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March 31, 2026

URGENT: FIELD SAFETY NOTICE
(FSCA 01-26)

ACTION REQUIRED
Thermo Fisher Scientific B·R·A·H·M·S PlGF Plus KRYPTOR
when run on **B·R·A·H·M·S KRYPTOR compact PLUS** analyzer (only)

Dear Valued Customer,

The purpose of this letter is to advise you that B·R·A·H·M·S GmbH part of Thermo Fisher Scientific Inc., is conducting a Field Safety Corrective Action for the *in vitro* diagnostic product B·R·A·H·M·S PlGF Plus KRYPTOR test when run on the **B·R·A·H·M·S KRYPTOR compact PLUS** analyzer only, as listed below (Table 1). The test is used for the quantitative determination of the concentration of Placental Growth Factor (PlGF) in human serum and plasma. Our records indicate that you have purchased units of the affected product. Please read the following information carefully.

Table 1: List of affected Products (only when run on B·R·A·H·M·S KRYPTOR compact PLUS)

Product Description	Catalog Number	Lot Number	Expiration Date (YYYY-MM-DD)	UDI
B·R·A·H·M·S PlGF Plus KRYPTOR	859075N	59171	2026-11-23	(01)04260157632196(17)261123(10)59171A
B·R·A·H·M·S PlGF Plus KRYPTOR	859075N	59177	2026-11-23	(01)04260157632196(17)261123(10)59177A

REASON FOR FIELD SAFETY CORRECTIVE ACTION

Customers using the B·R·A·H·M·S KRYPTOR compact PLUS analyzer have observed quality control values out of range at the lowest quality control level (QC Level 1) for the B·R·A·H·M·S PlGF plus KRYPTOR test which required troubleshooting steps to resolve. No complaints of patient harm, serious injury, or death have been reported.

DESCRIPTION OF THE ISSUE

The B·R·A·H·M·S PlGF plus KRYPTOR test utilizes the B R A H M S PlGF plus QC kit containing three quality control levels (QC1, QC2, QC3) corresponding to three defined PlGF concentration ranges (30, 100, and 400 pg/mL).

B·R·A·H·M·S GmbH has received complaints reporting underestimation of **QC Level 1 (QC1)** when using certain B·R·A·H·M·S KRYPTOR compact PLUS analyzers. The underestimation may result in

QC1 values falling outside the established control range (±20% of target). This is not observed on the B·R·A·H·M·S KRYPTOR GOLD analyzer.

When Quality Control procedures are performed as instructed, out-of-range QC results are identified prior to patient result release. Per the Instructions for Use (HN-CUS-3543, Rev. 05.1_EN), laboratories should perform Quality Control testing and verify that results fall within ±20% of target values prior to reporting patient results.

If Quality Controls are not performed according to the Instructions for Use, the underestimation of QC1 may go undetected and could potentially contribute to erroneously low PlGF values.

INTENDED PURPOSE

The B·R·A·H·M·S PlGF plus KRYPTOR test is an automated immunofluorescent assay for the quantitative determination of the concentration of placental growth factor (PlGF) in human serum and plasma (EDTA).

The B·R·A·H·M·S PlGF plus KRYPTOR test is indicated as an aid to be used in conjunction with the clinical evaluation for non-invasive risk assessment of fetal trisomy 21 in first trimester in pregnant women.

The B·R·A·H·M·S PlGF plus KRYPTOR test is indicated as an aid to be used in conjunction with the clinical evaluation for non-invasive risk assessment for developing pre-eclampsia in first, second, and third trimester in pregnant women.

The B·R·A·H·M·S PlGF plus KRYPTOR test is indicated as an aid to be used in conjunction with the B·R·A·H·M·S sFlt-1 KRYPTOR test and the clinical evaluation for the diagnosis and/or short-term prognosis of pre-eclampsia in pregnant women with suspected pre-eclampsia.

RISK TO HEALTH / IMPACT ON PATIENT RESULTS

The B·R·A·H·M·S PlGF plus KRYPTOR test is not intended to be used as a stand-alone test. The results of this test should only be interpreted in conjunction with clinical signs, symptoms and other diagnostic measures.

