



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.

SENTINEL

DIAGNOSTICS

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

 JUN 28, 2019
Mario Fangareggi
Head of Marketing

 JUN 28, 2019
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