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IMPORTANT PRODUCT NOTICE

HemosIL Quality Controls (See Product List Below):
Discontinuation of Reconstituted Stability Claims at 2-8°C

August 6, 2025

Dear Valued HemosIL® Quality Control Customer:

This notification is intended to inform your facility that, moving forward, Werfen will no longer support the labeled 2-8°C reconstituted stability claims for the HemosIL quality control products listed in the table below. This change will be effective with the lot numbers indicated and for all subsequent lots.

Part No.	Product Name	UDI-DI	Discontinuation of 2-8°C Reconstituted Claims	Effective from Lot No. Forward
0020003110	HemosIL Normal Control Assayed	08426950071068	24 hours at 2-8°C: PT, Fibrinogen, APTT, TT, Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C and Protein S and 8 Hours at 2-8°C: Factors	N0451813
0020003210	HemosIL Low Abnormal Control Assayed	08426950078982	24 hours at 2-8°C: PT, Fibrinogen, APTT, TT, Antithrombin, Protein C and Protein S	N0653527
0020003310	HemosIL High Abnormal Control Assayed	08426950078999	24 hours at 2-8°C: PT and APTT	N0653807
0020004200	HemosIL Low Fibrinogen Control	08426950451976	24 hours at 2-8°C: Fibrinogen	N0754771
0020013900	HemosIL Normal Control 1	08426950660651	24 hours at 2-8°C: PT, APTT, TT, Fibrinogen, and Antithrombin	N0653541
0020014000	HemosIL Abnormal Control 2	08426950660668	24 hours at 2-8°C: PT, APTT, TT, Fibrinogen, and Antithrombin	Lot No. Pending
0020014100	HemosIL Abnormal Control 3	08426950660675	24 hours at 2-8°C: PT and APTT	N0653520

Notes: Until the Instructions for Use (IFUs) are formally updated in future lots to remove the 2-8°C reconstituted stability claims, the above lots and new production lots will include a sticker on the outer box advising customers: "Do not store reconstituted controls at 2-8°C."

HemosIL Normal Control 1, HemosIL Abnormal Control 2, and HemosIL Abnormal Control 3 are not available in all countries.

The next lot of HemosIL Abnormal Control 2 is not scheduled to be manufactured until the end of 2025.

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Issue Description and Scope

Werfen has determined that the 2-8°C reconstituted stability claims for the HemosIL quality control products listed above will no longer be supported, effective with the lot numbers indicated, and will be removed from the respective Instructions for Use (IFUs) in future lots. This decision was made as part of our ongoing commitment to ensure that labeled stability claims remain accurate and consistently supportable.

It is important to note that this change does not affect lots manufactured prior to those listed, which continue to be supported in accordance with the reconstituted 2-8°C stability claims currently stated in their respective IFUs.

All other stability claims provided in the respective IFUs remain unchanged.

Mandatory Customer Actions

Please take the following actions immediately:

- **Post** this notification on each of your ACL Elite, ACL Elite Pro, ACL TOP Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series instruments.
- From the listed lots forward, **do not store controls at 2–8°C after reconstitution.**
- **Inform** your laboratory staff about this notification.
- **Forward** this notification to all affected departments and locations within your facility.
- **Retain** a copy of this notification for your records.

Your prompt attention to this Medical Device Correction is greatly appreciated.

Sincerely,

Carol Marble

Carol Marble
Senior Director of Regulatory Affairs
Instrumentation Laboratory Co. A Werfen Company