



URGENT MEDICAL DEVICE CORRECTION

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

February 22, 2022

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

This notification is intended to advise your facility regarding a potential carryover issue recently identified on the following ACL TOP Family, ACL TOP Family 50 Series models, 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

• Issue Description and Impact

We have become aware of a potential carryover issue that 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 does not occur on every instrument. Our internal investigation has confirmed that the issue only occurs when HemosIL Liquid Anti-Xa is run in combination with both of the following reagents:

Part Nos.	UDI	Reagent Names
0020302600	08426950580324	HemosIL Liquid Anti-Xa
0020302601	08426950808855	
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.

• Mandatory Customer Actions

Based on the above, please take the following **immediate** actions to mitigate the potential carryover issue:

- **Do Not** run HemosIL Liquid Anti-Xa in the same batch as **both** HemosIL Liquid Antithrombin **and** HemosIL Q.F.A. Thrombin (Bovine).
- **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.
- **Complete and return** the Mandatory Response Tracking Form to acknowledge the above actions.

• Mandatory Response Tracking Record

- Return the completed and signed Mandatory Response Tracking Form to:
 - Fax No.: +353 1 2952333
 - Or
 - E-mail: Quality@brennanco.ie

• Contact Information for Questions

- For technical questions, please contact the Werfen Technical Support Center at 1-800-678-0710, Option # 1 (ACL Coagulation Products).

We are actively investigating this potential carryover issue and 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.