Impact on Patient Results for fetal trisomy 21 (T21) indication:
Erroneously low PlGF values may result in a woman being assigned a higher risk of carrying a fetus with Trisomy 21 (T21). If this change does not shift her into a different risk group (low, intermediate, or high), her care will continue according to standard practice.

However, if erroneously low PlGF values cause her to be placed in a higher risk group (for example, from low to intermediate or intermediate to high), additional assessment for fetal T21 will be recommended by the clinician. Based on the overall risk assessment, analysis of fetal chromosomal DNA might be recommended either by non-invasive or invasive procedures.

Impact on Patient Results for risk assessment of developing pre-eclampsia:
Erroneously low PlGF values might lead to an intensified patient monitoring (of mother and fetus) and more-frequent maternal examination of blood pressure, measurement of urine protein concentration and eventually an increased number of blood examinations (e.g. platelet count liver enzymes). Based on the women's overall risk assessment prophylactic low dose aspirin treatment might be recommended and prescribed by the clinician in the first trimester screening.

Impact on Patient Results for aid in diagnosis and/or short-term prognosis of pre-eclampsia:
B·R·A·H·M·S PlGF plus KRYPTOR QC1 corresponds to PlGF concentrations observed in women at higher risk of progression to preeclampsia. Erroneously low PlGF values lead to an elevated sFlt-1/ PlGF ratio. An erroneously elevated sFlt-1/ PlGF ratio might lead to hospitalization for extensive examinations and surveillance (e.g. measurement of blood pressure, additional ultrasound scans and laboratory examination of blood and urine).

No patient injuries associated with this issue have been reported to date.

ACTIONS BEING TAKEN BY THE MANUFACTURER

B·R·A·H·M·S GmbH is investigating the root cause of the underestimation of the B·R·A·H·M·S PlGF plus KRYPTOR QC1 when using the **B·R·A·H·M·S KRYPTOR compact PLUS** analyzer with high urgency and will take necessary actions to prevent a recurrence of this issue. As soon as corrective measures have been taken by the manufacturer, we will notify you immediately.

ACTIONS TO BE TAKEN BY A USER

1. **Ensure to perform routine Quality Control testing** of the **B·R·A·H·M·S PlGF plus KRYPTOR** test (PN: 859075N, LN: 59171, 59177) on a daily basis before processing and analyzing patient samples.

2. If Quality Control results fall outside ±20% of target values, follow the troubleshooting procedures described in the B·R·A·H·M·S KRYPTOR compact PLUS User Manual or contact your local service and support organization.

3. If Quality Control results are within the acceptable range, the product may continue to be used as intended and there is no risk to patient results previously generated.

4. If routine **daily Quality Control testing** of the **B·R·A·H·M·S PlGF plus KRYPTOR** test (PN: 859075N; LN: 59171, 59177) was not performed before processing and analyzing patient samples, past results should be re-evaluated by a clinician, as appropriate.

5. Retain a copy of this letter for your laboratory records.

6. Please complete the response form attached to this FSN within 10 days of the date of this letter and return to Thermo Fisher as instructed in the form to: EU-Vigilance@thermo.com

Please forward this letter 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.

We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

For further questions, please contact your local support team.

Sincerely,
B·R·A·H·M·S GmbH

Dr. Elli Neu
Director Quality & Compliance
Specialty Diagnostics Group

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FSCA RESPONSE FORM
(FSCA 01-26)
Thermo Fisher Scientific B·R·A·H·M·S PIGF Plus KRYPTOR

☐ I confirm I have read, understood, and have taken action or determined no action is needed at our location according to the attached Field Safety Notice instructions.

☐ I understand that this FSN applies to the medical device listed in Table below.

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Do you have any knowledge of adverse medical events associated with the products listed in this Field Safety Notice?

☐ Yes ☐ No

If yes, please explain: _____

and contact: EU-Vigilance@thermo.com

PLEASE RETURN COMPLETED AND SIGNED FORM TO EMAIL WITHIN 10 DAYS UPON RECEIPT to EU-Vigilance@thermo.com

Name/Title:	
Date:	
Company/Institute:	
Phone:	
Email:	
Fax: (Optional)	
Signature:	

It is important that your organization takes action as detailed in this letter and also replies without delay by using this response form. Your reply is evidence, which Thermo Fisher Scientific and Regulatory Authorities need to monitor the progress.