

Field Safety Notice

SBN-CPS-2019-010

CPS / Coagulation

Version 1

26-Jul-2019



cobas t 711: Lifted cuvettes

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| Product Name | cobas t 711 coagulation analyzer Cuvette COBAS INTEGRA® |
| System | cobas t 711 |
| GMMI / Part No | 06355790001 21043862001 |
| Device Identifier | |
| Production Identifier (Product name/Product code) | Affected are all t 711 coagulation analyzer serial numbers <i>Note: There may be other affected identifiers that are affected globally. Please contact the product owner if the device is obtained from an overseas dealer.</i> <div>No affected customers in Singapore</div> |
| SW Version | All |
| Type of Action | Field Safety Corrective Action |

Dear Valued Customer,

Roche Diagnostics regrets to inform you of reported cases affecting the **cobas t 711** coagulation analyzers.

Description of Situation

This FSN is relevant only for **cobas t 711** coagulation analyzers already installed at customer sites, or in case these analyzers will be installed prior to a corrective action being fully implemented.

The affected lots of cuvettes (Cuvette **COBAS INTEGRA®**) may be slightly elevated in the incubator block of the **cobas t 711** coagulation analyzer.

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

In the worst case, the cuvettes are not seated properly and remain slightly elevated in the incubator block during measurement.

This can result in unjustified Clot.E or NoClot Flags.

Furthermore, 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 will differ depending on where it occurred, either the cuvette blank position or a measurement position.

The following scenarios may be 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).

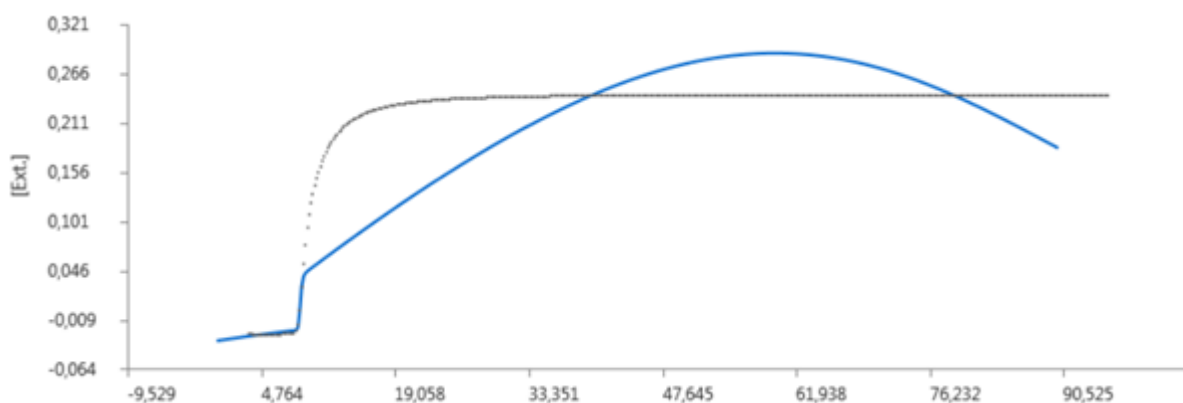


Figure 1: Example of negative absorbance area

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.

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Actions taken by Roche Diagnostics

Correction:

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. Please refer to the list attached for further details.

Stock material:

Affected cuvette lots have been blocked for countries with **cobas t 711** coagulation analyzer installations and are therefore no longer being delivered.

A process is in place to prevent deliveries of cuvettes not suitable for use on **cobas t 711** coagulation analyzer in case a country will commence installations of the **cobas t 711** coagulation analyzer.

Corrective Action:

Long term, adaption of the design to align the tolerances between cuvette and incubator block is planned.

Actions to be taken by the customer/user

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

There are two possible actions:

- Use unaffected lots on **cobas t711**
- Return the affected material to the affiliate

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 (attached to this FSN).

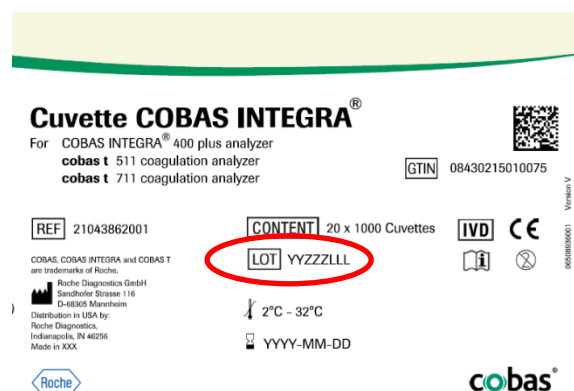


Figure 2: Label on box

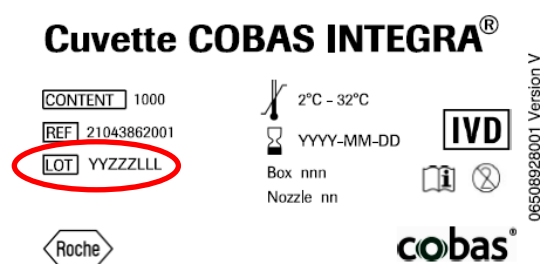


Figure 3: Bag Label

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

Communication of this Field Safety Notice

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

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.

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

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

Email: sg.regulatory@roche.com