

URGENT – Field Safety Notice
Company
Contact
Department
Street
Zip Code Town
Country

Hennigsdorf, June 18th, 2021

Urgent: Field Safety Notice FSCA 01-21

Product: B·R·A·H·M·S Solution 2 KRYPTOR GOLD

FSCA-ID: FSCA 01-21

Topic: On-board stability issue on B·R·A·H·M·S KRYPTOR GOLD instrument

Dear Customer,

We have recently informed you about the Field Safety Corrective Action on BRAHMS Solution 2 KRYPTOR GOLD. Please note that lot number 388902 is also affected. Please refer to the table below for all affected lots.

Please read the following information carefully.

Details on affected device:

Product	B·R·A·H·M·S Solution 2 KRYPTOR GOLD
Kit Reference No.	89992

Expiry Date / Lot-No.	2021-10-27 / 854203
	2022-03-23 / 942551
	2022-07-19 / 388902
	2022-07-19 / 988902
	2022-11-22 / 189328
	2023-01-10 / 230098
	2023-02-28 / 251292

Description of the problem:

We have to inform you about an on-board stability issue when using B·R·A·H·M·S Solution 2 KRYPTOR GOLD on B·R·A·H·M·S KRYPTOR GOLD instrument.

B·R·A·H·M·S Solution 2 KRYPTOR GOLD is a solution used for reagent kits reconstitution. For the lots listed above, the on-board stability will not meet our current claim of 29 days at 18 to 30 °C.

Internal testing has identified that reagent kits reconstituted with B·R·A·H·M·S Solution 2 KRYPTOR GOLD used within the claimed on-board stability can potentially lead to inaccurate under or overestimation of results. Unopened B·R·A·H·M·S Solution 2 KRYPTOR GOLD bottles stored at 2 to 8°C are not affected by this field safety notice.

We advise you to replace the opened bottle of B·R·A·H·M·S Solution 2 KRYPTOR GOLD after 7 days.

Note: B·R·A·H·M·S Solution 1 KRYPTOR GOLD is not affected by this field safety notice.

Impact of patient results:

Impact of potential erroneous patient results are mitigated by the fact that patient results should not be interpreted on its own but should be interpreted in conjunction with other laboratory and clinical findings as described in the respective Instructions for Use. Requirement for review of reported results should be determined by the appropriate technical expert.

Below is the list of reagent kits that need to be reconstituted with B·R·A·H·M·S Solution 2 KRYPTOR GOLD and hence, can be potentially affected by the described B·R·A·H·M·S Solution 2 KRYPTOR GOLD on-board stability issue:

Product	Kit Reference No.
B·R·A·H·M·S AFP KRYPTOR	816.075
B·R·A·H·M·S CYFRA 21-1 KRYPTOR	811.050
B·R·A·H·M·S NSE KRYPTOR	821.050
B·R·A·H·M·S anti-TPO α KRYPTOR	852.075
B·R·A·H·M·S anti-Tgn KRYPTOR	830.075
B·R·A·H·M·S PCT sensitive KRYPTOR	825.050
B·R·A·H·M·S CA125 II KRYPTOR	805.075
B·R·A·H·M·S CEA KRYPTOR	817.100
B·R·A·H·M·S CgA II KRYPTOR	839.050
B·R·A·H·M·S hCG+ β KRYPTOR	841.050
B·R·A·H·M·S uE3 KRYPTOR	803.075
B·R·A·H·M·S MR-proADM KRYPTOR	829.050

Advice on actions to be taken by the user:

1. Discard any **opened** bottle of B·R·A·H·M·S Solution 2 KRYPTOR GOLD, which is stored on-board of B·R·A·H·M·S KRYPTOR GOLD instrument over 7 days.
2. Discard any **opened** bottle(s) of B·R·A·H·M·S Solution 2 KRYPTOR GOLD, which are stored inside or outside the refrigerator.
3. After opening B·R·A·H·M·S Solution 2 KRYPTOR GOLD for the reconstitution of reagent kits, record the date opened. After 7 days discard and replace with a new **unopened bottle** that has been stored at 2 to 8°C.
4. B·R·A·H·M·S Solution 2 KRYPTOR GOLD unopened bottles stored at 2 to 8°C and being within the expiration date, can be used for reconstituting reagent kits following the above instructions.

Please order free of charge additional B·R·A·H·M·S Solution 2 KRYPTOR GOLD through your regular process.

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. Keep this notification on file.

Please verify the 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. Elli Neu
Director QA & Product Compliance

Neuendorfstrasse 25
D-16761 Hennigsdorf/Germany

Tel: +49 (0)3302 883 845
Fax: +49 (0)3302 883 819
E-mail: elli.neu@thermofisher.com

The signature confirms that this Field Safety Notice has been reported 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. Elli Neu

Director QA & Product Compliance

>Company<

>Department<

>Contact<

>Street<

>Zip Code Town<

>COUNTRY<

VIGILANCE RESPONSE FORM – FSCA 01-21

Please tick as appropriate:

☐ I confirm that I have received the information on

Product	B·R·A·H·M·S Solution 2 KRYPTOR GOLD
Kit Reference No.	89992
Expiry Date / Lot-No.	2021-10-27 / 854203 2022-03-23 / 942551 2022-07-19 / 388902 2022-07-19 / 988902 2022-11-22 / 189328 2023-01-10 / 230098 2023-02-28 / 251292

☐ I have read and understood the advice on actions to be taken as mentioned in this Field Safety Notice.

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.**