Field Safety Notice

SBN-RPD-2015-015

RxD / Point of Care Reflotron
Version 1
06-Jul-2015

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

Product Name	Reflotron Uric Acid
Product Description	Reflotron Uric Acid test
GMMI / Part No Device Identifier	10745103202
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

We would like to inform you that Roche Diagnostics has decided to reduce the hematocrit value limit to a maximum of 48% for the products Reflotron Uric Acid when measuring patient samples from whole blood.

Description of Situation

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.

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.

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Actions taken by Roche Diagnostics

For the affected products an separate *Important Note* sheet is added to the package/box of Reflotron Uric Acid showing the following text:

> 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.

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.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

We sincerely apologize for any inconvenience caused by this issue and hope for your understanding and support.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd
Email: sg.regulatory@roche.com

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ACKNOWLEDGMENT RECEIPT

This is to acknowledge the receipt of Roche Safety Board Advisory Notice: SBN-RPD-2015-015, dated 6-Jul-2015, regarding modified hematocrit value limit for Reflotron Uric Acid when measuring samples from whole blood.

Received by:

_____

Name & Signature

_____

Hospital & Stamp

_____

Date

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