SENTINEL
DIAGNOSTICS

Urgent Field Safety Notice
N. 06/2020

Product Name	List Number (LN)	Lot Number	Expiration Date
ARCHITECT Fructosamine	3R05-31	All	All

Date: June 25th, 2020

Details on affected devices:

The purpose of this letter is to inform you of an error in the Spanish and French electronic versions of the Fructosamine Instruction for Use (IFU). In the "ASSAY PARAMETERS--Reaction mode" section, the Reaction mode was incorrectly translated as "End up", instead of the correct reaction mode of "Rate up".

Description of the problem:

The Spanish and French electronic versions of the IFU on the Abbott website, www.corelaboratory.abbott, contained the incorrect Reaction mode: End up, due to a translation error. All other translations of the IFU on the Abbott website and the copy of the IFU physically packed with the kit, contain the correct information. The ARCHITECT assay file also contained the correct reaction mode.

Patient Impact:

There is potential for inaccurate results if the incorrect assay reaction mode was used.

Actions to be taken:

If you had previously downloaded the Spanish or French version Fructosamine IFU from the Abbott website, please download the updated IFU that is appropriate for your laboratory.

- Spanish version IFU G07524R01
- French version IFU G07515R01

If you had manually changed the reaction mode in the assay file to "End up", this should be changed to the correct reaction mode of "Rate up". Any results generated using the "End up" reaction mode are potentially inaccurate and should be reviewed.

For detailed information on viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

Transmission of this Field Safety Notice:

- Review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported patient results.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
- Please retain this letter for your laboratory record.

Contact reference person:

If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.

Best regards

June 25th, 2020

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Head of Marketing

June 25, 2020

Patricia Dupé
Head of Quality System