



**UPDATED-URGENT FIELD SAFETY NOTICE**  
**MANDATORY TEST LIBRARY UPGRADE TO 02.05.00 ON THE ACL**  
**ELITE®/ELITE PRO HEMOSTASIS TESTING SYSTEMS**

February 3, 2023

Dear Valued ACL Elite /ACL Elite Pro Customer:

This notification is intended to advise your facility that Werfen is releasing a **Mandatory** Test Library upgrade on the ACL Elite/Elite Pro Hemostasis Testing System (Test Library 02.05.00).

The following instruments will be upgraded:

<b>Product Name</b>	<b>Part Number</b>
ACL Elite	0000880311
ACL Elite Pro	0001000311
ACL Elite Refurb	0000880311R
ACL Elite Pro Refurb	0001000311R

This is a follow up to the original notification that advised your facility of the removal of HemosIL<sup>®</sup> Liquid Anti-Xa (PN 0020302600/0020302601) on the ACL Elite/Elite Pro.

This **Mandatory** Test Library release, among other features, removes the test definition for HemosIL Liquid Anti-Xa (PN 0020302600/0020302601).

The 02.05.00 **Mandatory** Library release can be installed on ACL Elite/Elite Pro systems, currently running software version 04.00.00 or 03.01.04, with Library 02.03.00 or higher. Any ACL Elite/Elite Pro system running a Test Library prior to 02.03.00 will first require an upgrade to ACL Elite/Elite Pro software 04.00.00 or 03.01.04, with Test Library 02.03.00, before upgrading to Test Library 02.05.00.

Your local Werfen representative will install the 02.05.00 **Mandatory** Test Library at your next scheduled preventative maintenance or service applications visit.

If you have any questions or require further assistance, please contact your local Werfen representative.

Sincerely,



Anuja Khan, PhD  
Regulatory Affairs Manager II  
Instrumentation Laboratory, Co.