

URGENT FIELD SAFETY NOTICE: MANDATORY TEST PARAMETER UPGRADE

PARAMETERS P-16.8.00 ON ACL TOP FAMILY MODELS:

ACL TOP, ACL TOP CTS, ACL TOP 700, ACL TOP 700 CTS, ACL TOP 700 LAS,
ACL TOP 500 CTS, ACL TOP 300 CTS

PARAMETERS P-18.6.03 & P-18.8.00 ON ACL TOP FAMILY 50 SERIES MODELS:

ACL TOP 750, ACL TOP 750 CTS, ACL TOP 750 LAS,
ACL TOP 550 CTS, ACL TOP 350 CTS

August 11, 2023

Dear Valued ACL TOP Family / ACL TOP Family 50 Series Customer:

This updated notification is to advise your facility regarding the release of Mandatory Parameters for the ACL TOP Family and the ACL TOP Family 50 Series.

• Reason for the Mandatory Upgrade

Mandatory Parameters P-16.8.00 for the ACL TOP Family, and P-18.6.03 and P-18.8.00 for the ACL TOP Family 50 Series, contain the final mitigations to address the following field actions:

- Reduction of on-board stability claim from 7 days to **4 days** for HemosIL[®] Liquid Anti-Xa.
- Reduction of on-board stability claim from 3 days to **24 hours** for HemosIL[®] Homocysteine Controls.
- Updated test definitions to mitigate carryover for HemosIL[®] Liquid Anti-Xa.

NOTE: This upgrade is mandatory for all ACL TOP Family / ACL TOP Family 50 Series regardless of whether the above reagents are currently in use.

The above changes to the on-board stability claims apply to all currently released lots and future lots of HemosIL Liquid Anti-Xa and HemosIL Homocysteine Controls.



• Mandatory Customer Actions

Please take the following actions:

- Share this information with your laboratory staff and update your internal procedures, as needed.
- Forward this notification to all affected locations in your facility.
- Post this notification on all affected systems in your facility.

NOTE: All customers with ACL TOP Family 50 Series systems with software (SW) versions 6.1.0, 6.2.0, 6.3.0 (Windows 7 OS) must be upgraded to SW 6.4.1 prior to installation of these parameters. For ACL TOP Family 50 Series systems with Windows 10 OS, you must be at SW version 6.5.2 prior to installation of these parameters. All ACL TOP Family customers need to be at a minimum of SW version 5.2.0 to install the Mandatory Test Parameters.

Your local Werfen Representative will install the applicable Mandatory Test Parameters at your next scheduled preventative maintenance or service applications visit, no later than **September 20, 2024**.

We appreciate your prompt attention to this important notification.

Sincerely,

A handwritten signature in blue ink that reads "Anuja Khan".

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