

# Field Safety Notice

## SBN-CPS-2017-014

CPS / Clin Chem fully automated

Version 1

31-July-2017

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

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

Dear Valued Customer,

#### Description of Situation

It has come to our attention that on the **cobas c 501** or **c 502** analyzers TPLA samples with high titres 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-titre 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**

## cobas c 501/c 502: TPLA Gen.2 sample carry-over

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 has no impact on the TPLA titres 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.)

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 has no impact on the RPR titres 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 titre 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

## **cobas c 501/c 502: TPLA Gen.2 sample carry-over**

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**

This notice must be passed on to all those who need to be aware within your organization or to any other organization/individual where the potentially affected devices have been distributed/supplied. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA. 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

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