Urgent Field Safety Notice

SBN-CPS-2019-010

CPS / Coagulation

Version 3

Nov-2020

cobas t 511/ t 711: Lifted cuvettes

Product Name	**cobas t 511 coagulation analyzer** **cobas t 711 coagulation analyzer** Cuvette **COBAS INTEGRA®**
System	**cobas t 511/ t 711**
GMMI / Part No **Device Identifier**	06356460001 06355790001 21043862001
Production Identifier (Product name/Product code)	**cobas t 511 and t 711 coagulation analyzer, selected serial numbers**
SW Version	All
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

We are happy to inform you that the issue regarding elevated cuvettes on **cobas t** 511 and **cobas t** 711 coagulation analyzers is now resolved.

Description of Situation

This Field Safety Notice (FSN) is relevant for all **cobas t** 511 coagulation analyzers with serial numbers (SN) below 5000 and **cobas t** 711 coagulation analyzers with serial numbers (SN) below 1500.

We are happy to inform you with version 3 of this notice that the issue is now resolved. The design of the incubator block was adapted to exclude tolerance chain overlap between the incubator block cavity and the cuvette. This was introduced to the series production from SN 5000 (**cobas t** 511 coagulation analyzer) and SN 1500 (**cobas t** 711 coagulation analyzer). For all previously released instruments affected by the issue, a mandatory modification has to be implemented.

History- description of issue:

In version 1 of this FSN we informed that the affected lots of cuvettes (Cuvette **COBAS INTEGRA®**) may be slightly elevated in the incubator block of the **cobas t** 711 and **cobas t** 511 coagulation analyzer.

This is due to the dimensions of the cuvette versus the size of the incubator block hole.

With version 2 of this FSN we informed that additional affected cuvette lots were identified as not suitable for use on **cobas t** 511/ 711 coagulation analyzers.

As described in the previous FSN versions, the cuvettes were not seated properly and remained slightly elevated in the incubator block during measurement, potentially resulting in unjustified Clot.E or NoClot Flags.

Furthermore, we described that the occurrence of lifted cuvettes may directly influence results for HIL, AT, D-Dimer, Derived Fibrinogen, Anti-Xa and Free Protein S tests.

The impact of this could differ depending on where it occurred, either the cuvette blank position or a measurement position.

The following scenarios were possible:

Unjustified NoClot or Clot.E Flag

Results that under normal conditions yield an unflagged result may become flagged with NoClot or Clot.E.
The clotting curve should be checked in order to determine if a cuvette was lifted.
This can be detected if the curve starts in the negative absorbance area (see example below).

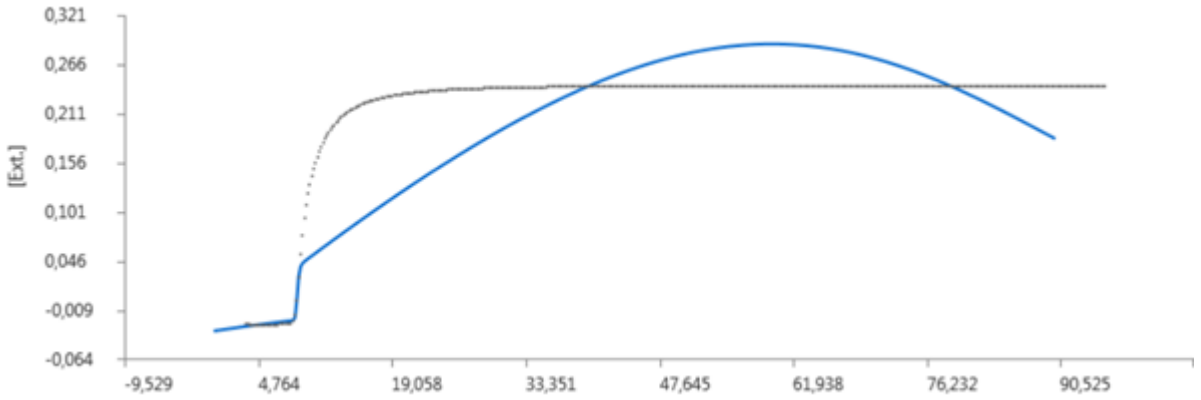

Figure 1: Example of negative absorbance area

Whether the sample is flagged as Clot.E or a NoClot depends on the individual sample and cannot be generally stated.
The following assays can be affected in this case:

