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UPDATED URGENT FIELD SAFETY NOTICE

HEMOSIL® LIQUID ANTI-XA, PART NOS. 0020302600 AND 0020302601 ALL LOTS
ACL TOP® FAMILY / ACL TOP® FAMILY 50 SERIES

March 15, 2023

Dear Valued HemosIL Liquid Anti-Xa Customer:

This notification is intended to advise your facility regarding an on-board instrument stability issue that affects all currently released lots, as well as future lots, of HemosIL Liquid Anti-Xa (Part Nos. 0020302600 and 0020302601) on the ACL TOP Family and ACL TOP Family 50 Series hemostasis testing systems.

Below is a list of all in-date product lots:

Product Name	Part No.	Lot No.	Exp. Date
HemosIL Liquid Anti-Xa	0020302600	N0806737	02/28/2023
		N1008103	04/30/2023
		N0311874	09/30/2023
		N0614235	12/31/2023
		N0916387	03/31/2024
		N0129118	07/31/2024
		N0522357	11/30/2024
		N1026479	03/31/2025
		N0138733	07/31/2025
	0020302601	N1007812	04/30/2023
		N0513383	11/30/2023
		N0715001	01/31/2024
		N1016744	04/30/2024
		N0229907	08/31/2024
		N0723871	01/31/2025
		N0825047	02/28/2025

- **Issue Description and Results Impact**

We have internally identified that HemosIL Liquid Anti-Xa (Part Nos. 0020302600 and 0020302601) is not meeting its labeled on-board instrument stability claim for the heparin assay of 7 days at 15-25°C for the ACL TOP Family and ACL TOP Family 50 Series. Initial testing supported a 5 day on-board stability claim, documented in our previous notification dated August 25, 2021; however, we received clearance for the HemosIL Liquid Anti-Xa with a reduced stability claim of 4 days at 15-25°C.

There are no known customer complaints to date. However, if an erroneous heparin result were to occur, there is a risk that a dose adjustment could be made if the result was to exceed an Anti-Xa threshold as defined by the internal procedures. The harm would be limited to risks associated with blood collection rather than a more serious complication.

- **Customer Actions**

At this time, we are updating the previous notification, dated August 25, 2021, of on-board stability reduction from 7 days to 5 days. The **on-board instrument stability claim has been reduced to 4 days** for **all in-date and future product lots** of HemosIL Liquid Anti-Xa (Part Nos. 0020302600 and 0020302601) on the ACL TOP Family and ACL TOP Family 50 Series. Please use the reduced on-board stability until a new ACL TOP Family/ACL TOP Family 50 Series Test Parameter reflecting this change is available.

Please take the following **immediate** actions:

- **Use** the following **reduced on-board instrument stability claim** for HemosIL Liquid Anti-Xa (Part Nos. 0020302600 and 0020302601) on the **ACL TOP Family and ACL TOP Family 50 Series**.

ACL TOP Family and ACL TOP Family 50 Series	
***Current* IFU On-board Instrument Stability**	***Reduced* On-board Instrument Stability**
7 Days	4 Days

- **Run** quality controls on ACL TOP Family and ACL TOP Family 50 Series before patient testing or every 8 hours and with each new vial in accordance with good laboratory practice.
- **Post** this notification on each of your ACL TOP Family / ACL TOP Family 50 Series instruments.
- **Share** this information with your staff, notifying them of the reduced on-board stability requirement of 4 Days for the ACL TOP Family and ACL TOP Family 50 Series.
- **Retain** a copy of this letter in your files as a record of the notification.

Please contact your local representative with any questions.

We appreciate your prompt attention to this important notification.

Sincerely,

[redacted]

Regulatory Affairs Manager II