

Customer Notification



PHC26-01.A.OUS

BCS XP
CS-2500 / CS-5100
CN-3000 / CN-6000

Title Protein S Ac kit lot 03628 – Protein S Ac Reagent lot 562954 may be cloudy after reconstitution.

Date Issued December 2025

Products

Assay	Siemens Material Number/Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date
Protein S Ac	10445968 / 000842768006678	03628	05-June-2025	04-June-2027

Issue Description

Siemens Healthineers has investigated customer complaints and confirmed that some Protein S Ac Reagent vials from lot 562954, included in Protein S Ac kit lot 03628 may appear cloudy after reconstitution.

The reagent should reconstitute into a clear solution. The affected vials are visibly different and can be easily identified by customers. If these vials are used for measurement, no valid calibration nor control measurements can be generated.

Siemens Healthineers is actively investigating the root cause of this issue. Based on current findings, the issue is limited to the product listed in the table above.

Customer Actions

- For the product listed in the table above, please perform the following steps:
- Inspect reconstituted vials of Protein S Ac Reagent lot 562954:
 - If Protein S Ac Reagent vials from lot 562954 are clear after reconstitution, they may be used as described in the Instructions for Use (IFU). Patient results can be reported as long as calibration is valid and quality control results are within range.
 - If Protein S Ac vials appear cloudy or milky after reconstitution, they will not produce valid results because neither calibration nor control measurements can be generated.
- If you experience this issue, you may request no-charge replacement product from your local Siemens Healthineers or distributor office. Please review your inventory of these products and assess your laboratory's replacement needs.
- Complete and return the Product Replacement Form attached to this letter.

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

Resolution The issue is limited to a low number of vials of Protein S Ac Reagent lot 562954 and is limited to this Protein S Ac Reagent lot only.

Single Registration Number (SRN) DE-MF-000005039

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,

This letter was created electronically and is valid without signature.

i.V. Nils Neumann
Director
Quality Systems & Compliance

i.V. Thomas Scholz
Marketing Manager
Global Marketing

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PRODUCT REPLACEMENT FORM

This response form is to request no charge replacement product for the enclosed Siemens Healthineers Customer Notification PHC26-01.A.OUS dated December 2025. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

- 1. Do you have the affected product(s) on hand? Please check inventories before answering. Yes No
- 2. Were affected Site Personnel notified? Yes No
- 3. Was a copy of the letter retained and posted with the current product labeling? Yes No

If the answer to the question #1 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	
<i>Protein S Ac; SMN: 10445968; Kit lot 03628</i>		
Name of person completing questionnaire:		
Title:		
Institution:		
Street:		
City:	State:	Zip Code:
Phone:	Country:	
Customer Sold To #	Customer Ship To #	

Please send a scanned copy of the completed form via email to **XXXX@XXXX** [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 the OUS letter the information will be filled in by the region) delete the Not Applicable text in yellow prior to sending].

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.

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