RANDOX

Urgent Field Safety Notice

Date: 24th July 2017

Complaint Reference: REC 296 **Action Type:** Device Modification

Detail on Affected Devices:

Our records indicate that your facility may have received the one or more of the following products.

Product	Catalogue Number	GTIN
Immunoassay Premium Plus Quality Controls	IA3109	05055273207255
	IA3110	05055273207262
	IA3111	05055273207279
	IA3112	05055273207286
Immunoassay Premium Quality Controls	IA2638	05055273203844
	IA2639	05055273203851
	IA2640	05055273203868
	IA2633	05055273203837

Reason for Recall:

Randox has confirmed that ACTH in our Immunoassay Premium Plus quality control and Immunoassay Premium quality control does not meet the quoted reconstituted stability claim in the product IFU. We now recommend that ACTH is to be assayed immediately after the 30-minute reconstitution procedure.

Risk to Health:

The quality control results which are not within range can lead to a delay in reporting ACTH results. ACTH is typically measured to aid in diagnosing the cause of abnormal cortisol. Abnormal cortisol levels are generally not associated with immediate life threatening disorders. Therefore a delay in ACTH reporting is unlikely to pose a serious risk to health. A review of previous results is not necessary as recovery outside control ranges is evident at the time of testing.

Form No. 6307-TS
REVISION (8)
27th September 2016

Action to be taken:

- Place a copy of the important notice in all kits remaining in stock.
- 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. Complete and return the vigilance response section of this form 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.

Contact Reference:

Randox Technical Services
Randox Laboratories Ltd,
55 Diamond Road,
Crumlin,
United Kingdom,
BT29 4QY
Email: technical.services@randox.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 Randox Technical Services.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

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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 Randox 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		

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