

Urgent Field Safety Notice

SBN-RDS -CoreLab-2021-009

RDS/CoreLab /Urinalysis
Version 1

cobas u pack (INT): Updated Urine Interference Claims

Product Name	cobas u pack - International market only
GMMI / Part No	06334601-001 cobas u pack International market only 07137940001 Instruction for Use (cobas u pack - International)
Production Identifier (Lot No./Serial No.)	all lots
SW Version	n/a
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

The interference testing of selected drugs and endogenous substances in urine was performed during IVDR readiness activities. The newly collected data for **cobas u pack** on **cobas u 601** urine analyzer deviated in some cases from the initially obtained data claimed in the current **cobas u pack** Instruction for Use (Material Nr. 07137940001 V2.0) for the international market. Therefore, the respective interference claims must be updated. Due to the residual medical risk associated with certain interferent/parameter combinations, customers must be informed using the FSN-RDS-CoreLab-2021-009.

Actions to be taken by Roche

Interference claims will be changed and respective Instructions for Use will be updated. The changed claims are applicable for all current and upcoming lots. Updated Instructions for Use (Material Nr.07137940001 V3) are expected to be available in July 2021.

Instructions for Use will be updated as follows:

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Section, Limitations - interference

		Old IFU (07137940001 V2.0)		New IFU (07137940001 V3.0)	
Therapeutic drug	Test Strip Parameter affected	No interference up to	Effect above stated concentration	No interference up to	Effect above stated concentration
Ascorbic Acid	GLU	400 mg/L	false normal results	250 mg/L	false normal results
Ibuprofen	ERY	800 mg/L	false negative results	750 mg/L	false negative results
Salicylic Acid	ERY	n.a.	n.a.	2400 mg/L	false negative results

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		Old IFU (07137940001 V2.0)		New IFU (07137940001 V3.0)	
Endogenous Substance	Test Strip Parameter affected	No interference up to	Effect above stated concentration	No interference up to	Effect above stated concentration
Glucose	LEU	n.a.	n.a.	10000 mg/L	false negative results
Uric Acid	ERY	n.a.	n.a.	800 mg/L	false negative results
Urobilinogen	NIT	120 mg/L	false positive results	90 mg/L	false positive and false negative results
Creatinine	NIT	n.a.	n.a.	9000 mg/L	false negative results

Actions to be taken by the customers

Customers are advised to consider the updated interference claims. Please make sure to refer to the latest version of the Instruction for Use (Material Nr. 07137940001, V3) as soon as it becomes available.

Note:

In this case, no general recommendations with respect to the review of previous results are given, taking into account that the issue occurs only under special circumstances. Any specific questions raised by the users should be addressed individually, considering all relevant clinical information.

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Communication of this Field Safety Notice (if appropriate)

<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:

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).

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.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com