



IMPORTANT PRODUCT NOTICE

**HemosIL® Factor V Leiden (APC™ Resistance V), Part No. 0020008700, All Lots
Reduction in ACL TOP On-Board Instrument Stability Claim**

January 21, 2026

Dear Valued HemosIL Factor V Leiden (APC Resistance V) 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 Factor V Leiden (APC Resistance V) (Part No. 0020008700) 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 in the table below:

Assay Trade Name	Part No.	UDI	Lot No.	Expiration Date (YYYY-MM-DD)
HemosIL Factor V Leiden	0020008700	08426950062424	N1047073	2026-04-30
			N0159574	2026-06-30
			N0259991	2026-07-31
			N0452466	2026-10-31
			N0654135	2026-12-31
			N0855549	2026-12-31
			N0755172	2027-01-31
			N1057804	2027-03-31

Issue Description and Result Impact

During internal stability testing, HemosIL Factor V Leiden (APC Resistance V) was found to not meet the labeled on-board instrument stability claim of 3 days at 15°C on the ACL TOP Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series. Testing supports a reduced on-board stability claim of **24 hours** for the ACL TOP systems. There are no known customer complaints related to this stability issue.

Important note: There is no change to the current 4-hour on-board stability claim for ACL Elite / ACL Elite Pro systems.

If patient testing was performed using reagents left on-board the instrument according to the current 3-day stability claim, activated protein C resistance (APCR) ratios could be falsely reduced. However, patients undergoing thrombophilia testing are typically already receiving treatment at the time of testing, and any abnormal screening result would be clarified through confirmatory genetic testing. Therefore, the potential harm is minimal and limited to minor complications associated with specimen recollection.

Mandatory Customer Actions

Please implement the following actions immediately:

- **Use the reduced on-board instrument stability claim of 24 hours** for HemosIL Factor V Leiden (APC Resistance V) (Part No. 0020008700) 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
3 Days	24 Hours

- **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.

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 Factor V Leiden (APC Resistance V). Until this update is implemented, lots will be distributed with a sticker indicating the reduced 24-hour on-board stability claim on the ACL TOP Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series.

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

Sincerely,

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