

Customer Notification

PHC25-01.A.OUS

CA-500/600 series, CS-2500 System, CS-5100 System, CN-3000 System, CN-6000 System

Title Dade® Actin® FS Activated PTT Reagent – Control recovery issues with Dade Ci-Trol 2 and Dade Ci-Trol 3

Date Issued November 2024

Issue Description Siemens Healthineers has confirmed through the investigation of customer complaints and internal investigation that for the APTT on the CA- / CS- and CN-Systems the Dade Ci-Trol 2 and Dade Ci-Trol 3 recovery in combination with Dade Actin FS Activated PTT Reagent lots 562467 up to 562473 might be at the upper limit of the assigned range or outside.

We will therefore provide you with new assigned values for most of all Dade Ci-Trol 2 and Dade Ci-Trol 3 lots in shelf life below.

All Dade Actin FS Activated PTT Reagent lots before 562467 and after 562473 are not affected by the issue and can be used in common way.

Products	Product	Siemens Material Number / Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date
Dade Actin FS Activated PTT Reagent	10284498 / 00842768003868	562467	2024-04-05	2026-04-04	
		562472	2024-05-28	2026-05-27	
	10445710 / 00842768030826	562467A	2024-04-05	2026-04-04	
		562469A	2024-04-26	2026-04-25	
		562470	2024-04-15	2026-04-14	
		562472A	2024-05-28	2026-05-27	
		562472B	2024-05-28	2026-05-27	
	10465678 / 00842768025662	562468	2024-04-05	2026-04-04	
	10445712 / 00842768003844	562468A	2024-04-05	2026-04-04	
		562471A	2024-05-15	2026-05-14	
		562473	2024-05-28	2026-05-27	
		562473A	2024-05-28	2026-05-27	
	10873828 / 00630414640327	562469	2024-04-26	2026-04-25	
	10873830 / 00630414640341	562471	2024-05-15	2026-05-14	

Customer Actions • For the product(s) listed in the table above, please perform the following steps:

Within the table below new assigned APTT values for Dade Ci-Trol 2 and Dade Ci-Trol 3 lots in shelf life in combination with Dade Actin FS Activated PTT Reagent lots 562467 up to 562473 can be found.

Some customers may have received system, control and reagent lot specific target values based on raised complaints. In this case, the earlier provided values can still be used.

Please note that some control lots might be missing in this table as no material for re-assignment was available anymore.

Dade Ci-Trol 2	New target value	Lower Range	Upper Range
548531	50.8 sec	44.7 sec	56.9 sec
548532	51.1 sec	45.0 sec	57.3 sec
548534	50.4 sec	44.3 sec	56.4 sec
548536	47.7 sec	41.9 sec	53.4 sec
548541	51.2 sec	45.0 sec	57.3 sec
548542	48.9 sec	43.1 sec	54.8 sec
548543	48.6 sec	42.7 sec	54.4 sec
548544	50.1 sec	44.1 sec	56.1 sec
548548	49.5 sec	43.5 sec	55.4 sec
548549	49.0 sec	43.1 sec	54.8 sec
548550	49.9 sec	44.0 sec	55.9 sec

Dade Ci-Trol 3	New target value	Lower Range	Upper Range
556567	67.8 sec	59.6 sec	75.9 sec
556573	73.4 sec	64.6 sec	82.2 sec
556574	76.5 sec	67.3 sec	85.7 sec
556591	65.1 sec	57.3 sec	72.9 sec

- Please retain this letter with your laboratory records and forward this letter to those who may have received the product.

Resolution All Dade Actin FS Activated PTT Reagent lots before 562467 and after 562473 are not affected by the issue and can be used in common way without any limitation.

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.V. Thomas Scholz
Marketing Manager
Global Marketing

**Single Registration
Number (SRN)**

DE-MF-00005039

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