



UPDATED IMPORTANT PRODUCT NOTICE

**HemosIL® von Willebrand Factor Antigen (PN 0020002300),
All Product Lots,
Reduced Open Vial Stability Claim to 14 Days at 2-8°C**

August 11, 2023

Dear Valued HemosIL von Willebrand Factor Antigen Customer:

This notification is a follow-up to advise your facility regarding a change to the labeled open vial 2-8°C stability claim for HemosIL von Willebrand Factor Antigen (Part No. (PN) 0020002300) that affects all currently released and future product lots. The new claim is 14 days at 2-8 °C.

Below is a list of all in-date product lots:

Product Name	Part No.	UDI	Lot No.	Manufacture Date (YYYY-MM-DD)	Expiration Date (YYYY-MM-DD)
HemosIL von Willebrand Factor Antigen	0020002300	08426950041177	B34906	2022-04-06	2023-09-30
			B35286	2022-09-16	2024-03-31
			B35530	2022-12-14	2024-06-30
			B35696	2023-03-28	2024-08-31

• Issue Description and Result Impact

This is a follow up to the original notification (dated April 20, 2022) that advised your facility of an issue with the labeled open vial 2-8°C stability claim for HemosIL von Willebrand Factor Antigen (PN 0020002300).

Our investigation into reported customer complaints identified that the product was not meeting its labeled claim for Open vial stability at 2-8°C of 3 months. A new open vial stability claims of 14 days at 2-8°C was established and cleared by the FDA.

Note: There is no impact on patient samples, as the data flag CE 5053 (Baseline Average High) is generated, and no results are reported.

• **Mandatory Customer Actions**

The open vial stability claim has been reduced to 14 days for all in-date and future product lots of HemosIL von Willebrand Factor Antigen (Part No. 0020002300). Based on the above, please take the following immediate actions for HemosIL von Willebrand Factor Antigen (PN 0020002300):

- **Use** the following **updated open vial stability claim** for HemosIL von Willebrand Factor Antigen (PN 0020002300).

<u>Current IFU Open Vial Stability at 2-8°C</u>	<u>Reduced Open Vial Stability at 2-8°C</u>
3 Months	14 Days

- **Share** this information with your staff, notifying them of the updated open vial stability claim for HemosIL von Willebrand Factor Antigen (Part No. 0020002300).
- **Retain** a copy of this letter in your files as a record of the notification.
- **Complete and return** the enclosed Mandatory Response Tracking Form to acknowledge the above actions.

Please contact your local representative with any questions.

Thank you for your prompt attention to this important notification.

Sincerely,



Anuja Khan
Regulatory Affairs Manager II
Instrumentation Laboratory Company
A Werfen Company