Urgent Field Safety Notice

SBN-RDS-CoreLab-2023-003

RDS / CoreLab / Coagulation
Version 1
April 2023

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

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 this FSN we would like to inform you about a recently identified issue on **cobas** t 511 and **cobas** t 711 coagulation analyzers.
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 carry over occurs when the coupling-nut is not tightened sufficiently. In this case aPTT Screen, aPTT Lupus and aPTT can be affected by carryover. Residual carry over 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.

Due to the associated safety risk, customers must be informed using the FSN-RDS-CoreLab-2023-003.

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Actions taken by Roche Diagnostics

Immediate workarounds are available to address both carryover scenarios:

1. Instructions for the customer how to sufficiently tighten the heated reagent probe. These will be added to the user assistance and maintenance workflows.
2. To mitigate the carryover risk in samples with prolonged clotting times, a reflex rule was set up to repeat the aPTT Screen orders with results above 50 sec. For this, with this FSN, *aPTT Screen Mod* assay will be implemented on **cobas** t 511 and **cobas** t 711 coagulation analyzer
3. Updated method sheet for aPTT Screen will include information regarding *aPTT Screen Mod* and is planned to be available in Q3 2023.

Actions to be taken by customers/users

- Customers are requested to check if the heated reagent probe is tight and to tighten it, as described in the attached instruction (attachment 1).
- In addition, to detect any residual carryover, which can affect samples with prolonged aPTT Screen clotting times, customers are requested to implement a reflex test and additional wash rules. For details, see attached instructions (attachment 1).

Please note, the following documents and e-barcodes are required for the measures to be taken. They will be released upon the publication of this FSN:

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

The method sheet for aPTT Screen will be updated to include information about *aPTT Screen Mod*. This is planned to be available in Q3 2023.

Attachment

- Instructions for tightening the probe and configuring the reflex test (Attachment 1)

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

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>,

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

Contact Details

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