

11/14/11

Urgent Field Safety Notice

BR-07011

September 2011

Berichrom® PAI (Product Code OWOA) lot # 541572

Dear Berichrom PAI Customer,

Our records indicate that you have received Berichrom PAI lot # 541572.

Siemens Healthcare Diagnostics has confirmed that the above lot can result in clinical significant lower PAI values compared to previous lots. High PAI concentrations (> 10 U/mL) might be underestimated and in the low reference range patient results will be measured too low.

Siemens is conducting a voluntary field corrective action. You should discontinue use of Berichrom PAI lot # 541572 and discard the remainder of this lot in your laboratory's inventory.

Please consult with your laboratory director regarding re-evaluation of previous test results.


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.

Siemens Healthcare Diagnostics will inform you as soon as a new lot will become available.

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.

Sincerely,


Director Auditing & Quality System Projects


Director Global Marketing Hemostasis

Siemens Healthcare Diagnostics Inc.

[Street Address]
[City, ST ZIP]

[Phone]
www.siemens.com/diagnostics

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[Tracking Number]

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FIELD CORRECTION EFFECTIVENESS CHECK

(Berichrom® PAI lot # 541572)

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated September 2011 regarding Berichrom® PAI lot # 541572. 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 we effectively communicate all necessary information? Yes No
- 2. Do you currently use Berichrom® PAI? Yes No
- 3. 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
(###) ###-####

Siemens Healthcare Diagnostics Products GmbH

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