RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Reissue Date: 12th Aug 2020

Complaint Reference: REC473 **REV 2**

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	Expiry Date	Manufacturing Date
STFR Calibrator	TF10161	05055273215557	522018	28 Mar 2022	04 May 2020
			507141	28 Dec 2021	10 Feb 2020
			493716	28 Mar 2021	11 Jun 2019
			491549	28 Dec 2020	16 May 2019
			477781	28 Sept 2020	09 Jan 2019
			474597	28 Sept 2020	04 Dec 2018
			459975	28 July 2020	25 Sept 2018
STFR Control	TF10162	05055273215601	495411	28 Aug 2021	04 Oct 2019
			489580	28 May 2021	19 June 2019
			474605	28 Sep 2020	03 Dec 2018
			460467	28 July 2020	01 Aug 2018

Reason for Action:

Randox have reviewed the standardisation for Soluble Transferrin Receptor (sTfR) as per the labelling claim and have realigned the sTfR Immunoturbidimetric method to the WHO reference material NIBSC code 07/202. As a result the Calibrator and Control batches listed in the table above have been reassigned. Patient values will increase with the new calibrator values and the shift is more pronounced within the normal range (0.65mg/L to 1.88mg/L). See patient correlation below (Fig. 1).

Form No. 6307-TS
REVISION (10)
4th Feb 2019

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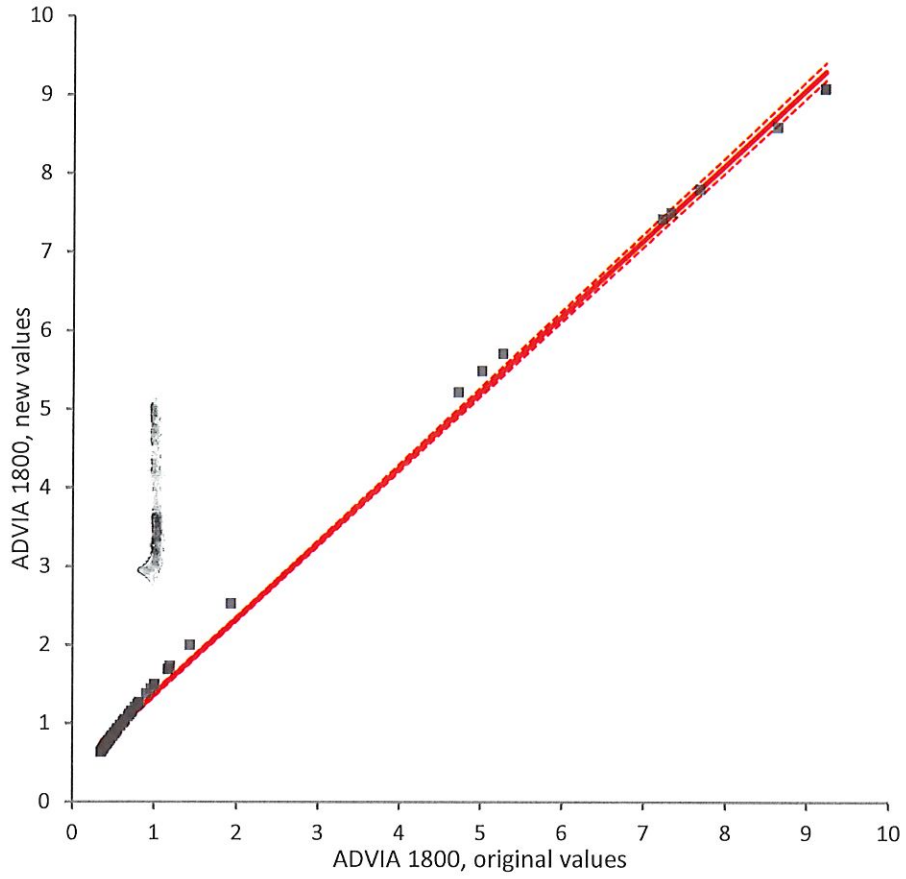

Fig. 1 Patient correlation using original assigned calibrator values and realigned calibrator values on Siemens ADVIA 1800

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 IDA (Iron Deficiency Anemia) and ACD (Anemia of Chronic disease). Analysis shows that sample classification remains unchanged following calibrator realignment.

Action to be taken:

- Refer to the attached IFUs for updated calibrator values and control targets and ranges. These can also be found on www.randox.com .

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Action to be taken continued

- 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.
- Complete and return the response form 12187-QA to technical.services@randox.com within five working days.

Transmission of Field Safety Notice: Send a copy of the FSN to all affected customers and to those who need to be aware within your organisation.

Please accept our apologies for any inconvenience caused. Thank you for your patience and understanding. If you have any questions or concerns, please contact Randox Technical Services.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

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