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IMPORTANT PRODUCT NOTICE
Alinity c Proteins Standard
Controls out of range

Date: 2024 June 27

Field Action Number: SV 24/01

Dear Valued Customer:

This Notification provides information regarding the use of a specific Alinity c Proteins Standard lot which has been identified to lead to Quality Control results out of acceptance range high per the control value sheet.

Product Name	List Number (LN)	UDI	Lot Number	Expiry Date
Alinity c Proteins Standard	08P67-01	(01)00380740151324 (17)250531(10)01594L823	01594L823	2025-05-31

Issue Description and Risk

The Alinity c Proteins Standard is intended for use in establishing the calibration for the Alinity c (A-1-AGP, A1-Antitrypsin) assays by turbidimetry. This standard is intended to be used together with the Alinity c (A-1-AGP, A1-Antitrypsin) reagents on the Alinity c analyzer.

Biokit, S.A. has identified that the use of Alinity c Proteins Standard lot 01594L823 results in Alinity c Proteins Control values out of acceptance range high when using any Alinity c A1-Antitrypsin reagent and controls lots. Other commercial controls and proficiency materials may potentially show the same issue when used in conjunction with Alinity c Proteins Standard lot 01594L823.

Although the same standards are used for calibrating both assays, no impact has been observed for the Alinity c A-1-AGP assay.

Impact on Patient Results

There is no impact to patient results as the issue will prevent release of test results, either because of failed quality control or an invalid calibration. Patient samples should not be run in these instances per the Instructions for Use recommendations.

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The issue observed may cause a delay in generating patient results if the controls report out of the acceptance range.

Investigation

An investigation is ongoing to determine the root cause of the observed issue.

Required Actions

- Biokit, S.A. requests that you **stop using Alinity c Proteins Standard lot 01594L823.**
- **Discard any remaining kits** of lot 01594L823 from your inventory.
- Complete and return the Abbott Customer Reply Form.
- Please retain this letter for your laboratory records.

We apologize for any inconvenience caused by this issue and appreciate your prompt attention to this notification. If you or any of your customers have any questions regarding this information, please contact your local area Abbott Customer Service.

Sincerely,

Àngels Roma
Quality & Regulatory Affairs VP
Biokit S.A.

Lliçà d'Amunt - 08186 Barcelona (Spain) - Tel. (34) 93 860 9000 - Fax (34) 93 860 9029