RANDOX

Field Safety Notice

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Date Issued: 19 November 2018

Complaint Reference: REC352 **Action Type:** Device Modification

Details of Affected Devices: Liquid Protein Calibrators (SP CAL (LIQ))

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 Protein Calibrators (SP CAL (LIQ))	IT2692	05055273204049	415879	28 Mar 2019	14 Jun 2017
			445262	28 July 2019	22 Mar 2018

Reason for Recall:

Randox is conducting a Device Modification for Liquid Protein Calibrators for the lots specified in the table above. The assigned value of Alpha-1-Acid-Glycoprotein (AGP), IgA and IgG in these calibrators has been adjusted to improve the alignment to reference material ERM-DA470k/ IFCC. Please refer to the new calibrator concentration targets found in the attached revised Value sheet. In addition, the units of measurement for IgG are incorrect. The current IFU states these as mg/L or g/L. This should be mg/dl or g/L.

Risk to Health:

Alpha1-acid glycoprotein (AAG / AGP) is a classical acute phase protein showing a 3-4 fold increase during inflammation or tissue damage. Decreased levels are associated with severe liver disease and protein losing syndromes and may be indicative of septic shock. Immunoglobulins are typically tested to review a person's immune system status. The tests are not specifically diagnostic but can be a strong indicator of a disease or condition. An erroneous result would be unlikely to cause a change in patient management when considered in conjunction with clinical symptoms. In addition, a significant change in recovery would be observed as a shift in patient mean and would be apparent to the laboratory. The risk to health would be negligible.

Form No. 6307-TS
REVISION (9)
24th October 2018

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The risk to health for reporting incorrect elevated IgG results due to incorrect units of measurement is negligible. The units of measurement are pre-defined on the analyser as mg/dl. In addition, if the concentration was entered as a factor of 10 lower the Quality Control results would also be elevated by a factor of ten and report as out of range.

Action to be taken:

- Please review all remaining stock. Add the attached important notice and replace the calibrator value sheet with the revised document provided.
- Discuss the contents of this notice with your Medical Director. Review results generated with the affected batches in line with the clinical profile of the patient.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
- Complete and return the response 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.

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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