

**Urgent Field Safety Notice
N. 04/2019**

Product Name	List Number (LN)	Lot Number	Expiration Date
Alinity c Lithium Reagent Kit	08P5320	n/a	n/a

Date: June 28th, 2019

Details on affected devices:

The purpose of this communication is to inform you that the assay file for the Alinity c Lithium Reagent Kit, List Number (LN) 08P5320, has been updated with an additional SmartWash parameter to prevent the potential for carryover from the Alinity c Lactate Dehydrogenase (LDH) Reagent Kit (LN 07P74). Please review the information carefully and follow the mandatory actions.

Description of the problem:

Carryover may be observed between the Alinity c Lithium reagent and the Alinity c LDH reagent on improperly maintained systems due to the presence of lithium lactate in the 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 Alinity c 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:

Please follow the instructions below:

1. Install the Alinity c Lithium assay file version 6 to implement the new LDH SmartWash.
2. For information on maintaining optimal system performance, refer to your Alinity ci-series Operations Manual.
3. Please review the content of this communication with your Medical Director and retain this letter for any future reference.

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.: 04/2019 Date:	Product: Alinity c Lithium Reagent Kit Code: 08P5320 Lot: n/a
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- 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