Urgent Field Safety Notice

SBN-RDS-CoreLab-2021-001

RDS/Core Lab / Coagulation
Version1
February 2021

cobas t 511/t 711: Streptokinase Interference with Anti-Xa assay

Product Name	Anti-Xa
System	**cobas t** 511 / **cobas t** 711
GMMI / Part No **Device Identifier**	Anti-Xa (**cobas t** 511 / **cobas t** 711) 08083576190
Production Identifier (Product name/Product code)	Lot independent
SW Version	n/a
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

Description of Situation

During internal verification studies, an interference by streptokinase was detected for the assay Anti-Xa on **cobas t** 511/ **t** 711. This interference was not observed during application work and therefore is not currently described in the method sheet under section Limitations-interference.

Allowed deviation of sample with 300'000 U/L streptokinase against sample without streptokinase according to the product specification Anti-Xa:

≤ 0.45 IU/mL: ≤ 0.045 IU/mL

> 0.45 IU/mL: ≤10%

During internal studies, a deviation of max. + 18% was observed for unfractionated heparin (UFH) samples with 300'000 U/L streptokinase. The measurements for low molecular weight heparin (LMWH) samples were within specification.

No related customer complaints were received.

The analysis of the additional plasminogen activators urokinase and alteplase did not show any interference,

Due to the residual medical risk related to the issue, customers must be informed via FSN-RDS-CoreLab-2021-001.

Actions to be taken by Roche Diagnostics

The respective disclaimer will be added in the method sheet

"The presence of dabigatran, streptokinase, danaparoid sodium, or factor Xa inhibitors such as apixaban, edoxaban, rivaroxaban and fondaparinux in the sample influences the assay results."

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It is planned to have the updated method sheet by the end of April 2021.

Actions to be taken by the customer/user

Customers are advised to consider the updated claim for streptokinase interference. Please make sure to refer to the latest version of the method sheet (V 2.0) as soon as it becomes available.

Note:

In this case, no general recommendations with respect to the review of previous results are given, taking into account that the issue occurs only under special circumstances. Any specific questions raised by the users should be addressed individually, considering all relevant clinical information.

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization where the devices have been distributed/supplied (if appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

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>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com