

RANDOX

Field Safety Notice

Randox Laboratories Ltd
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Date Issued: 12 November 2018

Complaint Reference: REC340

Action Type: Device Modification

Detail on Affected Devices: Evidence Investigator

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

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Evidence Investigator	EV3602 (EV3602R, EV4187)	05055273209952	n/a*	n/a	n/a

*n/a not applicable

Reason for Recall:

Evidence Investigator software version 2.1.1 is now available. This includes a number of new features as detailed in the Software Release Notes in the accompanying email.

The software has also been modified to allow for enhanced detection of reference and correction DTRs.

Risk to Health:

Failure to detect reference and correction DTRs causes no test result to be reported. This requires a re-run of the test sample. A delay in reporting results could lead to a delay in patient treatment of up to 2 to 24 hours depending on the test array. The test menu for the Evidence Investigator does not include time critical diagnostic tests therefore the risk to health is negligible.

Action to be taken:

- Review the software release notes provided for further information.
- Please complete the mandatory software upgrade. Software update files can be accessed via the FTP site, guidance notes can be found in the accompanying email. The files should be saved onto a blank USB device.
- Discuss the contents of this notice with your Medical Director.

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- Complete and return the attached response form 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


