

Dade Behring Marburg GmbH
P. O. Box 11 49
35001 Marburg, Germany
www.dadebehring.com

Phone: +49 (6421) 39-4601
Fax: +49 (6421) 39-4594

DADE BEHRING

To whom it may concern

Our Ref.
C. Dahler_Br-16505

Ext.
06421-39-4601

Fax
06421-39-4594

Date
July 01, 2005

**Field Correction
on
Coagulation Factor VIII Deficient Plasma (REF OTXW), lots 503846A,
503850C and 503853A,**

Dear Valued Dade Behring Customer:

Our records indicate that you received the Dade Behring Coagulation Factor VIII Deficient Plasma (REF OTXW) lot number(s) listed above.

We have confirmed that these lot numbers of Coagulation Factor VIII Deficient Plasma do not demonstrate acceptable product performance as patient samples may exhibit falsely high test results. Falsely high factor VIII patient results may lead to a misdiagnosis of the severity of hemophilia A or in the inability to accurately monitor factor VIII substitution therapy.

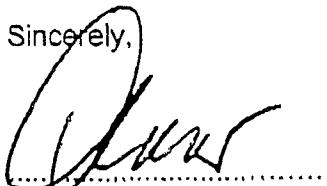
Please discontinue use of and discard any remaining inventory of the lots of Coagulation Factor VIII Deficient Plasma listed above.

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 this lot.

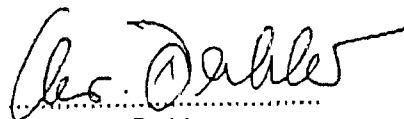
If you have any questions or need assistance with obtaining replacement product, please contact your local Dade Behring representative.

We understand how important quality products are for our customers and their patients. Please accept our sincere apologies for the inconvenience this may cause your laboratory.

Sincerely,



Dr. Norbert Dedner
Director
Field Quality Assurance



Christine Dahler
Senior Product Manager
Hemostasis Global Marketing

Dade Behring Marburg GmbH
P. O. Box 11 49
35001 Marburg, Germany
www.dadebehring.com

Phone: +49 (6421) 39-4601
Fax: +49 (6421) 39-4594

DADE BEHRING

To whom it may concern

Our Ref.
C. Dahler_Br-17205

Ext.
06421-39-4601

Fax
06421-39-4594

Date
July 01, 2005

**Field Correction
on
Coagulation Factor VIII Deficient Plasma (REF OTXW), lots 503847D,
503849D, 503849E, 503856B, 503856C, 503857A and 503858A for
use with BCS® and BCT* systems**

Dear Valued Dade Behring Customer:

Our records indicate that you have received the Dade Behring Coagulation Factor VIII Deficient Plasma (REF OTXW) lot number(s) listed above.

We have confirmed that these lot numbers of Coagulation Factor VIII Deficient Plasma do not demonstrate acceptable product performance when using with the BCS® and BCT* systems. Patient samples may exhibit falsely high factor VIII results which could lead to misdiagnosis of the severity of hemophilia A or the inability to accurately monitor factor VIII substitution therapy.

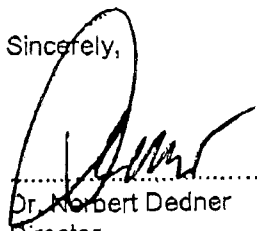
Please discontinue use of the above listed lots of Coagulation Factor VIII Deficient Plasma with the BCS® or BCT* system applications.

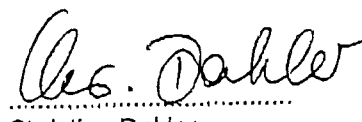
Please contact your Dade Behring representative for support.

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 this lot.

If you have any questions, please contact your local Dade Behring representative. We understand how important quality products are for our customers and their patients. Please accept our sincere apologies for the inconvenience this may cause your laboratory.

Sincerely,


.....
Dr. Norbert Dedner
Director
Field Quality Assurance


.....
Christine Dahler
Senior Product Manager
Hemostasis Global Marketing

Dade Behring Marburg GmbH
P. O. Box 11 49
35001 Marburg, Germany
www.dadebehring.com

Phone: +49 (6421) 39-4601
Fax: +49 (6421) 39-4594

DADE BEHRING

To whom it may concern

Our Ref.
C. Dahler_BR-17305

Ext.
06421-39-4601

Fax
06421-39-4594

Date
July 01, 2005

Field Correction

on

**Coagulation Factor VIII Deficient Plasma (REF OTXW), lots 503845A,
503855B for use with BCS® and BCT* systems**

Dear Valued Dade Behring Customer:

Our records indicate that you have received the Dade Behring Coagulation Factor VIII Deficient Plasma (REF OTXW) lot numbers listed above. We would like to inform you about the limited application when using these lot numbers of Coagulation Factor VIII Deficient Plasma with the BCS® and BCT* systems.

