytown, N.Y. 10591

RANDOX

Urgent Field Safety Notice

[redacted]

Date Issued: 26th May 22

Complaint Reference:REC597

Action Type: Device Modification

Detail on Affected Devices:

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

Device Name	Catalogue Number	GTIN	Batch / Lot number
Soluble Transferrin Receptors (STFR)	TF10159	05055273215564	All lots within expiry
Soluble Transferrin Receptors Calibrator Series (STFR CAL)	TF10161	05055273215557	All lots within expiry

Reason for Action:

Randox Laboratories Ltd have been notified of an escalation in complaints with regards to reports of atypical calibration curves that can result in a non-numerical result at a concentration in alignment with the Randox STFR Level 1 Control, or below.

It is relevant only to testing performed on the **Siemens Atellica® CH analyser**, software versions V1.25.2 or lower, when the assay parameters predetermined in the instrument software are utilised.

Further internal investigations have confirmed poor low-end accuracy. Results reported for the Randox STFR Level 1 Control, at a concentration of 1.7 mg/L, can be underestimated by up to 30%, and outside of assigned ranges.

Greater deviations for concentrations lower that 1.7 mg/L can be expected.

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Randox Laboratories Soluble Transferrin Receptors – Atypical Calibration Curves and Poor Low-End Accuracy

This issue affects all current lots within expiry of reagent and calibrator and is linked to the assay parameter calibration Standard Curve setting, specific to the Atellica® CH.

Risk to Health:

The STFR assay is not intended to be used as a standalone assay and borderline results will be interpreted in conjunction with other diagnostic tests such as ferritin. The (STFR/logFER) is used as an index for the diagnosis of IDDA (Iron Deficiency Anaemia) and ACD (Anaemia of Chronic disease).

Action to be taken:

For Siemens Atellica® CH analyser users only. No action required if the assay is being run on other platforms.

- The issue will be resolved in Atellica Solution Software (SW) version 1.25.3.
- Until all Atellica CH analysers in the laboratory are updated to SW 1.25.3, the assay can be run by Open Channel. Please contact applications@randox.com for an Atellica® CH Open Channel application sheet.
- If the assay is not run by Open Channel prior to installation of SW version 1.25.3, the assay must be re-calibrated once 1.25.3 is installed.
- Review results generated with the affected batches in line with the clinical profile of the patient.
- Discuss the contents of this notice with your Medical Director.

[redacted]

Please accept our apologies for any inconvenience caused. Thank you for your patience and understanding. [redacted]

[redacted]