

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

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

DADE BEHRING

To whom it may concern

Our. Ref.
BR-12306

Ext.
06421-39-

Fax
06421-39-5114

Date
29 May 2006

**Field Correction
on
BCS® Stirring Rack Unit**

Dear valued BCS® Customer,

Our records indicate that you are using a BCS® Stirring Rack Unit for an intermittent mixing of BC von Willebrand, (product code OUBD 37) reagents placed on a BCS® system.

We have observed a higher than expected replacement rate of the stirring rack due to a malfunction of the stirring rack. This may cause inadequate mixing of the reagents and may reduce the onboard stability of the BC von Willebrand reagents.

To ensure adequate mixing of reagents on your BCS® system with stirring rack please proceed as follow:

- Verify proper functionality of stirring rack by following the instructions provided in the enclosed Customer Support Bulletin
or
- Discontinue use of your stirring rack and manually swirl the BC von Willebrand reagent every 30 minutes once placed on the BCS® System.

All BC von Willebrand results should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Please report any concerns and contact your local Dade Behring representative.

Please distribute this information to all appropriate personnel in your laboratory, retain a copy with your files for future reference and forward this information to all parties that may have received the affected BCS Stirring Rack Units.

We are working diligently and remain committed to a rapid solution and will replace your stirring rack as soon as it becomes available.

We apologize for any inconvenience this action may have caused and thank you for your continued support.

Sincerely

A large black rectangular redaction box covering the signature of the Director of Field Quality Assurance.

Director
Field Quality Assurance

A large black rectangular redaction box covering the signature of the Marketing Manager of Global Marketing Hemostasis.

Marketing Manager
Global Marketing Hemostasis

Enclosure

Customer Bulletin BCS Stirring Rack

DADE BEHRING

Customer Bulletin for Testing the Function of the BCS® System Stirring Rack Unit

To verify the function of the stirrer, perform the following check once per day:

Perform the check prior to processing QC or patient samples in a stirring rack unit.

- Place a stirrer bar into an empty GW5 bottle. Either use a bar-coded bottle or manually identify the bottle in the software.
- Insert the bottle in position 3 of the stirrer rack.
- Load the stirrer rack in lane 4, the rack transport will move the rack to the rack processing platform.
- Verify the stirring function by watching the stirrer bar through the front lid or listening for the sound of the mixer motor. The stirring will be done within 10 sec of the rack being moved into the rack processing platform.
- When the stirrer function has been verified, remove the stirrer rack by clicking on the corresponding rack in the Analyzer dialog, then clicking the Eject button.