

<u>UPDATED</u>-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:

Product Name	Part Number
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 [®] 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,

