Siemens Healthcare Diagnostics GmbH, HC CEMEA CEE QT,
Siemensstrasse 90, 1210 Vienna

Name M.A. Roland Ertl
Department HC CEMEA CEE QT

Telephone +43 51707-38274
Mobile +43 (664) 8011738274
E-mail roland.re.ertl@siemens.com

Date October 23, 2017

Document Ref# PH-17-018.A.OUS

Urgent Field Safety Notice:

BCS®/ BCS® XP System
Prolonged results with BC Thrombin Reagent kit lots 46751 and 47184

Dear Sirs,

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

Table 1. Affected Product(s)

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date	Manufacturing Date
BC Thrombin Reagent	OWNA11	10446636	46751	2018-09-08	2016-11-01
BC Thrombin Reagent	OWNA11	10446636	47184	2019-02-21	2017-03-20

Reason for Field Safety Correction

Siemens Healthcare Diagnostics has confirmed that the BC Thrombin Reagent kit lots 46751 (contains Thrombin Reagent lot 517468) and kit lot 47184 (contains Thrombin Reagent lot 517469) produce unexpected prolonged Thrombin Time (TT) results for expected normal samples, and may recover above the upper limit of normal (< 21 sec.) as stated within the IFU (Instruction For Use).

Risk to Health

The reference range is shifted to an approximately 20 % prolonged TT. If the reference range is not adjusted for the current affected lot, this may lead to a higher number of resolution testing in the case of slightly prolonged TT. There is a potential for misinterpreting unexpected prolonged results as UF heparin contamination and some other thrombin inhibitors. This is assessed as being of negligible health risk (NHR).

Previously, TT was used for lysis monitoring (streptokinase) and (practically in combination) with UF heparin. A similar situation needs to be addressed if TT or diluted TT is used for Thrombin inhibitors assessment (e.g. dabigatran). Both of these rarely used indications are rated at low health risk (LHR).

A look-back is not recommended as hemostatic parameters vary over time and results at the time point of look-back measurement may not reflect the current patient status.

Actions to be Taken by the Customer

As stated in the Reference Guide (Application Sheet for Thrombin Time with BC Thrombin), reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the aforementioned variables are changed.

For the use of BC Thrombin Reagent as a screening assay for thrombin inhibition, please be aware that the affected lots react more sensitive with approximately 20% prolonged/elevated TT results. This will lead to an increased rate of results above the reference range if not adjusted. Therefore an adjustment of your laboratory specific reference ranges is reemphasized when changing to a new reagent lot, as per Application Sheet for Thrombin Time with BC Thrombin.

If you use one of the affected BC Thrombin kit lots for monitoring fibrinolytic therapy and/or heparin and thrombin inhibitor levels, please readjust the therapeutic ranges or recommendations accordingly. We would like to inform you that TT exhibits a non-linear, but hyperbolic dose-response relationship. Please contact your local Siemens support, if you need support for these special applications.

Please review this letter with your Medical Director.

Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 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 this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

We would like to emphasize that Siemens is working on the TT assay to enhance the standardization and commutability of the released lots to provide you with a higher lot-to-lot consistency in the near future.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

i.V. Dipl. Ing. Franz Schwarz
Head of RAQS Austria & SEE

i.A. DI Gottfried Prechtl
Product Manager Austria & SEE