

RANDOX
Urgent Field Safety Notice

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Date Issued: 7th Oct 2022

Complaint Reference: REC611 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	Lot Number	Expiry Date	Manufacturing Date
Serology I Positive Control	SR10352	05055273216509	036SR	28 th March 2023	30 th June 2021

Reason for Action:

Radox are issuing an updated Field Safety Notice following a customer report of negative results on the Ortho Vitros method. The Radox Serology I Positive Control SR10352 lot 036SR will test negative (Non-Reactive) for Marker HBsAg using the Beckman Coulter Dxl and Ortho Vitros methods. Radox can confirm the Positive control will produce a Reactive result on the Abbott Alinity, Siemens Atellica, Biomerieux Vidas and Roche e411 methods. Radox cannot guarantee that the control will produce a Reactive result on methods not included on this notice.

Figure 1: Methods affected

Marker	Method	Reactivity
HBsAg	Beckman Coulter Dxl	Non- Reactive
HBsAG	Ortho Vitros	Non – Reactive
HBsAG	All Instrument Methods not listed on this notice	Cannot Guarantee

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Figure 2: Methods not affected

Marker	Method	Reactivity
HBsAg	Abbott Alinity	Reactive
HBsAg	Siemens Atellica	Reactive
HBsAg	Biomerieux Vidas	Reactive
HBsAg	Roche e411	Reactive

Risk to Health:

Delay in reporting patient results on the Beckman Coulter Dxl and Ortho Vitros methods 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@radox.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 Radox Technical Services.

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

