

National Authorities
EEA

Mannheim, 13. April 2007
Program on identification of carry-over effects on Roche Analyzers

Dear Sir/Madam,

After identification of carry-over effects of Albumin and HbA1c to IgG, Roche Diagnostics internally identified carry-over interference with Vancomycin and Valproic Acid on cobas 501 analyzer as well with the Tobramycin assay on Modular P analyzer.

Consequently, Roche Diagnostics has strengthen the activities in this field and started a systematic program to check the parameter menu on possible further interferences. This may lead to identification of further carry-over interference issues which are presently unknown.

To avoid confusion, separate reports will be generated for each detected carry-over for each analyzer type. Attached please find initial reports for carry-over interference for Vancomycin, Valproic Acid and Tobramycin.

Roche Diagnostics GmbH
i. V. i.V.

 



Field Safety Notice

Notice Ref No:	< reference number >
Document Date:	05 April 2007

PRODUCT AFFECTED: ONLINE TDM Tobramycin

SYSTEM AFFECTED: MODULAR ANALYTICS <P>

MATERIAL NUMBERS: Cat. No. 04642511 190 and 04642503 190

LOT NO (IF APPLICABLE): All lots

SUMMARY OF ISSUE: Special wash requirements MODULAR ANALYTICS <P> for ONLINE TDM Tobramycin.

ACTION REQUIRED: Implementation of an extra wash cycle

CONTACTS: Technical Services:
Country:

Reason for bulletin:

Special wash requirements on MODULAR ANALYTICS <P> for ONLINE TDM Tobramycin due to carry-over from multiple ONLINE TDM and ONLINE DAT reagents to the ONLINE Tobramycin assay

Dear Customer

We would like to inform you that internal investigations revealed that multiple ONLINE TDM and ONLINE DAT reagents have been identified which may cause R1/R2 reagent probe carry-over to the ONLINE Tobramycin assay on the **MODULAR ANALYTICS <P>** system to different extent. The observed carry-over could result in an increased Tobramycin recovery of up to 113% for single assays. The following assays have been identified to possibly cause reagent carry-over to the ONLINE Tobramycin assay:

- ONLINE TDM Carbamazepine
- ONLINE TDM Gentamicin
- ONLINE TDM Phenytoin
- ONLINE DAT Cocaine II
- ONLINE DAT Methadone II
- ONLINE DAT Opiates II

- ONLINE DAT THC II

These carry-over effects can successfully be prevented by the implementation of a special wash step with NaOH-D.

Therefore, the following special wash steps have to be implemented when you are running the ONLINE Tobramycin assay on your **MODULAR ANALYTICS** <P> analyzer together with one of the above listed assays:

1. R1 reagent probe wash evasion is recommended with the following programming:

Probe	From Reagent		To Reagent		Detergent	
	Test	Type	Test	Type	Type	Volume
R1	All Item	R1	Tobramycin	R1	D1	200 µL

2. R2 reagent probe wash evasion is recommended with the following programming:

Probe	From Reagent		To Reagent		Detergent	
	Test	Type	Test	Type	Type	Volume
R2	Opiates	R2	Tobramycin	R2	D1	170 µL

The Carry-over Evasion List will be updated accordingly.

Action required:

Programming of reagent special reagent probe washes as described above.

The definition and configuration of special washes is described in detail in the **MODULAR ANALYTICS SWA Software-Description** chapter 25: Utility menu – Special Wash screen.

For your convenience we have attached the respective instructions of the Software-Description to this Field Safety Notice.

We apologize for any inconvenience this problem may cause you.

Kind regards,