Urgent Field Safety Notice
SBN-RPD-2015-015

RxD / Point of Care Reflotron
Version 2
10-Dec-2015

Reflotron: Modified hematocrit value limit for UA when measuring samples from whole blood

Product Name	Reflotron Uric Acid, Reflotron PST Uric Acid, and Reflotron Uric Acid II
Product Description	Reflotron Uric Acid test
GMMI / Part No Device Identifier	10745103202, 10745103203, 04771443050, 11449192174
Production Identifier (Lot No./Serial No.)	N/A
SW Version	N/A
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We would like to inform you that as a final solution Roche Diagnostics has decided that the hematocrit value limit has to be reduced to a maximum of 48% for the products Reflotron Uric Acid, Reflotron PST Uric Acid and Reflotron Uric Acid II, when measuring patient samples from whole blood.

The modified method sheet for all mentioned affected products will be available from **LOT 135769** onwards.

Actions taken by Roche Diagnostics

As a result of Roche internal investigation concerning Reflotron Uric Acid, Reflotron PST Uric Acid and Reflotron Uric Acid II, it was decided to reduce the hematocrit value limit to a maximum of 48%, when measuring patient samples from whole blood.

The internal investigation detected deviations in Uric Acid results on Reflotron system, which can be above the internal specification of 5%, if the hematocrit values exceed 48%. This may lead to erroneously low Uric Acid results in blood samples with hematocrit values higher than 48%. Currently the hematocrit values are up to 55% for Reflotron Uric Acid, Reflotron PST Uric Acid, and Reflotron Uric Acid II.

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False low uric acid results might lead to delayed diagnosis and treatment of underlying disease (gout, inborn defect in purine metabolisms, etc.), especially in case of absence of other symptoms. Although erroneous Uric Acid results are unlikely to lead to an immediate serious adverse event, high frequency of occurrence of the issue, as well as high probability of occurrence (hematocrit higher than 48%) and difficult detectability contribute to the potential risk and should be taken into account. Therefore, a medical risk due to erroneous low Uric Acid results in samples with hematocrit above 48% cannot be excluded.

Actions to be taken by the customer/user

Please note that the hematocrit value limit has been reduced to a maximum of 48 %. Please take this into account when measuring patient samples from whole blood.

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 organization/individual where the potentially affected tests have been distributed/supplied.

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