

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 02-17**

**Product:** B•R•A•H•M•S anti-Tg<sub>n</sub> RIA  
**FSCA-ID:** FSCA 02-17  
**Topic:** Shift in the reference range of B•R•A•H•M•S anti-Tg<sub>n</sub> RIA

Date: 14/June/2017

Dear Customer,

**Details on affected device:**

Product:	<b>B•R•A•H•M•S anti-Tg<sub>n</sub> RIA</b>
Kit Reference No.:	27.1 / 27.5
Lot-No./ Expiry date:	149117 / 2017-06-15 149118 / 2017-06-15 149119 / 2017-06-15 155930 / 2017-06-29 155931 / 2017-06-29 162191 / 2017-07-12 162192 / 2017-07-12

**Description of the problem:**

Starting with B•R•A•H•M•S anti-Tg<sub>n</sub> RIA lot 119854 we informed you about a shift in the reference range depending on the storage of the sample. Internal monitoring detected an additional shift in the reference range for B•R•A•H•M•S anti-Tg<sub>n</sub> RIA. This shift was not visible at initial QC release of the product but showed with ageing of the assay. This might lead to erroneously high anti-Tg test results.

The potential risk for the patient is mitigated by the fact that 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.



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-Tg<sub>n</sub> RIA lot 149117, 149118, 149119, 155930, 155931, 162191 and 162192.
2. We will substitute the affected lot with a new lot at no additional cost for you. Please contact your local Thermo Fisher Scientific sales office or approved distributor in your region. We expect the new lot of B·R·A·H·M·S anti-Tg<sub>n</sub> RIA to be available by 26<sup>th</sup> of June, 2017.
3. Please discard your B·R·A·H·M·S anti-Tg<sub>n</sub> RIA lot 149117, 149118, 149119, 155930, 155931, 162191 and 162192 immediately, following the respective local regulations and guidelines.

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](mailto: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](mailto: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](mailto: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 02-17**

**Please tick as appropriate:**

I confirm that I have received the information on

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Lot-No./ Expiry date:	149117 / 2017-06-15
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	155930 / 2017-06-29
	155931 / 2017-06-29
	162191 / 2017-07-12
	162192 / 2017-07-12

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<sub>n</sub> RIA lot 149117, 149118, 149119, 155930, 155931, 162191 and 162192 on stock.

Residual stock of B·R·A·H·M·S anti-Tg<sub>n</sub> RIA lot 149117, 149118, 149119, 155930, 155931, 162191 and 162192 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](mailto:eu-vigilance@thermofisher.com) **within five days.**

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**FSCA-ID:** FSCA 02-17  
**Topic:** Shift in the reference range of B•R•A•H•M•S anti-Tg<sub>n</sub> RIA

Date: 14/June/2017

Dear Distributor,

**Details on affected device:**

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3. Please discard your B·R·A·H·M·S anti-Tg<sub>n</sub> RIA lot 149117, 149118, 149119, 155930, 155931, 162191 and 162192 immediately, following the respective local regulations and guidelines.
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. As required by your local regulation, please translate the Field Safety Notice into your local language and provide a copy of the translation to [eu-vigilance@thermofisher.com](mailto:eu-vigilance@thermofisher.com).
5. Please maintain records of all Field Safety Corrective Actions and vigilance response forms. 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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Email: [service.brahms@thermofisher.com](mailto:service.brahms@thermofisher.com)

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Dr. Bernhard Ciommer

Director Regulatory Affairs and Quality

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Sincerely

B·R·A·H·M·S GmbH

Dr. Bernhard Ciommer

Director Regulatory Affairs and Quality Assurance Compliance

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Residual stock of B·R·A·H·M·S anti-Tg<sub>n</sub> RIA lot 149117, 149118, 149119, 155930, 155931, 162191 and 162192 will be disposed by ourselves.

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.

Signature and date: