

**Berichrom[®] Heparin (Catalog No. OWLD11 / SMN 10446620)
lot numbers 42007, 42082, 42483 and 42569.
Reduced on board stability**

Dear valued customer,

Our records indicate that you have received Berichrom[®] Heparin (Catalog No. OWLD11; SMN 10446620) lot 42007, 42082, 42483 or 42569.

During recent investigations, Siemens Healthcare Diagnostics has observed that the above mentioned lots show a reduced on board stability (OBS) while used on BCS/BCS XP System or Sysmex[®] CA-7000 System as demonstrated by testing appropriate controls e.g. Berichrom Heparin Control 1.

If a decrease of heparin level is observed during OBS, it will be shown by a lower control recovery. It is extremely unlikely that an erroneously low heparin value may be reported which may trigger a higher dose of Heparin therapy which could slightly increase the risk of bleeding. The potential of an adverse event to the patient is considered to be very unlikely because only the lower therapeutic range is affected.

Siemens Healthcare Diagnostics is conducting a field corrective action for Berichrom Heparin lot 42007, 42082, 42483 and 42569. Please discontinue use and discard any remaining inventory of these lots independent of the analyzer in use.

A look back of previously reported Berichrom Heparin results is not recommended since the coagulation status changes over the time.

Please contact your local Siemens representative for an alternative lot of Berichrom Heparin for replacement.

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.

Siemens Healthcare Diagnostics Products GmbH

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

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

Page 1 of 3

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 yours,

Original signature is on file

Original signature is on file

Dr. Norbert Dedner
Director Quality Systems & Compliance

Marlen Suller
Senior Director Global Marketing Hemostasis

Siemens Healthcare Diagnostics Products GmbH

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

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

Page 2 of 3

FIELD CORRECTION EFFECTIVENESS CHECK

Berichrom® Heparin

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice BR-06913 dated August 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 Heparin, letter# BR-06913? 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 YOUR LOCAL SIEMENS REPRESENTATIVE

Siemens Healthcare Diagnostics Products GmbH

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

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

Page 3 of 3