

Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Control Plasma N
Device Model	10446234
Lot Number	All lots in shelf-life
Manufacturer	Siemens Healthcare Diagnostics Inc.
Country of Origin	Germany
Reference	<u>Attached</u>
Reason of Alert	NHRA initiates this FSN due to identifying recovery issues with Control Plasma N when used with Dade® Actin® FS Activated PTT Reagent and Coagulation Factor XI Deficient Plasma on CS and CN systems. Values may be at the upper limit or outside the range with Standard Human Plasma Lot ≥ 563119 . Patient results are unaffected, but testing delays may occur.
Action should be taken	Please refer to "Actions to be taken by Customer/ User" in the attached FSN And for more information please contact the authorized representative Wael Pharmacy Co. W.L.L at sharmi@waelpharmacy.com

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

Customer Notification

PHC24-01.A.OUS

CS-2500 System, CS-5100 System, CN-3000 System, CN-6000 System

Title Control recovery issues – Coagulation Factor XI Deficient Plasma in combination with Dade® Actin® FS Activated PTT Reagent

Date Issued July 2024

Issue Description Siemens Healthineers has confirmed through the investigation of customer complaints and internal investigation that on the CS and CN systems the Control Plasma N recovery in combination with Dade Actin FS Activated PTT Reagent and Coagulation Factor XI Deficient Plasma might be at the upper limit of the assigned range or outside, if measured in combination with Standard Human Plasma Lot greater than or equal to 563119.

We will therefore provide you with new assigned values for the affected Control Plasma N lots below.

For future Control Plasma N lots, CS and CN System specific assigned values in combination with Dade Actin FS Activated PTT Reagent, Coagulation Factor XI Deficient Plasma and Standard Human Plasma lots greater than or equal to 563119 will be provided with the product delivery of the Coagulation Factor XI Deficient Plasma.

Siemens is working to restore the product performance.

Products

Product	Siemens Material Number / UDI-DI	Lot Number
Control Plasma N	10465698 / 00842768025839 10446234 / 00842768030857 10484201 / 00842768014239	All lots in shelf-life

Impact of Results Patient results are unaffected.

An apparent delay in testing may occur while resolving a quality control failure.

Customer Actions

- For the product(s) listed in the table above, please perform the following steps:
Within the table below new assigned values for Control Plasma N in combination with Dade Actin FS Activated PTT Reagent, Coagulation Factor XI Deficient Plasma and Standard Human Plasma Lot greater than or equal to 563119 for the CS and CN Systems can be found.

All lots in shelf-life can be allocated into three clusters, which can be seen in the table below.

Siemens Healthineers

Siemens Healthcare Diagnostics Products GmbH All Rights Reserved
Emil-von-Behring-Str. 76, 35041 Marburg, Germany
siemens-healthineers.com



Control Plasma N Lot	New target value	Lower Range	Upper Range
507914, 507915, 507916, 507917, 507918 507920, 507921, 507922, 507923, 507924, 507925, 507926, 507927, 507928, 507929, 507930, 507931 507933, 507934, 507935 507945, 507946, 507947, 507948	109 %	88 %	131 %
507932 507937, 507938, 507939 507944 507949, 507950	118 %	94 %	142 %
507919 507936 507940, 507941, 507942, 507943	129 %	103 %	155 %

- External Quality Assessment (EQA) samples above 100% of norm might be also affected by the issue. Therefore, please follow your laboratory instructions to establish more accurate results in this area e.g., to verify the initial result, EQA sample testing could be repeated in a 1:2 and 1:4 dilution.
- Please retain this letter with your laboratory records and forward this letter to those who may have received the 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.

i.V. Nils Neumann
Director
Quality Systems & Compliance

i.A. Thomas Scholz
Marketing Manager
Global Marketing

**Single
Registration
Number
(SRN)** DE-MF-000005039

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