

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,

This letter was created electronically and is valid without signature.

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