We have confirmed that these lot numbers of Coagulation Factor VIII Deficient Plasma do not demonstrate acceptable product performance when using with particular settings of the BCS® and BCT* systems. Patient samples may exhibit falsely high factor VIII results which could lead to misdiagnosis of the severity of hemophilia A or the inability to accurately monitor factor VIII substitution therapy.

In order to ensure that your patient results will be determined correctly regarding the level of Factor VIII, we recommend that you use the following test procedure for the above mentioned lots of Coagulation FVIII Deficient Plasma.

a) When using the BCS® system:

- Do not use the normal setting (Test ID 31) for the determination of factor VIII with Pathromtin* SL reagent (REF OQGS).
- Determine factor VIII with Pathromtin* SL, Dade® Actin® (REF B4218-1, B4218-2), or Dade® Actin® FSL (B4219-1, B4219-2) reagents using the diluted settings ONLY (Test ID 451, 455, or 459, respectively) with the lowest calibration point set at 20%.
- Retest all patient samples with results lower than 20% with the low setting of Coagulation Factor VIII Deficient Plasma with Pathromtin* SL (Test ID 131), Dade® Actin® (Test ID 133) or Dade® Actin® FSL (Test ID 135) reagents..

b) When using the BCT system:

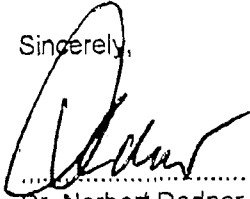
- Do NOT determine factor VIII with Pathromtin SL (Test ID 451, 131) or Dade® Actin® (Test ID 455, 133) reagents.
- Determine factor VIII with Dade® Actin® FSL reagent ONLY (Test ID 459, 135).

Please contact your Dade Behring representative to support you with the system specific details.

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 this lot.

If you have any questions, please contact your local Dade Behring representative. We understand how important quality products are for our customers and their patients. Please accept our sincere apologies for the inconvenience this may cause your laboratory.

Sincerely,



.....
Dr. Norbert Dedner
Director
Field Quality Assurance



.....
Christine Dahler
Senior Product Manager
Hemostasis Global Marketing

Dade Behring Marburg GmbH
P. O. Box 11 49
35001 Marburg, Germany
www.dadebehring.com

Phone: +49 (6421) 39-4601
Fax: +49 (6421) 39-4594

DADE BEHRING

To whom it may concern

Our Ref.
C. Dahler_Br-17405

Ext.
06421-39-4601

Fax
06421-39-4594

Date
July 01, 2005

Field Correction

on

**Coagulation Factor VIII Deficient Plasma (REF OTXW), lots 503848A,
503859B, 503860D and 536501 for use with BCT* system**

Dear Valued Dade Behring Customer:

Our records indicate that you have received the Dade Behring Coagulation Factor VIII Deficient Plasma (REF OTXW) lot number(s) listed above.

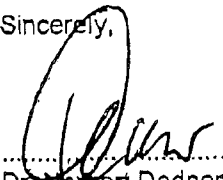
We have confirmed that these lot numbers of Coagulation Factor VIII Deficient Plasma do not demonstrate acceptable product performance when using particular APTT reagents with the BCT* system. Patient samples may exhibit falsely high factor VIII results which could lead to misdiagnosis of the severity of hemophilia A or the inability to accurately monitor factor VIII substitution therapy.

The lots of Coagulation Factor VIII Deficient Plasma listed above can only be used for the determination of factor VIII on the BCT* system in conjunction with Dade® Actin® FSL reagent (REF B4219-1, B4219-2).

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 this lot.

If you have any questions, please contact your local Dade Behring representative. We understand how important quality products are for our customers and their patients. Please accept our sincere apologies for the inconvenience this may cause your laboratory.

Sincerely,


.....
Dr. Norbert Dedner
Director
Field Quality Assurance


.....
Christine Dahler
Senior Product Manager
Hemostasis Global Marketing