

## Urgent: Field Safety Notice FSCA 03-15

**Product:** B·R·A·H·M·S PCT direct  
**FSCA-ID:** FSCA 03-15  
**Topic:** Falsely low PCT results with B·R·A·H·M·S PCT direct due to calibration bias

Dear Doctor,

Date: 01/Jun/2015

### Details on affected device:

Product:	B·R·A·H·M·S PCT direct				
Kit Reference No.:	126.025				
Lot-No.:	525699	577857	595599	623573	643864
Expiry Date:	2015-01-03	2015-05-02	2015-05-30	2015-07-25	2015-08-29

### Description of the problem:

We have to inform you that for the B·R·A·H·M·S PCT direct lot 525699, lot 577857, lot 595599, lot 623573, lot 643864, we observed lower PCT results when comparing the B·R·A·H·M·S PCT direct result to reference methods. This is caused by a calibration bias of up to -30 %, which can lead to falsely low PCT results. The risk caused by incorrect B·R·A·H·M·S PCT direct results is mitigated by the fact, that results obtained with B·R·A·H·M·S PCT direct should always be evaluated in the context of all laboratory findings and the total clinical status and medical history of the patient before introducing significant therapeutic measures. In high risk patients treatment should not be avoided based on a negative B·R·A·H·M·S PCT direct result as advised in the instructions for use. Nevertheless there is a risk of not treating patients with no obvious signs and symptoms of infection due to a falsely low PCT result.

Advise on action to be taken by the user:

1. Immediately check your inventory and discard all B·R·A·H·M·S PCT direct kits of lot 525699, lot 577857, lot 595599, lot 623573, lot 643864.
2. Stop using B·R·A·H·M·S PCT-direct lot 525699, lot 577857, lot 595599, lot 623573, lot 643864 you still have on stock and discard all remaining kits.
3. The measurement bias observed might lead to an erroneous assessment of the need for antibiotic treatment, especially in patients with a PCT value up to 40% above the clinically relevant cut-off. Thus please consider to review all patients having sought medical attention in whom antibiotic therapy was not started due to a low B·R·A·H·M·S PCT direct result at relevant cut off. If you see a clinical risk of an occult bacterial infection, please consider contacting the patient proactively to ensure appropriate diagnostic and therapeutic measures especially in patients suspected to have acute infections.

We will inform you on the availability of new B·R·A·H·M·S PCT direct lots as soon as possible.

You will be contacted by the responsible Thermo Fisher sales representative regarding reimbursement and further steps.

Please verify your receipt of this notification by completing the attached vigilance response form and return it to us by facsimile +49 (0)3302 883 640 or by e-mail to [eu-vigilance@thermofisher.com](mailto:eu-vigilance@thermofisher.com) within **five days** upon receipt.

Any technical questions you may have should be addressed to:

International Hotline: Tel: +49 3302 883 300

Any regulatory questions you may have should be addressed to:

Dr. Bernhard Ciommer, Director Regulatory Affairs and Quality Assurance Compliance

B·R·A·H·M·S GmbH

Tel: +49 (0)3302 883 752

Neuendorfstrasse 25

Fax: +49 (0)3302 883 640

D-16761 Hennigsdorf/Germany

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.

BRAHMS GmbH

Dr. Bernhard Ciommer

Director Regulatory Affairs and Quality Assurance Compliance

## VIGILANCE RESPONSE FORM – FSCA 03-15

I confirm that I have received the information on

<b>Product:</b>	B·R·A·H·M·S PCT direct				
<b>Kit Reference No.:</b>	126.025				
<b>Lot-No.:</b>	525699	577857	595599	623573	643864
<b>Expiry Date:</b>	2015-01-03	2015-05-02	2015-05-30	2015-07-25	2015-08-29

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

Residual stock of B·R·A·H·M·S PCT direct lot 525699, lot 577857, lot 595599, lot 623573, lot 643864 will be disposed by ourselves.

Name:

Institution:

Address:

Signature and date:

Please return this form by facsimile [+49 \(0\)3302 883 640](tel:+4903302883640) or by e-mail to [eu-vigilance@thermofisher.com](mailto:eu-vigilance@thermofisher.com) within **five days**.