

**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 28<sup>th</sup>, 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
Ri	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.

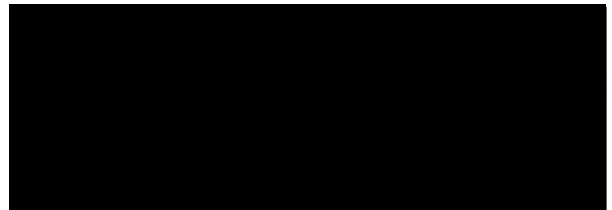
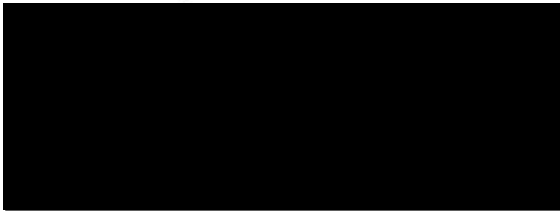
**Transmission of this Field Safety Notice:**

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



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](mailto: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

**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 28<sup>th</sup>, 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.

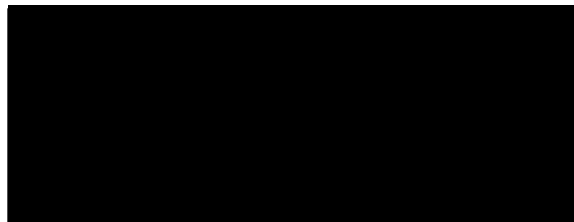
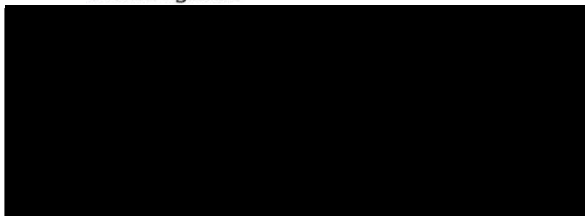
**Transmission of this Field Safety Notice:**

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



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](mailto: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