

RANDOX
Urgent Field Safety Notice

Radox Laboratories Ltd
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Date Issued: 28 Jun 23

Complaint Reference: REC679

Action Type: Device Recall

Detail on Affected Devices:

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

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Liquid Urine Control Level 2	UC5074	05055273207569	1209UC	28 Mar 24	28 Apr 22

Reason for Action:

Radox Laboratories is conducting a Device Recall for Liquid Urine Controls Level 2, UC5074, lot 1209UC due to the following:

- There is vial to vial variation resulting in some vials recovering positive for hCG, which should be negative and high and outside range for cortisol.
- There has been a transcription error for Creatinine in the Instructions For Use (IFU) The target and ranges for Creatinine for the Roche Creatinine Plus method have been listed incorrectly.

Risk to Health:

An incorrect control result from one of the affected vials may cause a delay in reporting patient results. hCG test are run on urine to confirm pregnancy and can also be measured as a tumour marker test.

Action to be taken:

- Discontinue use of and discard any of the above immediately. **Provide Radox with photographic evidence of the destruction of the kits.**
- Review your inventory of these products and assess your laboratories needs for reimbursement for discarded inventory.
- Review previous results for this controls and ensure patient results were not reported if control results were not within range.

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- 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

A handwritten signature in black ink, appearing to be 'K. Smith', is written over a horizontal line.