



**UPDATED - URGENT FIELD SAFETY NOTICE: POTENTIAL SAMPLE MISIDENTIFICATION**  
**MANDATORY SOFTWARE UPGRADE**  
**ACL TOP FAMILY 50 SERIES**

February 1, 2024

Dear Valued ACL TOP Family 50 Series Customer:

This updated notification (previous Urgent Field Safety Notice letter on Potential Sample Misidentification dated July 13, 2023) is to advise your facility regarding the release of Mandatory Software for the ACL TOP Family 50 Series systems to mitigate a rare potential for sample misidentification.

Part Nos.	UDI	Model Names	Software
00000280045	08426950729242	ACL TOP 550 CTS	v6.3.0 or later
00000280055	08426950784067	ACL TOP 750 CTS	
00000280065	08426950784081	ACL TOP 350 CTS	
00000280015	08426950784074	ACL TOP 750	
00000280035	08426950784050	ACL TOP 750 LAS	

**• Reason for the Mandatory Software Upgrade**

The following software versions will contain the final mitigations to address a potential sample misidentification:

- Software Version 6.4.1 or earlier and Windows 7 Operating System (OS) must be upgraded to Software 6.4.2.
- Software Version 6.5.1 or 6.5.2 Parameters P-18.6.00 and Windows 10 OS must be upgraded to Software 6.5.3

The potential sample misidentification may occur if:

- The user introduces a sample rack in any of the sample track positions on the ACL TOP Family 50 Series instruments and all samples are properly identified
- The barcode reader has not moved to another position
- The user decides to remove the rack and swap one of the samples (that was properly identified) with a sample that has a different ID
- The user reintroduces the sample rack in the same sample track

If these actions are performed within a very narrow window of time the misidentification could occur with no notification to the user.

While there are no reports of patient harm, it cannot be excluded that a sample could be misidentified, and patient management altered based on an incorrectly assigned result.



• <b>Mandatory Customer Actions</b>
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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: For Windows 7 OS, systems with Software Version 6.4.1 or earlier must upgrade to Software 6.4.2. For Windows 10 OS, systems with Software Versions 6.5.1 or 6.5.2 must upgrade to Software 6.5.3.

Your local Werfen Representative will install the applicable Mandatory Software at your next scheduled preventative maintenance or service applications visit, no later than **March 7<sup>th</sup>, 2025**.

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