Anlage 2

SIEMENS

Urgent Field Safety Notice
BR-00312
December 2011

Dade® Actin® FSL Activated PTT Reagent (B4219-1, B4219-2) lots 537360, 537360A, 537362, 537362A, 537365, 537365A, 537366, 537374, 537374A, 547301, 547301A, and 547306.

Increased Heparin sensitivity affecting Heparin therapy monitoring with Dade® Actin® FSL

Dear valued Customer,

Our records indicate that you have received one of the above mentioned lots of the Siemens APTT reagent, Dade® Actin® FSL Activated PTT Reagent.

During recent investigations, Siemens Healthcare Diagnostics has observed that the above mentioned lots show an increase in Heparin sensitivity over the shelf life which is demonstrated by testing with Dade® Citrol® Heparin Control, low and high.

This increased Heparin sensitivity prolongs the activated partial thromboplastin times (APTT) which may lead to a decision to decrease the anticoagulant dosage, increasing the risk of thromboembolism.

Siemens Healthcare Diagnostics is conducting a voluntary field corrective action. This action is only related to an increase in heparin sensitivity of the above mentioned lot numbers of Dade® Actin® FSL.

If you would like to continue working with your Dade® Actin® FSL reagent lot you must verify, on a regular basis, that your therapeutic range is still valid, e.g., by using a Heparin containing control. In the case that it is not valid, adjust your existing therapeutic range or establish a new one.

If you decide not to continue with your Dade® Actin® FSL reagent lot, contact your Siemens representative for a replacement lot. Once you have established new normal, therapeutic and quality control ranges, discard the remainder of your old lot.

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 lots.

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 4637
www.siemens.com/diagnostics

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

Sincerely,

[redacted]

FIELD CORRECTION EFFECTIVENESS CHECK

Dade® Actin® FSL Activated PTT Reagent lots 537360, 537360A, 537362, 537362A, 537365, 537365A, 537366, 537374, 537374A, 547301, 547301A and 547306

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated December 2011 regarding Increased Heparin sensitivity affecting Heparin therapy monitoring with Dade® Actin® FSL. 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 (###) ###-####

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg, Germany
Phone: ++49 6421 39 4637
www.siemens.com/diagnostics