

# RANDOX

## Urgent Field Safety Notice

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**Date Issued:** 2<sup>nd</sup> 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      | 28 <sup>th</sup> March 2023 | 30 <sup>th</sup> 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 Dxl 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 Dxl | 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:

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Delay in reporting patient results on the Beckman Coulter Dxl 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@radox.com](mailto: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**

  
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