SIEMENS

Urgent Field Safety Notice

BR-02913

February 2013

Dade® Actin® FSL Activated PTT Reagent

Lot 547311 (Cat. no. B4219-1 / SMN 10445713)
Lot 547312 (Cat. no. B4219-2 / SMN 10445714)
Lot 547316 (Cat. no. B4219-2J / SMN 10465681)
Lot 547316A (Cat. no. B4219-2 / SMN 10445714)
Lot 547316AA (Cat. no. B4219-2J / SMN 10465681)

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 lot numbers 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 anticoagulation dosage, increasing the risk of thromboembolism.

Siemens Healthcare Diagnostics is conducting a voluntary field corrective action. This action is related to the increase in Heparin sensitivity of the above mentioned lots. Please discontinue use of the affected lots and discard any remaining inventory of the affected lots.

A look back of previously reported Dade Actin FSL APTT results is not recommended since IFU as well as previous Siemens communication requests that you verify on a regular basis, that your therapeutic range is still valid e.g., by using a Heparin containing control. In the case that is not valid, adjust your existing therapeutic range or establish a new one.

Please contact your Siemens representative for an alternative lot of Dade Actin FSL as replacement.

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.

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

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

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

Sincerely yours,

[redacted]
Director Quality Systems & Compliance

[redacted]
Director Global Marketing Hemostasis Systems

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Dade® Actin® FSL Activated PTT Reagent

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice BR-02913 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 Dade Actin FSL Activated PTT Reagent, provided on February 2013, letter# BR-02913?	Yes ☐	No ☐
[This question is necessary only if the Effectiveness Check Letter is mailed separately from the FCA Letter]		
2. I have read and understood the Urgent Field Safety Notice instructions provided in the February 2013 letter #BR-02913	Yes ☐	No ☐
3. Did we effectively communicate all necessary information?	Yes ☐	No ☐
4. Do you now have any of the noted product on hand? (Please check inventories before answering.)	Yes ☐	No ☐
5. 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:

Dade® Actin® FSL Activated PTT Lot Number	Quantity Discarded	Replacement Quantity
547311		
547312		
547316		
547316A		
547316AA		

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Title:

Institution: Instrument Serial Number:

Street:

City: State: Phone:

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

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