RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Date Issued: 2nd Aug 2022

Complaint Reference: REC611

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	Lot Number	Expiry Date	Manufacturing Date
Serology I Positive Control	SR10352	05055273216509	036SR	28th March 2023	30th June 2021

Reason for Action:

Randox Serology I Positive Control SR10352 lot 036SR will test negative (Non-Reactive) for Marker HBsAg using the Beckman Coulter DxI method. The Positive control will produce a Reactive result on the Abbott Alinity, Siemens Atellica and Biomerieux Vidas methods.

Figure 1: Methods affected

Marker	Method	Reactivity
HBsAg	Beckman Coulter DxI	Non- Reactive

Figure 2: Methods not affected

Marker	Method	Reactivity
HBsAg	Abbott Alinity	Reactive
HBsAg	Siemens Atellica	Reactive
HBsAg	Biomerieux Vidas	Reactive

Risk to Health:

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

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Delay in reporting patient results on the Beckman Coulter DxI method due to the positive control 036SR testing negative (Non-Reactive) for Marker HBsAg.

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.

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

S Andersen

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