

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

Configure assay parameters – SmartWash				
<input type="radio"/> General	<input type="radio"/> Calibration	<input checked="" type="radio"/> SmartWash	<input type="radio"/> Results	<input type="radio"/> Interpretation
Assay: Lith				
COMPONENT	REAGENT/ASSAY	WASH	Volume	Replicates
R1	LDH00	Water	345	1
Sample Probe*		Water		
*Sample Probe Sample wash protocol is Maximum wash.				

2. For information on maintaining optimal system performance, refer to your ARCHITECT System Operations Manual.
- Please review the content of this communication with your Medical Director and retain this letter for your laboratory 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

✓ Mario Fangareggi
Head of Marketing

Patricia Dupé
Head of Quality System ✓

Please kindly fill in the attached form and send it back to us as soon as possible via fax (n. +39 02 34551464) or e-mail (customerservice@sentinel.it).

Urgent Field Safety Notice Receipt

Field Safety Notice N.: 02/2019	Product: Lithium
Date:	Code: 8L25-30
	Lot: n/a

- The undersigned declares to have read and understood the above mentioned Field Safety Notice.**

Name	
Title	
Company	
Complete Company address	
Telephone n.	
Fax n.	
e-mail address	

Notes/Comments:

Date, signature and company stamp