

Urgent Field Safety Notice

BR-05313

May 2013

Berichrom® PAI (Catalog No. OWOA15 / SMN 10446642) lot 541577

Dear valued customer,

Our records indicate that you have received Berichrom® PAI (Catalog No. OWOA15; SMN 10446642) lot 541577.

We have confirmed that this lot contains a wrong Table of Assigned Values (TAV). Please note the correct lot numbers and values for PAI Standard 1, PAI Standard 2 and PAI Control Plasma are as follows:

	Lot number	Concentration / Assigned Value
Standard 1	518797	0.00 U/mL
Standard 2	518897	5.49 U/mL
Control	518997	3.61 U/mL

Siemens Healthcare Diagnostics is conducting a field corrective action for Berichrom PAI lot 541577. If you use the reagent in a manual method, please be advised to use the Concentrations / Assigned Value as given in the table above. Please note that the values on the Lot Data CD for Siemens' official Berichrom PAI applications on BCS / BCS XP systems are correct.

If you have any questions or need assistance please contact your local Siemens representative.

Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files and forward this information to all parties that may use this product including others to whom you may have transferred the affected lots.

The Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) has been notified of this action.

We apologize for any inconvenience that this situation has caused. Thank you for your patience and continued support.

Siemens Healthcare Diagnostics Products GmbH

Emil-von-Behring-Str. 76
35041 Marburg, Germany

Phone: +49 6421 39-4511
www.siemens.com/diagnostics


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Sincerely yours,

Original signature is on file

Original signature is on file


Director Quality Systems & Compliance


Director Global Marketing Hemostase Reagents

Siemens Healthcare Diagnostics Products GmbH

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35041 Marburg, Germany

Phone: +49 6421 39-4511
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GPF-003-6 V4.0 Effective: 2012-03-09

Berichrom® PAI

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice BR-05313 dated May 2013 regarding a/m Issue.

Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare diagnostics at the fax number indicated at the bottom of this page.

1. Did your facility receive a field correction letter from Siemens Healthcare Diagnostics regarding Berichrom PAI, letter# BR05313? Yes No

[This question is necessary only if the Effectiveness Check Letter is mailed separately from the FCA Letter]

2. Did we effectively communicate all necessary information? Yes No
3. Do you now have any of the noted product on hand? (Please check inventories before answering.) Yes No
4. If the answer to the question above is Yes, do you intend to take the recommended action as requested? Yes No

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

**PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT
(###) ###-####**

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