Urgent Field Safety Notice
SBN-CPS-2017-014

CPS / Clin Chem fully automated
Version 1
20-July-2017

cobas c 501/c 502: TPLA2 sample carry-over

Product Name	**cobas c** 501 **cobas c** 502 TPLA2 RPR2
Product Description	**cobas c** 501 module **cobas c** 502 module
GMMI / Part No **Device Identifier**	GMMI 04745914001 (**cobas c** 501) GMMI 05964067001 (**cobas c** 502) GMMI 07404182190 (TPLA2) GMMI 07404174190 (RPR2)
Production Identifier (Lot No./Serial No.)	N/A
SW Version	All
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

It has come to our attention that on the **cobas c** 501 or **c** 502 analyzers TPLA samples with high titers of anti-treponemal antibodies can lead to carry over when measured with TPLA2 (Mediace TPLA Gen.2; GMMI 07404182190). This may lead to false reactivity in samples measured for TPLA immediately after the high-titer sample.

In general, diagnosis of syphilis requires confirmation with another serological test. However, in this case, it cannot be excluded that the sample contamination due to carry-over of positive material can also affect other syphilis tests.

The contamination was confirmed by the following experiments:
- Analyzing two negative patient samples immediately after a high-titre TPLA sample
- Performing the same experiment at a different site on a **cobas c** 502

In order to avoid unnecessary testing of initially reactive samples due to carry over, we have implemented an additional wash cycle prior to TPLA2 measurements on **cobas c** 501/**c** 502 analyzers. This wash cycle eliminates the risk of carry over and does not negatively impact TPLA titers of subsequent samples.

Internal data showed that no sample carry over is detectable for samples within the stated measuring range (4.6-250 T.U.)

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Affected systems are **cobas c** 501/502. Other systems are not concerned. The test is measured on these two modules only.

Customer data showed that after implementation of a special wash of the sample probe with D1 (SmpCln1), contamination after processing high-titre TPLA samples can be prevented.

No sample carry over has been reported from RPR samples to date. Internal data showed that no sample carry over is detectable for samples within the stated measuring range (0.5 - 8.0 R.U.)

Nevertheless, preventative implementation of sample probe carry over evasion for RPR2 is now also mandatory. This wash cycle eliminates the risk of carry over and does not negatively impact RPR titers of subsequent samples (as shown by internal analysis).

Actions taken by Roche Diagnostics

An additional wash cycle with D1 (SmpCln1) has been included prior to sample pipetting for TPLA2 and RPR2. Internal evaluations showed that this eliminates the risk of carry over and has no impact on the TPLA/RPR titer measurement in subsequent samples.

An updated Roche/Hitachi carry-over evasion list and updated *Special Wash Requirements* for TPLA2 and RPR2 on **cobas c** 501/502 will be published in Q4/2017.

The corresponding sample probe carry-over evasion (=SCE) file for **cobas c** 502 for TPLA2 and RPR2 can also be downloaded via the updated SCE file once available (expected in the course of Q4/2017).

Actions to be taken by the customer/user

Implementations of a sample probe wash with Detergent 1 (SampCln1).

The sample probe carry-over evasion for TPLA2 and RPR2 need to be defined manually as follows:

3. Sample probe carry-over on **cobas c** 501 analyzer

Reagent [Applications]	Detergent Type
TPLA2 [507*]	SampCln1
RPR2 [453*]	SampCln1

3. Sample probe carry-over on **cobas c** 502 analyzer

Reagent [Applications]	Detergent Type
TPLA2 [8507*]	SampCln1
RPR2 [8453*]	SampCln1

On **cobas c** 502, the corresponding sample probe carry-over evasion (=SCE) for TPLA2 and RPR2 can also be downloaded via the updated SCE file once available (expected in Q4/2017) including the information about the corresponding updated e-library packages.

In case you suspect discrepant reactive results due to carry-over or have specific questions, re-testing might be advisable in concordance with 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 or to any organization/individual where the potentially affected devices have been distributed/supplied. *(If appropriate).*

Please transfer this notice to other organizations/individuals on which this action has an impact. *(If appropriate).*

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

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.

Kind regards,

Contact Details

To be completed locally:
Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com

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