

Thromborel® S

Thromborel S lot 565662 – Reduced on-board stability

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

Table 1. Thromborel S Affected Product(s)

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing / 1 st Distribution Date (YYYY-MM-DD)
Thromborel S	OUHP29	10446442	565662	2021-03-04	2019-03-05

Reason for Field Corrective Action

The purpose of this communication is to inform you of an issue with the product indicated in Table1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Products GmbH has confirmed that Thromborel S lot 565662 is showing a decreased on-board stability after reconstitution. Therefore, Thromborel S lot 565662 does not meet the claims given within the respective Reference Guides (Application Sheets). This applies for all analyzer the reagent is intended to be used with.

The reduced on-board stability will be detected by the Quality Controls as they will be found outside the assigned ranges given within the Table of Assigned Values.

Siemens Healthcare Diagnostics Products GmbH is currently investigating this issue.

Risk to Health

The reduced on-board stability of the Thromborel S lot 565662 is detected by the tight criteria for our Quality Controls, which are working as intended and behave equivalent to the patient samples.

Quality Controls recovering outside the assigned range lead to invalid runs and patient results must not be reported.

Therefore, it is not necessary to review previous test results or to repeat testing as there is no additional incremental risk based on the current use of the assay.

Actions to be Taken by the Customer

Please review this letter with your Medical Director.

Discontinue use of Thromborel S lot 565662 and discard the remaining kits of the affected lot.

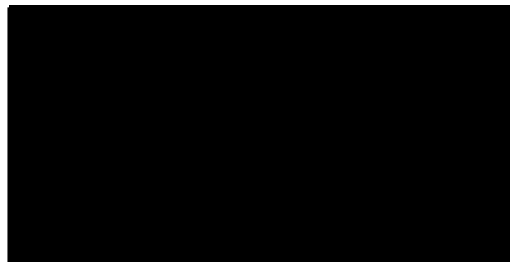
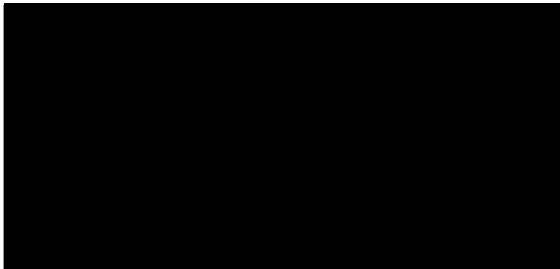
Review your inventory of these products to determine your laboratory's replacement needs and contact your Siemens Healthineers representative for an alternative lot of Thromborel S replacement.

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,



Thromborel is a trademark of Siemens Healthcare Diagnostics Products GmbH

FIELD CORRECTION EFFECTIVENESS CHECK

Thromborel S lot 565662 – Reduced on-board stability

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Medical Device Recall PH-20-001_A OUS dated October 2019 regarding Thromborel S lot 565662 – Reduced on-board stability. 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 Field Corrective Action 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
Thromborel S Catalog # OUHP29 / SMN # 10446442 Lot 565662	

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: uscctsfcaecfax.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.

If you have any questions, contact your local Siemens Healthineers technical support representative.