

Dade® Actin® Activated Cephaloplastin Reagent
Dade Actin Activated Cephaloplastin Reagent lots 557297 and 557298 – shorter control values observed during shelf-life

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

Table 1. [Platform or Module Name] Affected Product(s)

Assay	Catalog Number	Siemens Material Number (SMN)	Size	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing / 1 st Distribution Date (YYYY-MM-DD)
Dade Actin Activated Cephaloplastin Reagent	B4218-2J	10465677	10 x 2 mL	557297	2020-10-23	2018-10-24
		10465679	10 x 10 mL	557298		

Reason for Correction

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Products GmbH has confirmed that Dade Actin Activated Cephaloplastin Reagent lots 557297 and 557298 leads to shorter control values during shelf-life for the APTT determination and does not meet the control ranges given within the Table of Assigned Values (TAV). This applies for all analyzers the reagent is intended to be used with.

Siemens Healthcare Diagnostics Products GmbH is currently investigating this issue.

Risk to Health

The drift during shelf-life of the Dade Actin Activated Cephaloplastin Reagent of the affected lots is detected by the Quality Controls. As the Quality Controls behave equivalent to the patient samples, the described performance change will be recognized by control recovery out of the assigned range.

Actions to be Taken by the Customer

Please review this letter with your Medical Director.

Discontinue use of Dade Actin Activated Cephaloplastin Reagent lots 557297 and 557298 and discard the remaining kits of the affected lots.

Review your inventory of these products to determine your laboratory's replacement needs and contact your Siemens Healthineers representative for an alternative lot of Dade Actin Activated Cephaloplastin Reagent replacement.

Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

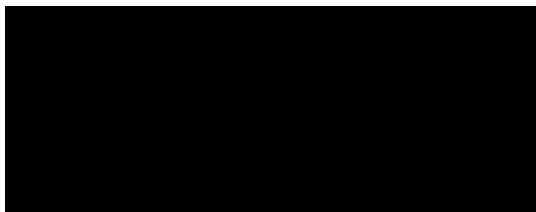
Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,



I. V. Dr. Norbert Dedner
Senior Director
Quality Systems & Compliance



I. A. Eva-Maria Landmann
Marketing Manager
Global Marketing Hemostasis

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FIELD CORRECTION EFFECTIVENESS CHECK

Dade Actin Activated Cephaloplastin Reagent lots 557297 and 557298 – shorter control values observed during shelf-life

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Field Corrective Action PH-20-002_A JP dated November 2019 regarding Dade Actin Activated Cephaloplastin Reagent lots 557297 and 557298 – shorter control values observed during shelf-life. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions 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(s) 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 Discarded/ Replacement Quantity Required
Dade Actin Activated Cephaloplastin Reagent Catalog # B4218-2J / SMN 10465677 Lot 557297	
Dade Actin Activated Cephaloplastin Reagent Catalog # B4218-2J / SMN 10465679 Lot 557298	

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

Country:

Customer Sold To #:

Customer Ship To #:

Please send a scanned copy of the completed form via email to XXXX@XXXX (for the US ONLY letter use the following e-mail address: uscctsfaecfax.team@siemens-healthineers.com, for the OUS letter the information will be filled in by the region).

Or to fax this completed form to the Customer Care Center at XXXXXX (For US ONLY letter, use the following phone number: (312) 275-7795, for the OUS letter the information will be filled in by the region) delete the Not Applicable text in yellow prior to sending.