SIEMENS

Urgent Field Safety Notice

32258 Rev. A

December 2014

RAPIDPoint® 405/500 Systems
RAPIDLab® 1245/1265 Systems

Neonatal Bilirubin Reporting When tHb Is Out-of-Range High

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

Table 1. RAPIDLab® and RAPIDPoint® Systems Affected Products

System	Siemens Material Number (SMN)
RAPIDPoint® 405 Blood Gas Analyzer	10310464, 10322347, 10314817, 10317193, 10318999, 10320055, 10322347, 10328278, 10328302, 10336784
RAPIDPoint® 500 Blood Gas Analyzer	10492730, 10696855, 10696857, 10697306
RAPIDLab® 1245 Blood Gas Analyzer	10321844, 10491393, 10337179
RAPIDLab® 1265 Blood Gas Analyzer	10491395, 10321852, 10335524

Reason for Urgent Field Safety Notice

This letter is to remind you that the neonatal bilirubin (nBili) parameter may have increased variability when the nBili concentration is >12 mg/dL (205 µmol/L) and the tHb concentration exceeds the upper reportable range of >25 g/dL (15.5mmol/L). When this occurs, the analyzer may report an nBili result that is higher or lower than expected. The nBili parameter is dependent on tHb. For nBili to be accurately measured, the tHb channel must be in calibration and have no associated error codes. Refer to the table below for how the analyzer reports these scenarios.

tHb	nBili	tHb reported on the analyzer	nBili reported on the analyzer
> 25 g/dL (15.5 mmol/L)	>12 mg/dL (205 µmol/L)	-----↑	nBili result
> 25 g/dL (15.5 mmol/L)	≤12 mg/dL (205 µmol/L)	-----↑	-----?

This issue potentially impacts only those customers who report nBili results.

511 Benedict Avenue
Tarrytown, NY 10591
www.siemens.com/diagnostics

GPF-003 -6 V5.1 Effective: 2014-07-07
Related Procedure: GP-003 DX-Field Action

As noted in the operator's guide, the following is stated in the neonatal bilirubin interference section of the *Operator's Guide*.

> **Limitations:**
>
> As with all diagnostic tests, do not base a definitive diagnosis on the results of a single test. A physician should make a diagnosis after all clinical and laboratory findings are evaluated.
>
> On whole blood, the total analytical error may be higher than the fixed limits of +/- 20%. The measured total analytical error includes many sources of error such as day-to-day variation, instrument-to-instrument differences, and variability in the reference method used for comparison.

Risk to Health

The risk to health as a result of this issue is limited to a potential delay in hyperbilirubinemia detection while the result is being confirmed by biochemical means if the result is lower than expected. There is negligible risk to health if a higher than expected result is obtained since phototherapy would already be initiated and exchange therapy would require confirmation by biochemical testing in the laboratory.

Siemens is not recommending a review of previously generated results or repeat testing due to this issue.

Actions to be Taken by the Customer

- If your analyzer reports "-----↑"on the tHb result, and an nBili result is reported, do not use the nBili result reported from the analyzer.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 7 days.

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

We apologize for the inconvenience that this situation has caused. Thank you for your understanding.

If you have any questions, please contact your local Siemens technical support representative.

RAPIDLab and RAPIDPoint are trademarks of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

Neonatal Bilirubin Reporting When tHb Is Out-of-Range High

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice [Letter Number] dated December 2014 regarding Neonatal Bilirubin Reporting When tHb Is Out-of-Range High. Please read the question and indicate the appropriate answer. Please return this completed form to Siemens Healthcare Diagnostics using the contact details provided at the bottom of this page.

I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes ☐	No ☐
Signed:	Date:	

Name of person completing questionnaire:	
Title:	
Institution:	Instrument Serial Number:
Street:	
City:	Post Code:
Phone:	Email:

It is important that your organisation takes the actions detailed in the FSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this FSN. Your organisations reply is evidence which, Siemens Healthcare, and subsequently the HPRA, needs to monitor the progress of the FSN. Without your reply Siemens Healthcare cannot verify the completeness of the FSN and the HPRA may need to issue a Medical Device Alert.

Please return this completed FC Effectiveness form within 14 days to:

FAX: 016297401

EMAIL: CruinnFSNGroup@cruinn.ie

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