

# Urgent Field Safety Notice

## SBN-CPS-2016-009

CPS / ClinChem fully automated  
Version 2  
23-May-2016

### Increased recovery of patient results with ONLINE TDM Gentamicin assay

<b>Product Name</b>	Gentamicin
<b>Product Description</b>	ONLINE TDM Gentamicin 100 Tests c 311, c 501/502 ONLINE TDM Gentamicin 100 Tests c 701/702 ONLINE TDM Gentamicin Mod P
<b>GMMI / Part No Device Identifier</b>	04490843190 ONLINE TDM Gentamicin 100 Tests c 311, c 501/502 05841291190 ONLINE TDM Gentamicin 100 Tests c 701/702 03800504190 ONLINE TDM Gentamicin Mod P
<b>Production Identifier (Lot No./Serial No.)</b>	<b>ONLINE TDM Gentamicin 100 Tests c 311, c 501/502</b> Lots 119166, 611780, 617623 <b>ONLINE TDM Gentamicin 100 Tests c 701/702</b> Lots 119167, 611783, 617624 <b>ONLINE TDM Gentamicin Mod P</b> Lots 119161, 611779
<b>SW Version</b>	Not applicable
<b>Type of Action</b>	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

#### Description of Situation

Investigations have confirmed an increase in native patient sample result recovery of approximately 15-20 % when using ONLINE TDM Gentamicin with recent Preciset TDM I lots 615118, 619681, 126387, 140735. TDM controls and EQA (External Quality Assessment) samples also show an increased recovery of approximately 15%. A combination with TDM control set lot 125783 does not show this effect.

These observations were confirmed for the ONLINE TDM Gentamicin reagent kits for use on **cobas c** and **MODULAR ANALYTICS** <P> comparing recovery with previous vs. recent Preciset TDM I lots but also compared to Gentamicin on COBAS INTEGRA (GENTM). The issue is most likely related to the Preciset TDM I calibrator. Based upon internal data the ONLINE TDM Gentamicin reagent is showing an increased recovery. In

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contrast to these observations, test results obtained by the Roche Gentamicin COBAS INTEGRA assay (GENTM) are not impacted. As a consequence and precautionary measure you must stop using ONLINE TDM Gentamicin reagent until further notice.

False high results of levels of gentamicin may lead to incorrect dosage reduction of drug. Too low dosage may result in the worst case subsequently in sub-therapeutic serum levels of gentamicin. Gentamicin is also used for treatment of contagious infections (e.g. Plague) therefore too low serum levels of drug may also lead to spread of infections. A medical risk for patients cannot entirely be excluded.

## Actions taken by Roche Diagnostics

The current Reagent/Calibrator combinations available do not meet specifications anymore. As a consequence we have decided **to stop temporarily further distribution** of the ONLINE TDM Gentamicin assay (GENT2) used on **MODULAR ANALYTICS <P>**, **cobas c 311** analyzer, **cobas c 501/502** and **c 701/702** modules for the time being. A timeline for a re-start of distribution once the product can be used again in a valid Reagent/Calibrator/Control combination will be communicated as soon as possible, current estimation is end of June 2016.

## Actions to be taken by the customer/user

### *ONLINE TDM Gentamicin (GENT2)*

As a consequence and precautionary measure you must stop using ONLINE TDM Gentamicin reagent until further notice.

Any kits of ONLINE TDM Gentamicin in inventory may be kept until further notice. There is no need to discard the products which are still in shelf life for the time being.

We will provide a solution within a short time period (4-6 weeks) allowing customers to continue using the Roche ONLINE TDM Gentamicin assay with the Preciset TDM I calibrator. We will inform you accordingly.

### *Preciset TDM I*

The Preciset TDM I calibrator can be continued to be used for all other TDM assays on **cobas c** and **MODULAR ANALYTICS <P>** (except for GENT2) and also for all TDM (including GENTM) on COBAS INTEGRA. There is no need to discard the products which are still in shelf life for the time being.

## 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.

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

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**The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:**

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.

Best 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.