



**URGENT FIELD SAFETY NOTICE – CLOSURE NOTIFICATION**  
**HemosIL Heparin Calibrators**  
**Part No. 0020300600 – All In-Date and Future Lots**

March 4, 2026

Dear Valued HemosIL® Liquid Anti-Xa Customer:

This letter provides final closure to the Urgent Field Safety Notice issued on December 18, 2024, regarding HemosIL Heparin Calibrators (Part No. 0020300600) used with the HemosIL Liquid Anti-Xa assay (Part Nos. 0020302600, 0020302601, 0020302602). While this notification was distributed to affected customers at that time, we recognize that some newer users may not have received the original communication. As described in that notification, the value assignment of certain HemosIL Heparin Calibrator lots showed a bias against the WHO International Standards for UFH and LMWH, which could have resulted in reduced recovery when measuring heparin in controls and patient samples. The product enhancement described below has been completed to address this issue and represents the final corrective action for this field action.

#### **Final Corrective Actions**

Werfen has implemented the following permanent corrective actions:

##### **1. Transition to Lot-Specific Value Assignment with 2D Barcode Implementation**

Werfen has implemented a new manufacturing value assignment process for HemosIL Heparin Calibrators (Part No. 0020300600), transitioning from predefined fixed target values to lot-specific target values.

Beginning with **Lot No. N1157997**, calibrator kits include 2D barcode functionality. When scanned using the standard barcode reader on ACL TOP instruments (all models and families), the lot-specific target values are automatically populated in the instrument user interface. Customers will no longer be required to manually enter their target values for Heparin Calibrators 1, 2, and 3 when using lots that include 2D barcode functionality.

This enhancement:

- Ensures accurate and consistent lot-specific value assignment
- Eliminates manual data entry
- Reduces the potential for transcription errors
- Enhances traceability and workflow efficiency

## 2. Instructions to Update ACL TOP Material Definitions

As fixed values are no longer appropriate for these calibrators, they will be removed from the material definitions in a future software and parameter upgrade, which applies only to newly manufactured ACL TOP instruments. For all existing ACL TOP instruments, users must manually update the user-definable material names and target values, following the instructions below:

- Access the “Material Definitions” screen on each ACL TOP instrument.
- Locate the existing Heparin Calibrator material definitions that include the fixed target values of 0.0, 0.8, and 2.0 IU/mL (e.g., HEP CAL 2 (0.8)).

- Update each “Material Name” to HEP CAL 1, HEP CAL 2, and HEP CAL 3 by deleting the fixed values and parentheses, as follows:

<b><i>Current ACL TOP Material Definitions with Fixed Target Values</i></b>	<b><i>Updated ACL TOP Material Definitions with Lot-Specific Target Values</i></b>
HEP CAL 1 (0.0)	HEP CAL 1
HEP CAL 2 (0.8)	HEP CAL 2
HEP CAL 3 (2.0)	HEP CAL 3

- Save changes after completing the above edits.
- For assistance, please contact your local representative.



**Mandatory Customer Actions and Field Action Closure**

To help us confirm receipt of this final communication and complete the regulatory tracking, please take the following actions:

- **Update** the Heparin Calibrator material definition names on all ACL TOP instrument(s) and save the changes as described in Section 2 above.
- **Share** this information with all relevant laboratory staff.
- **Forward** this notification to all affected locations within your facility.
- **Retain** a copy of this notification for your records.

The above product enhancement is designed to ensure more accurate, efficient, and traceable heparin measurements. Based on the completion of these actions, Werfen considers this Urgent Field Safety Notice to be closed. Werfen remains committed to maintaining the highest standards of quality, regulatory compliance, and patient safety.

Thank you for your cooperation and support throughout this field action.

Sincerely,

A handwritten signature in blue ink, appearing to read "Keith Kelly", with the date "04 MAR 2021" written to the right of the signature.

Keith Kelly

Senior Regulatory Affairs Manager

Instrumentation Laboratory Co.

A Werfen Company