

Customer Notification

Control recovery issues – Coagulation Factor XI Deficient Plasma in combination with Dade Actin® FS Activated PTT Reagent (PHC24-01A)

Control recovery issues – Coagulation Factor XI Deficient Plasma in combination with Dade Actin® FS
Activated PTT Reagent (PHC24-01A) (PHC24-01A)– Customer Notification

Document history

Version	Date	Author	Comments
Version 1.0	June 2026	Daisy Odey	First release version

Summary

The Legal manufacturer of Coagulation Factor XI Deficient Plasma has confirmed that on the CS and CN systems, the Control recovery for the FXI assay, when measured in combination with Dade Actin® FS Activated PTT Reagent, might be at the upper limit of the assigned range or exceed it if measured in combination with Standard Human Plasma Lot greater than or equal to **563119**. This customer notification provides an interim mandatory guidance on resolving this issue. This notification applies to the Single Point (single dilution) method and not the MDA (Multiple Dilution Analysis) method.

Affected Products

Assay	Material Number / Unique Device Identification	Lots Number
Dade Actin® FS Activated PTT Reagent	10284498 / 00842768030826	All lots in shelf life until further notice
	10445710 / 00842768003844	
	10445712 / 00842768003868	
	10465678 / 00842768025662	
	10873828 / 00630414640327	
	10873830 / 00630414640341	

Affected Analyser Series

Analyser	Serial Number
Sysmex CS-2400 System	All serial numbers
Sysmex CS-2500 System	
Sysmex CS-5100 System	
Sysmex CN-3000 System	
Sysmex CN-3500 System	
Sysmex CN-6000 System	
Sysmex CN-6500 System	

Issue description

It has been confirmed through the investigation of customer complaints and internal investigation that on the CS and CN systems, the Control Plasma N recovery for FXI assay (FXI_FS) might be at the upper limit of the assigned range or exceed it when Dade Actin® FS Activated PTT Reagent is used in combination with Coagulation Factor XI Deficient Plasma, if measured in combination with Standard Human Plasma Lot greater than or equal to **563119**. To manage this, an updated application for Factor XI determination on CS and CN systems is being provided with the changes below:

- New pre-dilution: 1:2 (previously 1:1)
- Re-dilution rule 1:1: Applied for samples below 10% of normal to allow accurate measurement down to the lower limit of the measuring range

