SIEMENS

Customer Notification

BR-02216

December 2015

Siemens BCS / BCS XP System

Unflagged, potentially false short clotting times for PT on BCS / BCS XP with Dade Innovin

Dear Siemens customer,

Our records indicate that you are using a Siemens BCS®/BCS® XP Automated Blood Coagulation Analyzer in your laboratory and may use Dade® Innovin® for your PT screening assay:

Table 1.

Instrument/Assay	Siemens Material Number (SMN)
BCS	10454728 (BCS RECONDITIONED) 10454729 (BCS RECONDITIONED) 10454742 (BEHRING COAGULATION SYSTEM) 10459303 (BCS RECONDITIONED) 10460659 (BCS INSTRUMENT) 10461881 (BCS INSTRUMENT)
BCS XP	10459330 (BCS XP SYSTEM, COMPLETE) 10462449 (BCS XP ANALYZER SYSTEM) 10461894 (BCS XP) 10470625 (BCS XP REFURBISHED)
Dade Innovin	10284500 10445704 10445705 10445706 10465673 10465674

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Reason for Customer Notification

Siemens Healthcare Diagnostics has observed that in very rare cases false short clotting times for PT on BCS and BCS XP with Dade Innovin can occur. This has also an effect for false high PT % of the norm or false low PT INR values.

These false short clotting times were observed with turbid, hemolytic and/or icteric samples from intensive care patients. The corresponding reaction curves of these rare samples showed a pre-peak, which can lead to falsely short clotting time. In rare cases the result was not flagged by the existing check algorithms. An example is given in Figure 1. (left: expected reaction curve; right: erroneous evaluated reaction curve).

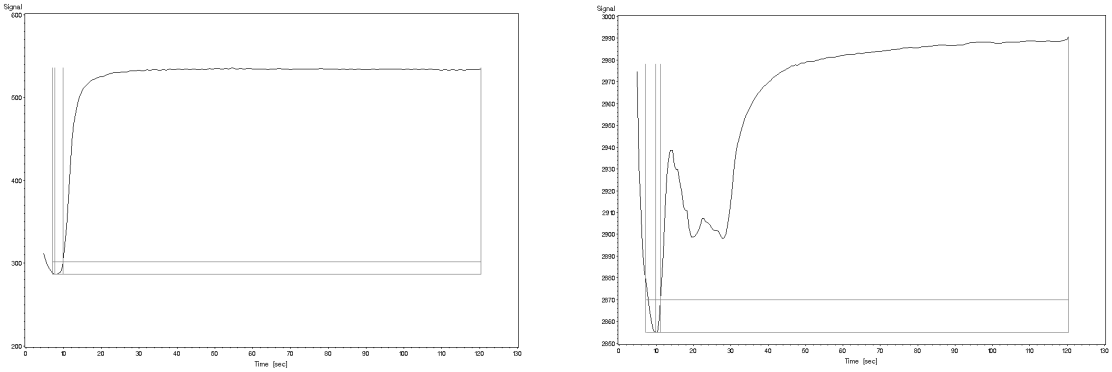

Fig. 1: Examples for expected and erroneous PT reaction curves.

Risk to Health

Under the conditions that there is an interference (as detailed above), there is a potential to miss a prolonged prothrombin time. In the majority of these situations the patient is either being intensively monitored or has a clinically apparent condition such as jaundice which would point to a reduction in hepatic clotting factor synthesis.

Siemens is not recommending a look back.

Actions to be Taken by the Customer

Siemens would like to reemphasize the importance of checking the inference levels given in the respective Application Sheets of the BCS and BCS XP systems, as such an effect can occur in turbid, hemolytic or icteric samples from intensive care patients.

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An irregular reaction as shown in Fig. 1, right panel, can be visually identified. Siemens is working on an advanced algorithm to identify these curves, which will be implemented after completion of all validation activities.

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.

Original signature on file

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Quality Systems & Compliance

Original signature on file

Marlen Suller
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