

URGENT FIELD SAFETY NOTICE

HemosIL® AcuStar ADAMTS13 Activity, Part No. 0009802048, All Lots

Reduction in On-Board Stability Claim

June 18, 2026

Dear Valued HemosIL® AcuStar ADAMTS13 Activity Customer,

This letter is to inform you of a reduction in the on-board instrument stability claim for all current and future lots of **HemosIL AcuStar ADAMTS13 Activity (Part No. 0009802048)** when used on the ACL AcuStar® system.

A list of in-date lots is provided in the table below:

Trade Name	Part No.	UDI	Lot No.	Expiration Date (YYYY-MM-DD)
HemosIL AcuStar ADAMTS13 Activity	0009802048	08426950602422	B37916	2026-09-01
			B38144	2026-12-16
			B40093	2027-03-01

Issue Description and Result Impact

Customer complaints have reported that the HemosIL AcuStar ADAMTS13 Activity assay does not meet its labeled on-board stability claim of 56 days at 2-8°C on the ACL AcuStar system across multiple lots. Internal testing has demonstrated an increase in measured ADAMTS13 activity at the 10% medical decision level (MDL), with values observed to exceed the established acceptance criteria by up to 0.6%.

Further investigation has identified a previously unrecognized issue whereby erroneously high patient results may occur after extended on-board use, while quality control results may remain within acceptable limits. Undetected erroneously high results may lead to delayed or inappropriate clinical decision-making. In patients being evaluated for thrombotic thrombocytopenic purpura (TTP), this may delay initiation of appropriate treatment with potential for serious, critical, or catastrophic consequences.

Therefore, effective immediately, the on-board stability claim for the HemosIL AcuStar ADAMTS13 Activity assay (Part No. 0009802048) is reduced from 56 days to 28 days when stored at 2-8°C on the ACL AcuStar system.

Mandatory Customer Actions

Please implement the following actions immediately:

- **Use the reduced on-board instrument stability claim of 28 Days** for HemosIL AcuStar ADAMTS13 Activity (Part No. 0009802048) on the ACL AcuStar.

HemosIL AcuStar ADAMTS13 Activity	
<u>Current</u> On-board Stability Claim	<u>Reduced</u> On-board Stability Claim
56 Days	28 Days

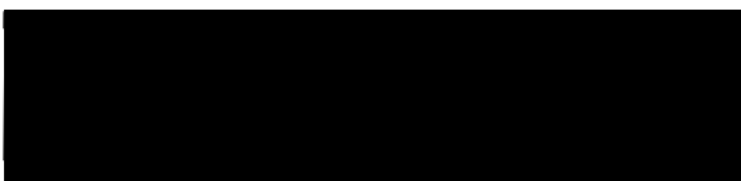
- **Run quality controls** in accordance with the labeled Instructions for Use.
- **Inform all laboratory staff** of this notification.
- **Post this notification** near your ACL AcuStar systems.
- **Retain a copy of this notification** for your records.
- **Complete and return** the Mandatory Response Tracking Form within 10 days of receiving this notification.

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

We apologize for any inconvenience this issue may cause your laboratory. The on-board instrument stability claim in the Instructions for Use will be updated in future lots of HemosIL AcuStar ADAMTS13 Activity. Until this update is implemented, lots will be distributed with a sticker indicating the reduced 28-day on-board stability claim on the ACL AcuStar system.

Thank you for your immediate attention to this Urgent Field Safety Notice.

Sincerely,



Senior Regulatory Affairs Manager
Instrumentation Laboratory Co.
A Werfen Company