RANDOX

# Urgent Field Safety Notice

Randox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

**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

RANDOX

## Urgent Field Safety Notice

Randox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

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



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

RANDOX

# Response Form

Randox Laboratories Ltd
55 Diamond Road, Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

**Please complete this form *even if you do not have any affected stock*.**

**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 |

Please check ALL appropriate boxes.

- ❑ I have read and understand the instructions provided in the Field Safety Notice.
- ❑ I have checked my stock and identified the affected kits.
- ❑ I have notified all those who need to be aware of this notice within the organisation.
- ❑ Field Safety Notice is not applicable to my use of the product.

Indicate disposition of affected product:

- ❑ no affected stock

Customer Details

| | |
|---|---|
| Company Name | |
| Address | |



Form No. 12187-QA
REVISION (2)
17 Jul 2019

RANDOX

## Response Form

Randox Laboratories Ltd
55 Diamond Road, Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

Total Quantity

| | |
|---|---|
| Received | |
| Distributed | |

| | | | |
|---|---|---|---|
| Completed By | Print Name:<br><br>Signature: | Date | |
| Contact Telephone | | | |
| Contact Email | | | |

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

**It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.**

**Your regulatory authority requires your response form as evidence of the effectiveness of the corrective actions detailed in the FSN.**



Form No. 12187-QA
REVISION (2)
17 Jul 2019

RANDOX

**Response Form**

Randox Laboratories Ltd
55 Diamond Road, Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

**PART 2 (To be completed by Distributors and Randox Offices only)**

**Area of Distribution**

- ❑ I have identified and notified my customers that were shipped or may have been shipped this product by (*specify date and method of notification*);

  **OR**

- ❑ Detailed below is a list of customers who received/may have received this product. Please notify my customers. (List of customers may also be sent in a separate attachment)

| Consignee | Country | Quantity Received | Analyser / Kit Serial / Lot Number | Replacements Required |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

Have your customers notified you of any adverse events associated with recalled product?

- ❑ YES
- ❑ NO

If yes, please explain: _____



Form No. 12187-QA
REVISION (2)
17 Jul 2019