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UPDATED- URGENT FIELD SAFETY NOTICE

Potential Carryover Issue Identified with a Specific Reagent Combination:
ACL TOP 300 CTS, ACL TOP 350 CTS, ACL TOP 500 CTS, ACL TOP 550 CTS, and ACL TOP 970 CL

9 Sept, 2022

Dear Valued ACL TOP 300 CTS/350 CTS/500 CTS/550 CTS/970 CL Customer:

This updated notification is intended to further clarify the Mandatory Customer Actions for the potential carryover issue identified on the following ACL TOP systems (previous FIELD SAFETY NOTICE letter dated Feb 22, 2022), when running a specific reagent combination:

Part Nos.	UDI	Model Names	
00000280060	08426950556916	ACL TOP 300 CTS	
00000280060R	08426950928027	ACL TOP 300 CTS (Refurbished)	
00000280065	08426950784081	ACL TOP 350 CTS	
00000280040	08426950453499	ACL TOP 500 CTS	
00000280040R	08426950928003	ACL TOP 500 CTS (Refurbished)	
00000280045	08426950729242	ACL TOP 550 CTS	
00000280097	08430793045476	ACL TOP 970 CL*	

- **Issue Description and Impact**

As previously stated, the potential carryover issue may cause elevated quality control and sample results for heparin, apixaban, or rivaroxaban when HemosIL Liquid Anti-Xa reagent is used in the same run ***with both*** HemosIL Liquid Antithrombin and HemosIL Q.F.A. Thrombin (Bovine). This potential carryover issue is specific to instrument models that utilize a single reagent probe. This instrument issue may not occur on every instrument.

Subsequent investigations have shown that the carryover issue only has the possibility of occurring if QFA Fibrinogen, Liquid Antithrombin, and Liquid Anti-Xa reagent aspirations occur in a specific sequence.

Part Nos.	UDI	Reagent Names
0020302600	08426950580324	HemosIL Liquid Anti-Xa
0020302601*	08426950808855	
0020302602*	00195226000016	
0020030100	08426950358701	HemosIL Liquid Antithrombin
0020300400	08426950440802	
0020300440	00195226000061	
0020301700	08426950573494	HemosIL Q.F.A. Thrombin (Bovine)
0020301800	08426950573500	

Note: HemosIL Liquid Antithrombin Part No. 0020002500, is not configured for the ACL TOP.

*Part numbers not available in all countries

- **Mandatory Customer Actions**

Based on the above**,** we are revising the instruction to not run HemosIL Liquid Anti-Xa in the same batch as both HemosIL Liquid Antithrombin and HemosIL Q.F.A. Thrombin (Bovine).

Please take one of the following ***immediate*** workflows to mitigate this potential carryover issue.

Revised Instructions:

1. **Use Separate instruments** to run Liquid Anti-Xa and Liquid Antithrombin.
2. **Batch Liquid Antithrombin.**: Run Liquid Antithrombin tests in isolation (analyzer status starting and ending in a READY state).
3. **Batch Anti-Xa, Apixaban and Rivaroxaban testing.** Run the maintenance activity "Enhanced Clean for Reagent Probe" or "Enhanced Clean for All Probes" from the maintenance menu, then run Liquid Anti-Xa (heparin), apixaban, and rivaroxaban tests in isolation (analyzer status starting and ending in a READY state).

- **Share** this information with your laboratory staff and follow your internal procedures.
- **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.

We will provide follow-up guidance when additional information is available.

We appreciate your prompt attention to this important notification.

Sincerely,

Reba Daoust
Regulatory Affairs Manager II
Instrumentation Laboratory Co.