RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Tel: +44 (0) 28 9445 1070

Date Issued: 6 Nov 23

Complaint Reference: REC699 **Action Type:** Device Modification

Please note, there are two sections within this notice. Review the document in full prior to completing the response form.

Part 1

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
SEROLOGY ToRCH IgM POSITIVE CONTROL	SR10349	05055273216424	157SR	28th May 2024	9th December 2022

Reason for Action:

Randox Laboratories can confirm there has been a decrease in the reactivity of HSV Type 1/2 IgM in the Serology ToRCH IgM Positive Control, SR10349, lot 157SR when tested on the DiaSorin Liaison XL. While still testing positive for HSV Type 1/2 IgM, we advise that all customers cease the usage of the control for this marker as a precaution. The other markers within this lot are not affected. Please discard all copies of the IFU and download the latest version from www.randox.com.

Risk to Health:

As the control material is still testing positive for HSV Type 1/2 IgM, there is no risk to health. If the control did test negative for this analyte, the affected run should be discarded, and the samples re-analysed.

Action to be taken:

- 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.
- Please discard all copies of the IFU and download the latest version from www.randox.com.

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

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- For any additional questions, please contact technical.services@randox.com

Part 2

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
SEROLOGY ToRCH IgM POSITIVE CONTROL	SR10349	05055273216424	216SR	28th February 2025	25th July 2023

Reason for Action:

Randox Laboratories can confirm there has been a transcription error in the Instructions For Use (IFU) for the Serology ToRCH IgM Positive Control, SR10349, lot 216SR. For Toxo IgM, the method listed was "Reactive", which has been updated to "Biomerieux Vidas". For HSV Type 1/2 IgM, the method listed was "Biomerieux Vidas", which has been updated to "DiaSorin Liaison XL". The IFU has been updated with the correct reactivity table and is available on www.randox.com, please discard the incorrect IFU. The updated reactivity table can be seen below.

Marker	Method	Reactivity
CMV IgM	Biomerieux Vidas	Reactive
Rubella IgM	Biomerieux Vidas	Reactive
Toxo IgM	Biomerieux Vidas	Reactive
HSV Type 1/2 IgM	DiaSorin Liaison XL	Reactive

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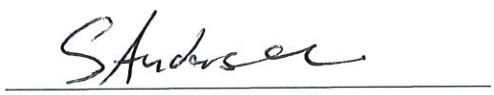
Transmission of the Field Safety Notice: Send a copy of the FSN to all affected customers and to those who need to be aware within your organisation.

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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