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 Date April 22, 2020  
 Document Ref# PH-20-009 A OUS

**Urgent Field Safety Notice:**

**Coagulation Factor V Deficient Plasma**

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

Dear Sirs,

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 Table1 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.

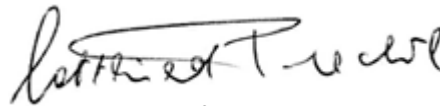
We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH



i.V. Dipl. Ing. Franz Schwarz  
Quality Management CEE



i.A. DI Gottfried Prechtl  
Product Manager Austria & SEE