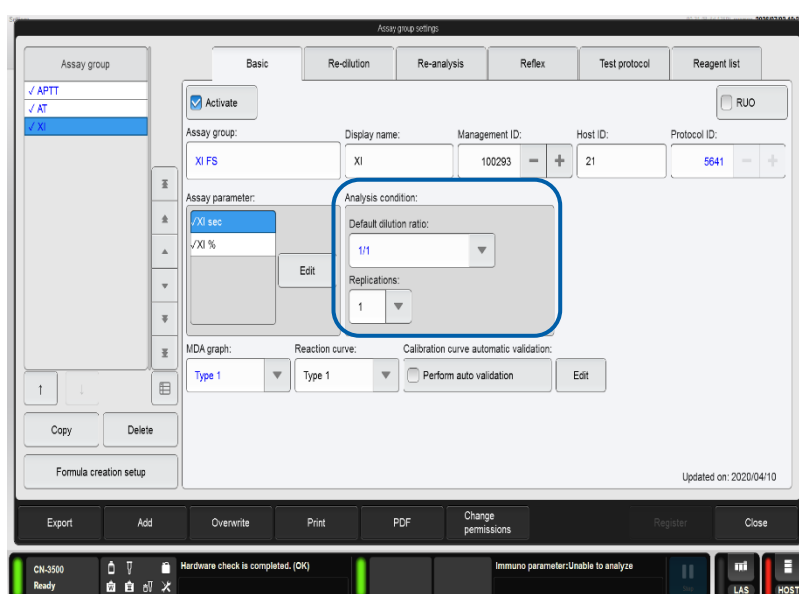


Figure 1: Previous FXI FS assay pre-dilution

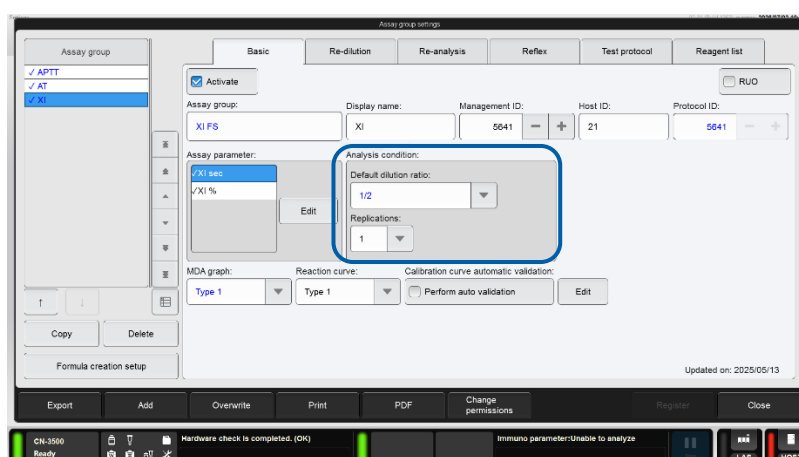


Figure 2: updated FXI FS assay pre-dilution

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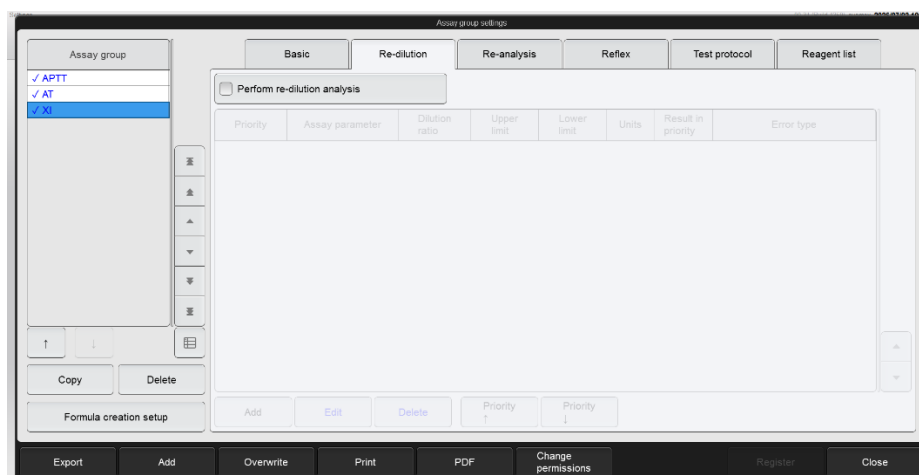


Figure 3: Previous FXI assay Re-dilution

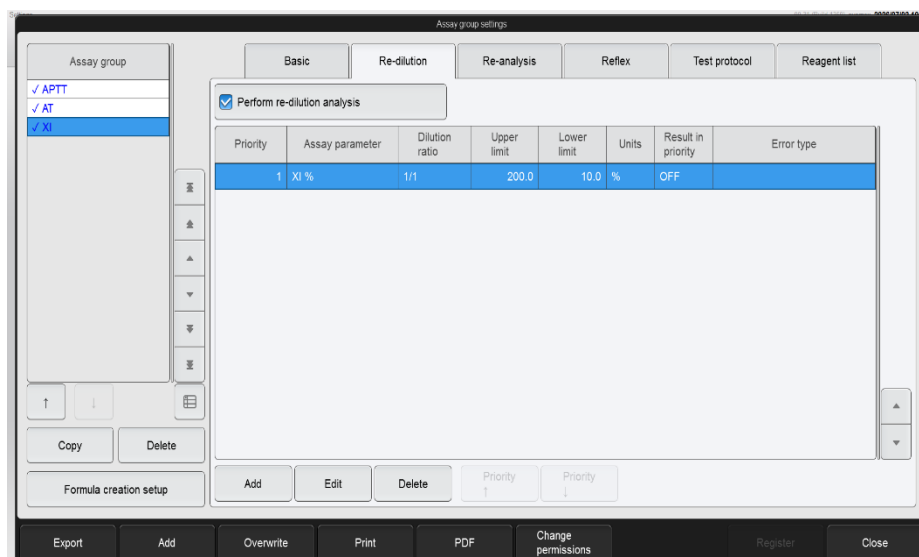


Figure 4: Updated FXI assay Re-dilution

This update ensures accurate determination of Control Plasma N values as listed in the Table of Assigned Values. It will also eliminate the need for the system-specific package insert currently included with the Coagulation Factor XI Deficient Plasma.

Impact on patient results and overall health risk

For clotting factor quantification, two analytical approaches are commonly used: the Single Point (single dilution) method and the MDA (Multiple Dilution Analysis) method. Currently, on CS and CN Systems, the Control Plasma N recovery for the special parameter “Factor XI with Dade Actin® FS” (Single point method), when used in combination with Factor XI Deficient Plasma and Standard Human Plasma lots from lot number 563119 onward, may be higher and fall outside the assigned range specified in the respective Table of Assigned Values. These QC failures lead to withholding patient results till a valid QC value is obtained. While this leads to delays in result reporting, it does not lead to incorrect patient results.

The MDA method determines activity using results obtained from multiple dilutions. Due to this measurement principle, it is less susceptible to dilution-dependent effects; therefore, the tendency toward elevated values observed with the Single Point method is not observed to the same extent.

Customer Actions

- Your local Sysmex representative or distributor office will contact you to coordinate the implementation of the update if you use the products listed above.
- After the update is completed, ensure that the updated application (1:2 dilution) for Factor XI determination on CS and CN systems, in combination with Dade Actin FS Activated PTT Reagent, is used until further notice. A follow-up communication will be provided when these listed actions are no longer necessary.
- Please retain this letter with your laboratory records and forward this letter to those who may have received the product.

References

1. Siemens Healthineers Customer Notification - PHC24-01. B