

B·R·A·H·M·S GmbH
Neuendorfstr. 25 · 16761 Hennigsdorf/Germany

URGENT - Field Safety Notice

Company

Contact partner

address

PLZ

Country

B·R·A·H·M·S GmbH

Neuendorfstraße 25

16761 Hennigsdorf

+49 (0) 3302 883 300

Fax +49 (0) 3302 883 388

Hennigsdorf, 03th February 2020

Urgent: Field Safety Notice FSCA 01-2020

Product: B·R·A·H·M·S uE3 KRYPTOR
FSCA-ID: FSCA 01-2020
Topic: Potential for incorrect measurement of uE3 concentration in patient samples in case quality controls are not measured as recommended

Dear Customer,

Please read the following information carefully.

Details on affected device:

| Product | B·R·A·H·M·S uE3 KRYPTOR |
|----------------------|--|
| Kit Reference No. | 803.075 |
| Lot-No./ Expiry Date | 03114A / 2020-02-02 03114B / 2020-02-02 03118A / 2020-06-10 03119A / 2020-06-10 03120A / 2020-09-09 03120B / 2020-09-09 |

Description of the problem:

We have to inform you about a possible under- or overestimation of uE3 concentration in patient samples when using B·R·A·H·M·S uE3 KRYPTOR kit lots 03114A, 03114B, 03118A, 03119A and 03120A, 03120B. This was confirmed by our internal testing. In case B·R·A·H·M·S uE3 KRYPTOR QC is NOT run once a day prior to patient sample measurements as recommended in the instructions for

use (IFU) and Good Laboratory Practice you will not be able to recognize the possible over- or underestimation observed with the above mentioned lots..

Depending on whether the kit was freshly opened or not and calibration was performed with freshly opened or on-board stored kit, the uE3 concentration in the patient sample can either be under- or overestimated. Both, an under- or overestimation may lead to an incorrect risk assessment for fetal chromosomal abnormalities.

If the uE3 concentration is underestimated 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. If the uE3 concentration is overestimated a potentially fetal trisomy 21 might not be detected via the screening.

In both cases, the impact of an incorrect risk assessment is mitigated by the fact that uE3 measurement is not interpreted by its own but in conjunction with other laboratory and clinical findings as described in the IFU.

Advice on actions to be taken by the user:

1. You may still use B·R·A·H·M·S uE3 KRYPTOR lots 03114A, 03114B, 03118A, 03119A, 03120A, 03120B however it is mandatory to run a quality control once a day prior to patient sample measurements. In case patient samples measurements are not run daily, a quality control must be performed on the day prior to the patient sample measurement.
2. If you detect an out of specification quality control result you need to re-calibrate the assay and confirm a valid quality control result before analyzing a patient sample.
3. In addition, as described in the IFU, you must perform a new calibration with every new reagent kit lot.
4. B·R·A·H·M·S recommends a re-evaluation of the results that have already been generated with the above mentioned lots of B·R·A·H·M·S uE3 KRYPTOR if a quality control was NOT run on a daily basis or at least on the day prior to patient sample measurements.

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:+4903302883819) 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

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

We apologize for any inconvenience this may cause you 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 accordingly.

Sincerely

B·R·A·H·M·S GmbH



ppa Dr. Bernhard Ciommer

Director Global Regulatory Affairs and Quality Assurance Compliance

B·R·A·H·M·S GmbH • Neuendorfstraße 25 • D-16761 Hennigsdorf
URGENT - Field Safety Notice

>Company<
>Department<
>Contact<
>Street<
>Zip Code Town<
>COUNTRY<

VIGILANCE RESPONSE FORM – FSCA 01-2020

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 | 03114A / 2020-02-02 |
| | 03114B / 2020-02-02 |
| | 03118A / 2020-06-10 |
| | 03119A / 2020-06-10 |
| | 03120A / 2020-09-09 |
| | 03120B / 2020-09-09 |

I have read and understood the advice on actions to be taken as mentioned in this Field Safety Notice and have implemented daily QC tests for the listed lots prior to patient sample measurements. In case patient samples measurements are not run daily, I confirm that a quality control is performed on the day prior to the routine measurement

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.**