

Coagulation Factor V Deficient Plasma**Coagulation Factor V Deficient Plasma lot 504974 – incorrect vials observed**

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

Table 1. Coagulation Factor V Deficient Plasma Affected Product(s)

Product	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing Date (YYYY-MM-DD)
Coagulation Factor V Deficient Plasma	ORSM19	10446269	504974	2021-03-05	2019-09-06

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 some packages of Coagulation Factor V Deficient Plasma lot 504974 may contain incorrect vials, which lead to control results out of range according to the Table of Assigned Values (TAV).

Risk to Health

The incorrect vials will lead to control results out of range.

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

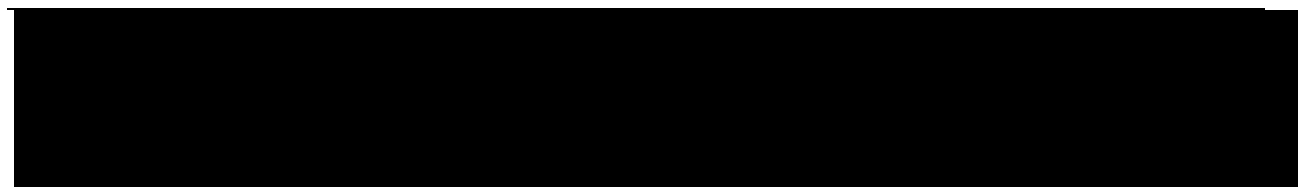
Therefore, it is not necessary to review previous test results or to repeat testing as the incremental risk based on the current use of the assay is negligible.

Actions to be Taken by the Customer

Please review this letter with your Medical Director.

Discontinue use of the affected Coagulation Factor V Deficient Plasma lot listed in Table 1 and discard the remaining material of this lot.

Review your inventory of these products to determine your laboratory's replacement needs and contact your Siemens Healthineers representative for an alternative Coagulation Factor V Deficient Plasma lot.

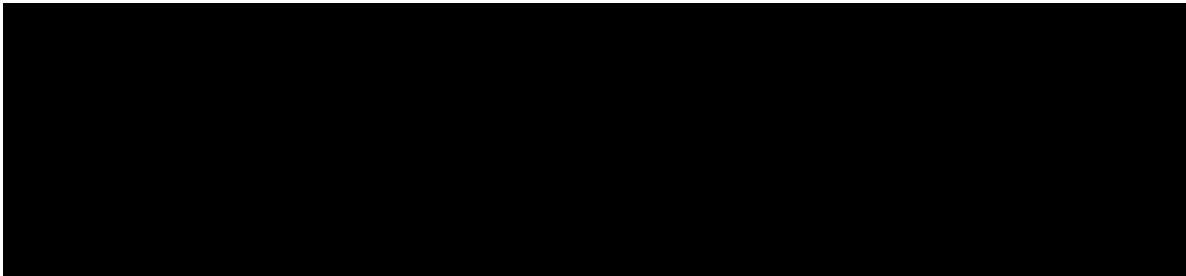


Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

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,



FIELD CORRECTION EFFECTIVENESS CHECK

Coagulation Factor V Deficient Plasma lot 504974 – incorrect vials observed

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Field Corrective Action PH-20-009 A OUS dated April 2020 regarding Coagulation Factor V Deficient Plasma lot 504974 – incorrect vials observed. 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
Coagulation Factor V Deficient Plasma SMN 10446269 Lot 504974	

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 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.

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

