

## Urgent Field Safety Notice

BR-01315

March 2015

### Dade Actin Activated Cephaloplastin Reagent

#### Control recovery out of assigned ranges

---

Dear valued customer,

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

Table 1.

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Numbers
Dade® Actin® Activated Cephaloplastin Reagent	B4218-1	10445709	557128, 557129, 557130, 557131, 557132, 557133, 557134, 557135, 557140, 557141

#### Reason for Correction

Siemens Healthcare Diagnostics has confirmed internally that for the above mentioned lots the recovery of controls can be found outside the assigned ranges. Furthermore, a drift in the normal range towards higher results has been observed. This indicates a change of the product performance over shelf life which is the reason for this field action.

#### Risk to Health

Siemens has confirmed a drift greater 3 seconds in the normal APTT range and / or greater 15 % in the pathological range over shelf-life.

It is possible that patients with values close to the medical decision points could exhibit a deviation of up to 4 seconds for the normal range and up to 33% for the pathological range. The described drift towards higher APTT values will be recognized in most cases by control recovery out of the assigned range.

Siemens does not recommend a look back of previously generated results since the coagulation status changes over the time, and does recommend that this communication is reviewed with the laboratory medical director.

*Dade Actin Activated Cephaloplastin Reagent - Control recovery out of assigned ranges*

### **Actions to be Taken by the Customer**

Please discontinue use and discard any remaining material of the above mentioned lots of Dade Actin Activated Cephaloplastin Reagent. Please contact your local Siemens technical support representative for an alternative lot of Dade Actin Activated Cephaloplastin Reagent which can be used for further processing the APTT determination.

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.

Sincerely yours,

*Original Signature is on File*

*Original Signature is on File*

  
Director Quality Systems & Compliance

  
Manager Global Marketing Hemostasis

*Dade<sup>®</sup> and Actin<sup>®</sup> are trademarks of Siemens Healthcare Diagnostics.*

**FIELD CORRECTION EFFECTIVENESS CHECK**

Dade® Actin® Activated Cephaloplastin Reagent - Control recovery out of assigned ranges

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice BR-01315 dated March 2015 regarding Dade Actin. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

- 1. I have read and understood the [Letter Type] instructions provided in this letter. Yes  No
  
- 2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes  No

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
Dade Actin; B4218-1; 10445709 Lot 557128		
Lot 557129		
Lot 557130		
Lot 557131		
Lot 557132		
Lot 557133		
Lot 557134		
Lot 557135		
Lot 557140		
Lot 557141		

Dade Actin Activated Cephaloplastin Reagent - Control recovery out of assigned ranges

Name of person completing questionnaire: \_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_

Instrument Serial Number: \_\_\_\_\_

Street: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Phone: \_\_\_\_\_

Country: \_\_\_\_\_

Customer Sold To #: \_\_\_\_\_

Customer Ship To #: \_\_\_\_\_

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.