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IMPORTANT PRODUCT NOTICE

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

August 25, 2021

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 / ACL TOP Family 50 Series and ACL Elite and ACL Elite Pro 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	N0495119	10/31/2021
		N0696580	12/31/2021
		N1098983	04/30/2022
		N1099582	04/30/2022
		N0100838	07/31/2022
		N0302437	09/30/2022
		N0604946	12/31/2022
		N0806737	02/28/2023
		N1008103	04/30/2023
		N0311874	09/30/2023
		N0614235	12/31/2023
	0020302601	N0797525	01/31/2022
		N1099574	04/30/2022
		N0403391	09/30/2022
		N0705566	12/31/2022
		N1007812	04/30/2023
		N0513383	11/30/2023

- **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 nor the on-board instrument stability claim for the heparin assay of 3 days at 15°C for the ACL Elite and ACL Elite Pro.

Our investigation has concluded that HemosIL Liquid Anti-Xa is stable for 5 days only for the heparin assay at 15-25°C on-board ACL TOP Family and ACL TOP Family 50 Series and not meeting claims on the ACL Elite and ACL Elite Pro.

Therefore, we are reducing the ACL TOP Family and ACL TOP Family 50 Series on-board instrument claims for HemosIL Liquid Anti-Xa from 7 days to 5 days. For ACL Elite and ACL Elite Pro instruments, HemosIL Liquid Anti-Xa assay claims are being removed.

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 institutional protocol. The harm would be limited to risks associated with blood collection rather than a more serious complication.

- **Customer Actions**

At this time, the **on-board instrument stability claim has been reduced from 7 days to 5 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. IL has taken the commercial decision to **remove claims** for HemosIL Liquid Anti-Xa (Part Nos. 0020302600 and 0020302601) from the ACL Elite and ACL Elite Pro Instruments.

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* On-board Instrument Stability**	***Reduced* On-board Instrument Stability**
7 Days	5 Days

- **Discontinue use** of HemosIL Liquid Anti-Xa (Part Nos. 0020302600 and 0020302601) on the **ACL Elite and ACL Elite Pro**.
- **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 and/or ACL Elite, ACL Elite Pro instruments.
- **Share** this information with your staff, notifying them of the reduced on-board stability requirement of 5 Days for the ACL TOP Family and ACL TOP Family 50 Series and/or notifying them to immediately discontinue use of HemosIL Liquid Anti-Xa (Part Nos. 0020302600 and 0020302601) on the ACL Elite and ACL Elite Pro.
- **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,
Reba Daoust
Reba Daoust
Regulatory Affairs Manager II