SIEMENS

Urgent Field Safety Notice

BR-02513

February 2013

Prolonged PT on Sysmex® CS-2000i/2100i Systems with Thromborel S

Siemens Catalogue and Material Nos. OUHP295 / 10446442 & OUHP495 / 10446445
Sysmex Japan Catalogue and Material Nos. OUHP295J / 10469932 & OUHP495J / 1046993

Dear valued customer,

Our records indicate that you may use a Sysmex CS-2000i or Sysmex CS-2100i System for determination of Prothrombin Time (PT) and related coagulation factors with Thromborel S.

Our investigations have confirmed that with Sysmex CS-2000i and CS-2100i Systems the last (up to 4) measurements out of a Thromborel S vial might be erroneously prolonged (longer PT sec., lowered % of Norm, increased INR). This might occur if the reagent in the vial is nearly used up and has been placed on board of the Sysmex CS-2000i/CS-2100i Systems for more than 4 hours. Please note that other systems are not affected.

Siemens Healthcare Diagnostics is conducting a voluntary field corrective action. Your local Siemens representative will contact you as soon as a technical solution is available. In the meantime please be advised to mix the reagent carefully every 4 hours.

As the coagulation status changes over the time a look back is not recommended.

Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files and forward this information to all parties that may use this product including others to whom you may have transferred the affected reagent for use on the above mentioned Sysmex CS-2000i/CS-2100i Systems.

If you have any questions or need assistance please contact your local Siemens representative.

The Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) has been notified of this action.

Siemens Healthcare Diagnostics Products GmbH

Emil-von-Behring-Str. 76
35041 Marburg, Germany

Phone: +49 6421 39-4511
www.siemens.com/diagnostics

GPF-003-6 V4.0 Effective: 2012-03-09

We apologize for any inconvenience that this situation has caused. Thank you for your patience and continued support.

Sincerely yours,

Original signature is on file

[redacted]
Director Quality Systems & Compliance

Original signature is on file

[redacted]
Director Global Marketing Hemostase Reagents

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This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated February 2013 regarding a/m Issue. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare diagnostics at the fax number indicated at the bottom of this page.

1. Did your facility receive a field correction letter from Siemens Healthcare Diagnostics regarding _____ Yes ☐ No ☐

   [This question is necessary only if the Effectiveness Check Letter is mailed separately from the FCA Letter]

2. Did we effectively communicate all necessary information? Yes ☐ No ☐

3. Do you now have any of the noted product on hand? (Please check inventories before answering.) Yes ☐ No ☐

4. If the answer to the question above is Yes, do you intend to take the recommended action as requested? Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State: Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT (###) ###-####

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