werfen

URGENT FIELD SAFETY NOTICE

ACL TOP Family 50 Series / ACL TOP 970 CL
Potential Sample Misidentification

July 13, 2023

Dear Valued ACL TOP Family 50 Series / ACL TOP 970 CL Customer:

This notification is intended to notify your facility of a rare potential for sample misidentification under certain unusual circumstances identified on the ACL TOP Family 50 Series (software (SW) version 6.3.0 or later) and ACL TOP 970 CL (SW version 1.1.0).

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	
00000280097	08430793045476	ACL TOP 970 CL	1.1.0

• Issue Description and Impact

Our investigation into reported customer complaints identified that a sample misidentification could occur if the customer performs the following actions listed below within a small window of time.

All the following conditions must be true:

- User introduces a sample rack in any of the sample track positions on the ACL TOP Family 50 Series/ACL TOP 970 CL 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.

- **Mandatory Customer Actions**

Based on the above please take one of the following ***immediate*** workflows to mitigate this issue.

To avoid the potential sample misidentification, users should **not** change any samples in the sample rack that have been properly identified. If the user decides they must remove a sample from a sample rack that has been properly identified by the ACL TOP Family 50 Series/ACL TOP 970 CL Instrument, they may do so only after the bar code reader has returned to the home position or the samples have been completely resulted. Alternatively, a user may remove a properly identified sample from a sample rack and must leave that sample rack position empty.

- **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.
- **Retain** a copy of this notification for your records.
- **Complete and return** the Response Tracking Form to acknowledge the above actions.

We appreciate your prompt attention to this important notification.

Sincerely,

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