

# RANDOX

## Urgent Field Safety Notice

**Date:** 7<sup>th</sup> Aug 17

**Complaint Reference:** 302      **Action Type:** Device Modification

**Detail on Affected Devices:**

Our records indicate that your facility may have received the following product.

| Assay                 | Catalogue Number | GTIN           | Batch / Lot number | Expiry Date                 | Manufacturing Date          |
|-----------------------|------------------|----------------|--------------------|-----------------------------|-----------------------------|
| Lipid Control Level 3 | LE2670           | 05055273204209 | 2526CH             | 28 <sup>th</sup> March 2020 | 28 <sup>th</sup> April 2017 |

**Reason for Recall:**

Randox have confirmed a labelling error for Lipoprotein (a) target values listed in Cat no LE2670 Lot number 2526CH. The target values printed are 62.2 mg/dl and 30 nmol/l. The correct concentrations should be 30mg/dl and 62.2nmol/l respectively.

**Risk to Health:**

QC results would appear out of the manufacturer assigned ranges. This may lead to a delay in reporting patient results and therefore a delay in diagnosis. A review of previous results is not necessary as recovery outside control ranges is evident at the time of testing.

**Action to be taken:**

- Place a copy of the updated value sheet in all kits.
- Discuss the contents of this notice with your Medical Director.
- Compliance with your country' s Regulatory Authority requires a return of the attached response form. Please complete and return the vigilance response section of this to [technical.services@randox.com](mailto: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.

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## Urgent Field Safety Notice

**Contact Reference:**

Radox Technical Services  
Radox Laboratories Ltd,  
55 Diamond Road,  
Crumlin,  
United Kingdom,  
BT29 4QY  
Email: [technical.services@radox.com](mailto:technical.services@radox.com)  
Tel: +44 (0) 28 9445 1070  
Fax: +44 (0) 28 9445 2912

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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## Urgent Field Safety Notice

**Vigilance Response Form** (Response Plan must be completed by the importer of the device)

**Importer Details**

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

**Total Quantity**

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

**Area of Distribution**

(To be completed by Distributors and Radox Offices)

| Consignee | Country | Quantity Received | Analyser Serial Number | Replacements Required |
|-----------|---------|-------------------|------------------------|-----------------------|
|           |         |                   |                        |                       |
|           |         |                   |                        |                       |
|           |         |                   |                        |                       |

I have read and understood the Urgent Field Safety Notice. The actions to be taken are completed.

|              |       |
|--------------|-------|
| Completed By | Date  |
| Contact      | Tel   |
|              | Email |

