

Urgent Field Safety Notice

SBN-RDS-CoreLab-2023-003

RDS / CoreLab / Coagulation

Version 2

May 2025

FSN-RDS-CoreLab-2023-003 cobas® t 511/ t 711: PT-aPTT carryover

Product Name	aPTT Screen cobas t 600T
	aPTT Lupus cobas t 600T
	aPTT cobas t 600T
GMMI / Part No Device Identifier/ UDI-DI	07153716190 aPTT Screen cobas t 600T UDI-DI: 07613336119853
	07153678190 aPTT Lupus cobas t 600T UDI-DI: 07613336119846
	07153589190 aPTT cobas t 600T UDI-DI: 07613336119853
Production Identifier (Lot No./Serial No.)	n/a
SW Version	n/a
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

With version 2 of this FSN we would like to inform you about the final solution of the issue reported in version 1 of this FSN, where an identified issue on **cobas** t 511 and **cobas** t 711 coagulation analyzers was reported.

During internal measurements, carryover from PT Rec and PT Rec-based factor assays (FII, FV, FVII, FX) to aPTT assays (aPTT, aPTT Lupus and aPTT Screen) was detected.

The carryover takes place over the heated reagent probe that pipettes the start reagent of PT Rec and aPTT assays. If the heated probe is pipetting the affected reagent directly after pipetting PT Rec or with one other pipetting in between, a carryover effect was observed.

The carryover occurs when the coupling-nut is not tightened sufficiently. In this case aPTT Screen, aPTT Lupus and aPTT can be affected by carryover. Residual carryover can occur even if the probe is tightened. In this case, the carryover effect is much smaller and only aPTT Screen is affected for results above 50 sec.

A carryover from the PT Rec reagent to the aPTT assays will speed up the reaction. Thus, the carryover effect will lead to discrepant lower aPTT results, as the clotting time will become shorter. The incorrect low result may impact the interpretation of results and medical decisions based on those.

Two scenarios, which can lead to carryover, were observed:

1. In case that the heated reagent probe is not firmly tightened (affects aPTT, aPTT Lupus and aPTT Screen)
2. In case of samples with prolonged clotting, the carryover effect is possible even if the heated reagent probe is tightened sufficiently as described in the attached instructions (affects aPTT Screen only).

To date, no customer complaints were received.

The instructions on how to tighten the coupling-nut manually provided with version 1 of this FSN have been proven effective, and there were no customer complaints reporting carryover-events due to insufficient manual

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tightening of the coupling-nut since publication of version 1. Internal monitoring of cobas t 511 / 711 analyzers also demonstrated this method to be effective, as no carryover events were detected since publication of version 1 of this FSN.

Customers must be informed using the FSN-RDS-CoreLab-2023-003 version 2

Actions taken by Roche Diagnostics

Solutions are available to address both carryover scenarios:

1. Instructions for the customer how to sufficiently tighten the heated reagent probe **have been added** to the user assistance and maintenance workflows.
2. To mitigate the residual carryover risk in samples with prolonged clotting times, aPTT Screen Mod has been implemented for **cobas t 511** and **cobas t 711** coagulation analyzers, which can be triggered via a reflex test for aPTT Screen results >50sec (to be set up by customer as described in "Actions to be taken by customers").
3. The method sheet for aPTT Screen was updated to include information regarding *aPTT Screen Mod*.

Extensive investigations have shown that improvements to eliminate the residual carryover are not possible.

Actions to be taken by customers/users

- Customers are requested to **mount the heated probe according to the maintenance workflow or user assistance. Special attention is required during the mounting of the heated probe (Also see attachment 1).**
- In addition, to ensure correct results for samples with aPTT Screen clotting times >50 sec, customers are requested to **keep the already implemented reflex test and to make sure to have the latest carryover file installed (carryover evasion files are automatically installed with SW 2.3.0 or higher). See attached instructions (attachment 1), aPTT Screen IFU and user assistance.**

Please note, the following documents and e-barcode are required for the measures to be taken.

- e-Barcode aPTT Screen Mod V1 **or higher**
- e-Barcode Reagent Carryover Evasion (COE) V7 **or higher**
- Method Sheet Clean V7.0 **or higher**
- Method Sheet Deproteinizer V5.0 **or higher**

The method sheet for aPTT Screen has been updated to include information about *aPTT Screen Mod*.

Attachment

- Instructions for tightening the probe and configuring the reflex test (Attachment 1)
- Changes to Instructions for Use (Attachment 2)
- Method Sheet aPTT Screen

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

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Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com