

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 <sup>st</sup> 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 Table 1 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,

...  
Senior Director  
Quality Systems & Compliance

...  
Product Manager  
Global Marketing Hemostasis

Thromborel is a trademark of Siemens Healthcare Diagnostics Products GmbH