

## Urgent Field Safety Notice

33293 Rev. A

August 2015

### RAPIDPoint® 500 System

#### Incorrect Sodium Calibrator Value Assignment

Our records indicate that your facility may have received the following RAPIDPoint® 500 Measurement Cartridges:

Siemens Material Number (SMN)	Description	RAPIDPoint 500 Cartridge Serial Numbers Affected
10491449	RAPIDPoint 500 Measurement Cartridge Lactate (750 tests)	2517102517 through 2519000012  <b>See note below</b>
10491448	RAPIDPoint 500 Measurement Cartridge Lactate (400 tests)	
10491447	RAPIDPoint 500 Measurement Cartridge Lactate (250 tests)	
10844813	RAPIDPoint 500 Measurement Cartridge Lactate (100 tests)	

**NOTE:** Cartridges within this serial number range that have a green dot on the box and/or the cartridge are not affected. Please refer to Figures 1 and 2 on the next page.

#### Reason for the Urgent Field Safety Notice

During the manufacturing process, the Sodium high calibrator value was incorrectly assigned for the RAPIDPoint 500 Measurement Cartridge serial numbers indicated above, causing a negative bias on both QC and patient samples. The following table indicates the negative bias Siemens observed using patient specimens.

Expected Sodium (mmol/L)	Median Bias (mmol/L)	Range of Bias (mmol/L)
126.5	-1.2	-1.6 to -0.6
149.0	-2.6	-3.6 to -2.1
166.0	-4.8	-6.1 to -3.4
182.1	-5.6	-7.5 to -3.6

#### Risk to Health

This issue causes a varying negative bias across the measurement range, with the bias increasing with increasing sodium concentrations. Taking into account the magnitude of the bias

## Incorrect Sodium Calibrator Value Assignment

near the reference interval, this issue is not expected to cause clinically significant changes to patient treatment decisions for hypernatremia. Therefore, Siemens is not recommending a review of previously generated results.

### Additional Information

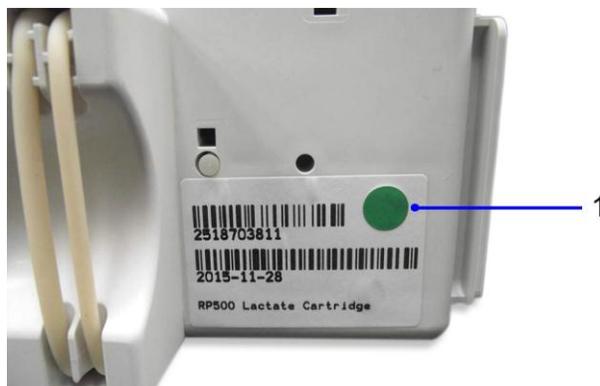
**NOTE:** Cartridges within the affected serial number range that have a green dot on the box and/or the cartridge are not affected. Please refer to Figures 1 and 2 below.

**Figure 1. Green Dot on Exterior Package Label Indicating Acceptable Cartridges**



1 Location of green dot

**Figure 2. Green Dot on Cartridge Label at Rear of Cartridge**



1 Location of green dot

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

- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 7 days.
- Please 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**

Incorrect Sodium Calibrator Value Assignment

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 33293 Rev. A dated August 2015 regarding Incorrect Sodium Calibrator Value Assignment. Please read the question 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 information provided in this letter. Yes  No

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

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

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

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

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

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

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