

## Urgent Field Safety Notice

POC 16-022.A.US-OUS

September 2016

### RAPIDPoint® 400/405 Systems

#### Chloride Calibrator Value Assignment Error

Our records indicate that your facility may have received the following product(s):

**Table 1. Affected Products**

Siemens Material Number (SMN)	Description	Cartridge Serial Numbers Affected
10329756 10341161	RAPIDPoint® 400 Measurement Cartridge	2610900214  through 2621001325
10844812 10283222 10313971 10310469	RAPIDPoint® 405 Measurement Cartridge	

#### Reason for this Urgent Field Safety Notice

Siemens Healthcare Diagnostics has confirmed an error in the value assignment for the Chloride calibrators in the RAPIDPoint 400 and RAPIDPoint 405 Measurement Cartridge serial numbers indicated in Table 1 above.

Table 2 below indicates the potential chloride recoveries that that may be observed.

**Table 2. Potential Chloride Recoveries**

Expected Chloride (mmol/L)	Maximum % Bias Due to Error	Potential Chloride (mmol/L) Recovery
65	-2.3%	64
90	+1.4%	91
100	+2.3%	103
110	+3.7%	114
122	+5.0%	128
132	+5.9%	140

All the other electrolytes (Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>) and blood gas parameters are correctly assigned in these measurement cartridges.

## **Risk to Health**

Given that normal values for chloride are 96 to 106 mmol/L, the results in Table 2 above indicate that, at extremely high chloride values (>122 mmol/L), a positive bias of 5% or greater may be observed. The bias at an extreme value of chloride (>120 mmol/L) as an isolated laboratory result would have a negligible health risk, and major mitigating factors would require abnormalities in other chemistries, blood gas values, and clinical condition to trigger specific intervention for the chloride value alone.

## **Actions to be Taken by the Customer**

- Complete and return the Field Correction Effectiveness Check form attached to this letter within 7 days.
- Review this letter with your Medical Director.

Please retain this letter with your laboratory records, and forward it to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

RAPIDPoint is a trademark of Siemens Healthcare Diagnostics.

**FIELD CORRECTION EFFECTIVENESS CHECK**

Chloride Calibrator Value Assignment Error

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 16-022.A.US-OUS, dated September 2016, regarding a Chloride Calibrator Value Assignment Error. Please read the question below and indicate the appropriate answer.

Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

I have read and understood the instructions provided in this Urgent Field Safety Notice. Yes  No

Name of person completing questionnaire: \_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_ Instrument Serial Number: \_\_\_\_\_

Street: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_

Phone: \_\_\_\_\_ Country: \_\_\_\_\_

To fax this completed form please send it to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.