

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

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

Urgent: Field Safety Notice FSCA 01-17

Product: B•R•A•H•M•S anti-Tg_n RIA
FSCA-ID: FSCA 01-17
Topic: Shift in the reference range of B•R•A•H•M•S anti-Tg_n RIA

Date: 15/May/2017

Dear Customer,

Details on affected device:

Product:	B•R•A•H•M•S anti-Tg_n RIA
Kit Reference No.:	27.1 / 27.5
Lot-No./ Expiry date:	127137 / 2017-05-04
	134428 / 2017-05-18
	141439 / 2017-06-01

Description of the problem:

Starting with B•R•A•H•M•S anti-Tg_n RIA lot 119854 we informed you about a shift in the reference range depending on the storage of the sample. During additional quality control testing we observed for B•R•A•H•M•S anti-Tg_n RIA lot 127137, lot 134428 and lot 141439 an additional shift in the reference range. This shift might lead to erroneously high anti-Tg test results.

The potential risk for the patient is mitigated by the fact that the IFU recommends, that every laboratory establishes its own reference ranges based on representative patient collectives and/or test the validity of the manufacturer's commercial test kit data. Additionally, anti-Tg test results must always be evaluated in the clinical context of the patient. Initiation or withdrawal of therapy is never based on an isolated anti-Tg result. Hence, in case elevated anti-Tg results do not fit the overall clinical picture of the case, further testing, such as for example other laboratory parameters (e.g. Tg; TPO-antibodies) or ultrasound should be ordered by the attending physician to come to a definite result.

To ensure your safety and satisfaction please follow the actions as described as follows:

Advice on actions to be taken by the user:

1. Please check your inventory for B·R·A·H·M·S anti-T_g_n RIA lot 127137, lot 134428 and lot 141439.
2. We will substitute the affected lot at no additional cost for you. Please contact your local Thermo Fisher Scientific sales office or approved distributor in your region.
3. Please discard your B·R·A·H·M·S anti-T_g_n RIA lot 127137, lot 134428 and lot 141439 following the respective local regulations and guidelines, as soon as you receive the replacement kits. A new B·R·A·H·M·S anti-T_g_n lot is available in our stock for replacement.

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:+493302883819) or by e-mail to eu-vigilance@thermofisher.com **within five days** upon receipt. Once we have received this form, we will immediately replace your affected kits.

Any technical questions you may have should be addressed to:

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

Any regulatory questions you may have should be addressed to:

B·R·A·H·M·S GmbH
Dr. Bernhard Ciommer
Director 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 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 Regulatory Affairs and Quality Assurance Compliance

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VIGILANCE RESPONSE FORM – FSCA 01-17

Please tick as appropriate:

I confirm that I have received the information on

Product:	B·R·A·H·M·S anti-Tg_n RIA
Kit Reference No.:	27.1 / 27.5
Lot-No./ Expiry date:	127137 / 2017-05-04
	134428 / 2017-05-18
	141439 / 2017-06-01

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 anti-Tg_n RIA lot 127137, lot 134428 and lot 141439 on stock. Please provide us with an equivalent number of B·R·A·H·M·S anti-Tg_n RIA kits as a replacement

Residual stock of B·R·A·H·M·S anti-Tg_n RIA lot 127137, lot 134428 and lot 141439 will be disposed by ourselves.

Signature and date:

Please return this form by fax [+49 \(0\)3302 883 819](tel:+49(0)3302883819) or by e-mail to eu-vigilance@thermofisher.com
within five days.

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To ensure your safety and satisfaction please follow the actions as described as follows:

Advice on actions to be taken by the distributor:

1. Please check your inventory for B·R·A·H·M·S anti-Tg_n RIA lot 127137, lot 134428 and lot 141439.
2. We will substitute the affected lot at no additional cost for you. Please contact service.brahms@thermofisher.com.
3. Please discard your B·R·A·H·M·S anti-Tg_n RIA lot 127137, lot 134428 and lot 141439 following the respective local regulations and guidelines, as soon as you receive the replacement kits. A new B·R·A·H·M·S anti-Tg_n lot is available in our stock for replacement.
4. We kindly ask you to notify your customers of this Field Safety Corrective Action. Please make use of the Field Safety Notice attached to this letter. If you have translated the Field Safety Notice into local language please provide a copy of the translation to eu-vigilance@thermofisher.com
5. Please maintain records of all Field Safety Corrective Actions and effectiveness checks. If necessary we will request copies of these records to be provided to us.
6. We (BRAHMS GmbH) will inform all involved EU Competent Authorities about this Field Safety Corrective Action.

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.

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

I confirm that I informed my customers as advised and forward a copy of the response form or my documentation of effectiveness to BRAHMS GmbH.

In case of the need of replacement please contact:

Customer Service Tel +49 3302 883 300

Email: service.brahms@thermofisher.com

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.