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Urgent: Field Safety Notice FSCA 01-19

Product: B·R·A·H·M·S uE3 KRYPTOR
FSCA-ID: FSCA 01-19
Topic: Underestimation of uE3 concentration in patient samples

Hennigsdorf, 05 February 2019
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Dear Customer,

Details on affected device:

Product:	B·R·A·H·M·S uE3 KRYPTOR
Kit Reference No.:	803.075
Lot-No./ Expiry date:	03111 / 2019-07-24

Description of the problem:

We have to inform you that we have become aware about an underestimation of approximately 30% of uE3 concentration in patient samples when using B·R·A·H·M·S uE3 KRYPTOR kit lot 03111. This effect was confirmed by our internal testing.

This underestimation may lead to incorrect risk assessment for fetal chromosomal abnormalities. A patient may be considered at higher risk for fetal trisomy 21 and consequently additional or different treatment/investigation decisions need to be considered by the physician.

The impact of an incorrect risk assessment is mitigated by the fact that uE3 measurement is not interpreted by its own but only in conjunction with other laboratory and clinical findings as advised by labeling.

Advice on actions to be taken by the user:

1. Please stop using the affected lot 03111 of B·R·A·H·M·S uE3 KRYPTOR.
2. Please check your inventory for B·R·A·H·M·S uE3 KRYPTOR lot 03111.
3. We will substitute the affected lot B·R·A·H·M·S uE3 KRYPTOR lot 03111 with a new lot with no additional cost for you. Please contact your local Thermo Fisher Scientific sales office or approved distributor in your region.
4. Please discard any B·R·A·H·M·S uE3 KRYPTOR lot 03111 immediately, following the respective local regulations and guidelines.
5. B·R·A·H·M·S recommends a re-evaluation of the results that have been already generated with B·R·A·H·M·S uE3 KRYPTOR lot 03111.
6. Please check medians with the new lot in case medians have been adjusted with B·R·A·H·M·S uE3 KRYPTOR lot 03111.

Newly produced B·R·A·H·M·S uE3 KRYPTOR kits (lot 03112) will be available in calendar week 08/2019.

Please forward this notice to those who need to be aware within your organization or to any organization to whom the potentially affected devices have been transferred.

Please verify your receipt of this notification by completing the attached vigilance response form and return it to us by fax [+49 \(0\)3302 883 819](tel:+49(0)3302883819) or by e-mail to eu-vigilance@thermofisher.com **within five days** upon receipt.

Any technical questions you may have should be addressed to:

International KRYPTOR Hotline Tel +33 466 365246
Email: FRNIMproductsupport@thermofisher.com

Any regulatory questions you may have should be addressed to:

B·R·A·H·M·S GmbH
Dr. Bernhard Ciommer
Director Global Regulatory Affairs and
Quality Assurance Compliance
Neuendorfstrasse 25
D-16761 Hennigsdorf/Germany

Tel: +49 (0)3302 883 752
Fax: +49 (0)3302 883 819
E-mail: bernhard.ciommer@thermofisher.com

For any other questions, please contact:

Customer Service: +49 (0)3302 883 300
Email: service.brahms@thermofisher.com

The signature confirms that this Field Safety Notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction. We are currently in the process of identifying the root cause and will implement corrective actions according to the identified root cause.

Sincerely
B·R·A·H·M·S GmbH



Dr. Bernhard Ciommer
Director Global Regulatory Affairs and Quality Assurance Compliance

>Company<
>Department<
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VIGILANCE RESPONSE FORM – FSCA 01-19

Please tick as appropriate:

I confirm that I have received the information on

Product:	B·R·A·H·M·S uE3 KRYPTOR
Kit Reference No.:	803.075
Lot-No./ Expiry date:	03111 / 2019-07-24

I understand the advice on actions to be taken as mentioned in this Field Safety Notice.

We currently have kits of B·R·A·H·M·S uE3 KRYPTOR lot 03111 on stock.

Residual stock of B·R·A·H·M·S uE3 KRYPTOR lot 03111 will be disposed by ourselves.

Signature and date:

Please return this form by fax [+49 \(0\)3302 883 819](tel:+493302883819) or by e-mail to eu-vigilance@thermofisher.com
within five days.