



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:

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,



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



MANDATORY RESPONSE TRACKING FORM

**MANDATORY TEST LIBRARY UPGRADE TO 02.05.00 ON THE ACL
ELITE®/ELITE PRO HEMOSTASIS TESTING SYSTEM**

The enclosed Field Safety Notice (dated February 3, 2023) is intended to advise your facility that Werfen is releasing a **Mandatory** Test Library upgrade of 02.05.00 on ACL Elite/ ACL Elite Pro Hemostasis Testing Systems.

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

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

Complete all sections of the form below and return via fax to your local Werfen representative

Facility Name _____

Street Address _____

City _____ State _____

Zip/Postal Code _____

Country _____ Country Code _____

ACL Elite/Elite Pro instrument Serial Number(s): _____

- Please check (✓) the box to indicate the completion of the required actions:** The installation of the 02.05.00 Mandatory Library has been completed by a Werfen Service Applications specialist.
- Share this information with your staff, notifying them of the removal of HemosIL Liquid Anti-Xa assay from the ACL Elite/ Elite Pro.

NOTE: Retain a copy of this letter in your files as a record of the notification

Name (please print) _____ Title _____

Signature _____ Phone No. _____