



IMPORTANT PRODUCT NOTICE

**HemosIL® Factor XIII Antigen, Part No. 0020201300, All Lots
Reduction in ACL TOP On-Board Instrument Stability Claim**

February 4, 2026

Dear Valued HemosIL Factor XIII Antigen Customer:

This letter is to inform you of a reduction in the on-board instrument stability claim for all in-date and future lots of HemosIL Factor XIII Antigen (Part No. 0020201300) when used on the ACL TOP Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series hemostasis systems.

A list of in-date lots is provided below:

Assay Trade Name	Part No.	UDI	Lot No.	Expiration Date (YYYY-MM-DD)
HemosIL Factor XIII Antigen	0020201300	08426950358725	B37352	2026-05-31
			B37538	2026-08-31
			B37753	2026-11-30

Issue Description and Result Impact

Customer complaints have been received indicating that HemosIL Factor XIII Antigen is not meeting its labeled on-board stability claim of 4 days at 15°C on the ACL TOP Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series systems, including reports of quality control (QC) results outside of range, and in one instance, erroneously low patient results when QC was not performed in accordance with labeled requirements. Based on internal investigation, Werfen is **temporarily reducing the on-board instrument stability claim from 4 days to 6 hours** on the ACL TOP systems, for all in-date lot and future lots. This reduced claim should be applied to ensure reliable reagent performance. To help minimize reagent waste associated with the reduced on-board stability period, laboratories may consider batching FXIII Ag testing where feasible.

If patient testing was performed using reagents left on-board according to the labeled 4-day stability claim, FXIII Ag results may be erroneously low, potentially prompting repeat testing, additional hematology consultation, or minor procedural delays. Patients are typically already under care at the time of testing, and any abnormal result would be clarified through repeat testing or confirmatory procedures. Therefore, any potential harm is limited to minor complications associated with specimen recollection, as well as patient anxiety, unnecessary consultation, or cancellation of a procedure.

Werfen has identified an improvement and is actively evaluating its impact on the on-board instrument stability claim for HemosIL Factor XIII Antigen. Customers will be informed of the final on-board instrument stability claim once testing is complete. Until the final claim is available, a temporary label will be applied to all current and future HemosIL Factor XIII Antigen lots to inform customers of the reduction in on-board instrument stability claim to 6 hours.

Mandatory Customer Actions

Please implement the following actions immediately:

- **Use the reduced on-board instrument stability claim of 6 hours** for HemosIL Factor XIII Antigen (Part No. 0020201300) on the ACL TOP Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series.

ACL TOP Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series	
<u>Current</u> On-board Instrument Stability Claim	<u>Reduced</u> On-board Instrument Stability Claim
4 Days	6 Hours

- **Where feasible, consider batching** FXIII Ag testing to help minimize reagent waste.
- **Run quality controls** in accordance with the labeled Instructions for Use.
- **Inform all laboratory staff** of this notification.
- **Post this notification** near your ACL TOP instruments.
- **Retain a copy of this notification** for your records.
- **Complete and return** the Mandatory Response Tracking Form **within 10 days of receipt:**
 - **Fax No.: 781-861-4207 Or E-mail: ra-usa.na@werfen.com**

If you have any technical questions, please contact your local representative.

We apologize for any inconvenience this issue may cause your laboratory and will notify you when the final on-board instrument stability claim for HemosIL Factor XIII Antigen is available.

Thank you for your prompt attention to this Important Product Notice.

Sincerely,



Keith Kelly
Senior Regulatory Affairs Manager
Instrumentation Laboratory Co.
A Werfen Company