



**URGENT FIELD SAFETY NOTIFICATION**  
**HEMOSIL VON WILLEBRAND FACTOR ACTIVITY, PN 0020004700**  
**IMMEDIATE REMOVAL OF IN-DATE PRODUCT LOTS FROM THE FIELD**

March 28, 2012

Dear Valued HemosIL von Willebrand Factor Activity Customer:

This notification is intended to advise your facility about a serious interference issue identified with all in-date product lots of **HemosIL von Willebrand Factor Activity, Part No. 0020004700**, as listed in the table below.

Product Name	Part No.	Lot No.	Exp. Date
HemosIL von Willebrand Factor Activity	0020004700	B01424	March 31, 2012
		B11498	July 31, 2012
		B11655	November 30, 2012
		B11687	January 31, 2013

• **Issue Description and Risk:**

The presence of human anti-bovine antibodies (HABIA) in a patient sample has been shown to cause an over-estimation of results with the HemosIL von Willebrand Factor Activity reagent. Since levels of HABIA vary in the patient population, small to large shifts in vWF Activity results are possible.

Patient samples that contain large amounts of this HABIA interference can exhibit significant positive bias. **The effects of this worst case situation can change a patient result from abnormal to normal, with potentially severe impact to patient treatment.**

• **Mandatory Customer Action:**

Please follow the instructions below:

- Discontinue use of HemosIL von Willebrand Factor Activity, PN 0020004700, ***immediately***.
- Use an alternate method for measuring von Willebrand Factor Activity until further notice.
- Check your inventory for the product lots of HemosIL von Willebrand Factor Activity, PN 0020004700, listed in the table above and ***document their destruction on the provided tracking form and return the completed form***.
- Contact your local representative for credit instructions.
- Share this information with your staff.
- Retain a copy of this letter in your files as a record of the notification.

IL has identified the root cause of the HABIA interference with our HemosIL von Willebrand Factor Activity reagent and is working diligently to address the issue with future product lots.

We appreciate your prompt attention to this important recall notification.

Sincerely,

Carol Marble  
Regulatory Affairs Director