SENTINEL DIAGNOSTICS

Urgent Field Safety Notice
N.02/2019

Product Name	List Number (LN)	Lot Number	Expiration Date
Lithium	8L25-30	n/a	n/a

Date: June 28th, 2019

Details on affected devices:

The purpose of this communication is to inform of an additional SmartWash parameter for the MULTIGENT Lithium reagent, List Number (LN) 8L25-30 to prevent the potential for carryover from the ARCHITECT Lactate Dehydrogenase (LDH) reagent (LN 2P56). Please review the information carefully and follow the mandatory actions.

Description of the problem:

Carryover may be observed between the MULTIGENT Lithium reagent and the ARCHITECT LDH reagent on improperly maintained systems due to the presence of lithium lactate in LDH reagent. As a result, falsely elevated lithium patient results may be generated. To minimize the potential for carryover, an additional SmartWash has been implemented for the MULTIGENT Lithium assay.

Patient Impact:

There is a potential to generate falsely elevated lithium patient results. Therefore, the following actions are mandatory.

Actions to be taken:

- If your laboratory ***does not*** have the LDH reagent installed on your system, no action is required.

- If the LDH reagent is installed on your instrument, please follow the instruction s below:

  1. Update the Lithium (LN 8L25- 30) assay parameters to add the new Smart Wash. For additional information, see the ARCHITECT System Operations Manual, Section 2, *Configure the SmartWash settings (c System).*

Configure assay parameters — SmartWash

OGeneral	OCalibration	• SmanWash	OResults	0 Interretation
Ass : Lith				
GOMPONENT	REAGENT/ASSAY	WASH	Volume	Repllcates
R1	LDHOO	Water		!
SampleProbe•		Water		

•sample Probe *Sample wash protocol* is **Maximumwash.**

  2. For information on maintaining optimal system performance, refer to your ARCHITECT System Operations Manual.

- Please review the content of this communi cat ion with your Medical Director and retain this letter for your laborat ory records.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization/individuals where the potentially affected devices have been transferred.

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,

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