- aPTT, aPTT Screen, aPTT Lupus
- PT Rec (applications A, B, C)
- Fibrinogen
- TT

Direct result Influence

A direct result influence on the following assays is possible, deviations of more than 30% might occur:

- AT
- D-Dimer
- Derived Fibrinogen
- Anti-Xa
- Free Protein S

The result influence can impact patient results, QC as well as calibration measurements.
In the latter case, replicate deviations are observed (Dup.E).

Influence on flags >I.H >I.I >I.L

The issue can lead either to a missing flag or to a wrongly flagged result.
*Note: Cuvette **COBAS INTEGRA®** is also used on **COBAS INTEGRA®** systems. **COBAS INTEGRA®** is not affected by this issue.*

Due to the residual medical risk associated with this issue, customers using the affected product were informed using the FSN-CPS-2019-010 versions 1 and 2. The issue is now resolved and the customers must be informed regarding necessary actions using the FSN-CPS-2019-010 version 3.

Actions taken by Roche Diagnostics

Production of new cuvettes
Only a small number of molding tools for cuvette production are affected. These have been identified and affected molding tools have been blocked for production.

The design of the incubator block was adapted to exclude tolerance chain overlap between the incubator block cavity and the cuvette. This was introduced to the series production from SN 5000 (**cobas t** 511 coagulation analyzer) and SN 1500 (**cobas t** 711 coagulation analyzer).

Instruments which were already distributed / installed at customers site:
Roche started the implementation process of the modification spare part in the field and will contact the affected customers to plan the instrument adaptation.

Actions to be taken by the customer/user

The following action was communicated in version 2 of this FSN. Since the end of July 2020 all delivered cuvettes can be used without restrictions on all systems.

The action below remains valid only to account for the possibility that customers may still have lots of stock that are not suitable for use with the **cobas t** 511/ **t** 711 coagulation analyzers.

From V2:

Please note: ***COBAS INTEGRA®*** *customers are not affected by this issue.*

Please do not use the affected lot numbers of cuvettes on the **cobas t** 511 and **cobas t** 711 coagulation analyzer.

There are three possible actions:

a. Use unaffected lots on **cobas t** 511**/ t**711
b. Usage of affected lot numbers for a **COBAS INTEGRA®** installation.
c. Return the affected material to the affiliate if you have no **COBAS INTEGRA®** instrument

The lot number can be found on the label of the box, and also on each bag. Please compare your lots to the list of lot numbers provided as described in the FSN-CPS-2019-010 version 2.

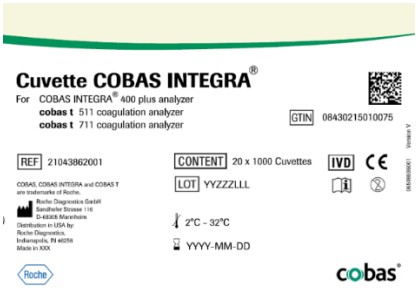

Figure 2 Box label

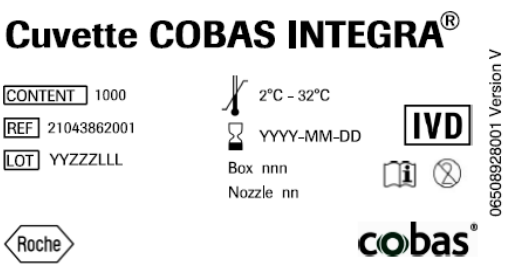

Figure 3: Bag label

Where stock of the Cuvette COBAS INTEGRA® is returned, replacement will be arranged by your local Roche representative.

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 caused 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