

## **URGENT FIELD SAFETY NOTICE**

**HemosIL Heparin Calibrators, Part No. 0020300600 – All In-Date Lots**

**UPDATE: HemosIL LMW Heparin Controls (Part No. 0020300200),  
Reassigned Target Values and Acceptance Ranges**

February 3, 2025

Dear Valued HemosIL® Liquid Anti-Xa Customer,

This letter provides an update regarding the previously issued *Urgent Field Safety Notice* (dated December 2024) for HemosIL Heparin Calibrators, Part No. 0020300600. The letter addressed a bias with the calibrators for unfractionated heparin (UFH) and low molecular weight heparin (LMWH). We have now completed the value assignment assessment for the on-market lots of HemosIL UF Heparin Controls and HemosIL LMW Heparin Controls.

### **Outcome of the Heparin Control Assessment**

- HemosIL UF Heparin Controls (Part No. 0020300300):**

The current labeled target values and acceptance ranges for on-market lots are accurate, and reassignment is not necessary.

- HemosIL LMW Heparin Controls (Part No. 0020300200):**

The table below outlines the reassigned target values and acceptance ranges for on-market control lots. These updated values and ranges should be used moving forward. Updated value assignments are in **bold** below.

Part No.	UDI No.	Lot No.	Expiration Date (YYYY-MM-DD)	Control Level	Reassigned Target Value	Reassigned Acceptance Range
0020300200	08426950472490	N0330228	2026-03-31	Low	<b>0.64 IU/mL</b>	<b>0.48 - 0.80 IU/mL</b>
				High	<b>1.62 IU/mL</b>	<b>1.30 - 1.94 IU/mL</b>
		N0632773	2026-06-30	Low	<b>0.67 IU/mL</b>	<b>0.50 - 0.84 IU/mL</b>
				High	<b>1.67 IU/mL</b>	<b>1.34 - 2.00 IU/mL</b>
		N0935135	2026-09-30	Low	<b>0.68 IU/mL</b>	<b>0.51 - 0.85 IU/mL</b>
				High	<b>1.78 IU/mL</b>	<b>1.42 - 2.14 IU/mL</b>
		N1036592	2026-10-31	Low	<b>0.68 IU/mL</b>	<b>0.51 - 0.85 IU/mL</b>
				High	<b>1.74 IU/mL</b>	<b>1.39 - 2.09 IU/mL</b>
		N0148986	2027-01-31	Low	<b>0.68 IU/mL</b>	<b>0.51 - 0.85 IU/mL</b>
				High	<b>1.74 IU/mL</b>	<b>1.39 - 2.09 IU/mL</b>
		N0441476	2027-04-30	Low	<b>0.66 IU/mL</b>	<b>0.50 - 0.83 IU/mL</b>
				High	<b>1.66 IU/mL</b>	<b>1.33 - 1.99 IU/mL</b>
		N0643673	2027-06-30	Low	<b>0.70 IU/mL</b>	<b>0.53 - 0.88 IU/mL</b>
				High	<b>1.76 IU/mL</b>	<b>1.41 - 2.11 IU/mL</b>
		N0845161	2027-08-31	Low	<b>0.66 IU/mL</b>	<b>0.50 - 0.83 IU/mL</b>
				High	<b>1.68 IU/mL</b>	<b>1.34 - 2.02 IU/mL</b>
		N1147397	2027-11-30	Low	<b>0.65 IU/mL</b>	<b>0.49 - 0.81 IU/mL</b>
				High	<b>1.73 IU/mL</b>	<b>1.38 - 2.08 IU/mL</b>

## Requested Customer Actions

Please take the following actions:

- **Follow** the instructions in the original *Urgent Medical Device Correction* letter to update the ACL TOP test parameters with the corrected value assignments for HemosIL Heparin Calibrators (Part No. 0020300600).
- **For HemosIL UF Heparin Controls (Part No. 0020300300)**, continue to use the current target values and acceptance ranges as labeled.
- **For HemosIL LMW Heparin Controls (Part No. 0020300200)**, use the reassigned target values and acceptance ranges for the Low and High Controls as provided in the table above.
- **Note:** if the 2D Barcode is scanned, customers need to manually override the uploaded values with those provided in this letter.
- **Follow** the instructions below to update the Quality Control Material Definitions with the updated values (same instructions for all Instrument models):
  - **Select** "Setup" from the menu bar and then select "Material List" from the dropdown menu.
  - From "Material List", double click on the Material Name "LMW Hep Low Control" and "LMW Hep High Control" (performed separately) to open "Material Definition".
  - From "Material Definition – LMW Hep Low Control or LMW Hep High Control", click on "Assigned Values" icon (picture of bullseye) under the header. An editable table titled "Assigned Values for IL Material Definition – Quality Control LMW Hep Low Control or LMW Hep High Control" will appear with the Anti-Xa Test Code, Active Lot, and Alternative Lot (if applicable).
  - In the "Assigned Values" table, select the Active and/or Alternative lot, and change the target values for "LMW Hep Low Control" and "LMW Hep High Control" to the reassigned values provided in the table.
  - After entering the reassigned values for "LMW Hep Low Control" and "LMW Hep High Control", click on "OK" to save the changes.
  - **Run** quality controls per labeled instructions for use. New acceptance ranges for HemosIL Low Molecular Weight Heparin Controls (Part No. 0020300200) are provided in the table. If needed, determine control ranges in accordance with your internal protocol.
  - **Repeat** the above instructions for updates to the Quality Control Material Definitions for all ACL TOP instruments.
- **Share** this information with your laboratory staff.
- **Forward** this notification to all affected locations within your facility.
- **Retain** a copy of this notification for your records.

Your acknowledgment of this update to the *Urgent Field Safety Notice* is greatly appreciated.

Sincerely,



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