### Important Product Notice HemosIL Fibrinogen-C (Part No. 0020301100) and HemosIL Fibrinogen-C XL (Part No. 0020003900) All Lots

# March 26, 2025

# Dear Valued HemosIL® Fibrinogen-C / HemosILFibrinogen-C XL Customer:

This notification is intended to advise your facility regarding an issue with the labeled reconstituted frozen stability claim for HemosIL Fibrinogen-C (Part No. 0020301100, UDI-DI 08426950478676) and HemosIL Fibrinogen-C XL (Part No. 0020003900, UDI-DI 08426950087618) that affects all current in-date lots, as well as future lots. See Appendix A at the end of this notification for a list of in-date product lots.

**Issue Description and Impact**

We internally identified that HemosIL Fibrinogen-C (Part No. 0020301100) and HemosIL Fibrinogen-C XL (Part No. 0020003900) are not meeting the labeled reconstituted frozen stability claim of 1 month at -20°C for the bovine thrombin reagent. Future shipments will contain a sticker that indicates “Do Not Freeze Reconstituted Reagent”.

Note: There is no change to the other labeled reconstituted stability claims for the bovine thrombin reagent of 3 days at 2-8°C and 3 days at 15°C on the ACL TOP® Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series\*.

To date, there are no known customer complaints related to this issue. The performance impact of this stability issue was assessed and determined to be negligible, with no expected impact on patient treatment.

A sticker indicating “Do Not Freeze Reconstituted Reagent” will be on future lots until the IFU of HemosIL Fibrinogen-C and HemosIL Fibrinogen-C XL the “Reagent storage and stability” section of the insert sheets is updated to read “Do Not Freeze Reconstituted Reagent”.

\*ACL TOP Family 70 Series is not available in all countries.

**Mandatory Customer Actions**

Based on the above, please take the following ***immediate*** actions:

* **Check** inventory for HemosIL Fibrinogen-C and HemosIL Fibrinogen-C XL **add** a note “Do Not Freeze Reconstituted Reagent”.
* **Post** this notification on each of your ACL TOP Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series instruments.
* **Share** this information with your laboratory staff, advising them to not freeze the bovine thrombin reagent.
* **Forward** this notification to all affected locations within your facility.
* **Retain** a copy of this notification for your records.

Your prompt attention to this Important Product Notice is greatly appreciated.

Sincerely,

Anuja Khan

Regulatory Affairs Manager II

Instrumentation Laboratory Co.

A Werfen Company

**Appendix A**

**In-Date Lots**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product** | **Part No.** | **Lot No.** | **Manufactured  Date (YYYY/MM/DD)** | **Expiration  Date (YYYY/MM/DD)** | **UDI** |
| HemosIL Fibrinogen-C | 0020301100 | N0239545 | 4/1/2023 | 3/31/2025 | 08426950478676 |
| N0733582 | 8/1/2023 | 7/31/2025 |
| N0835086 | 9/1/2023 | 8/31/2025 |
| N0148399 | 2/1/2024 | 1/31/2026 |
| N0340225 | 4/1/2024 | 3/31/2026 |
| N0643236 | 7/1/2024 | 6/30/2026 |
| N0844841 | 9/1/2024 | 8/31/2026 |
| N0158698 | 2/1/2025 | 1/31/2027 |
| N0159334 | 2/1/2025 | 1/31/2027 |
| HemosIL Fibrinogen-C XL | 0020003900 | N0330535 | 4/1/2023 | 3/31/2025 | 08426950087618 |
| N0431095 | 5/1/2023 | 4/30/2025 |
| N0733569 | 8/1/2023 | 7/31/2025 |
| N0834226 | 9/1/2023 | 8/31/2025 |
| N0935104 | 10/1/2023 | 9/30/2025 |
| N1136731 | 12/1/2023 | 11/30/2025 |
| N0249519 | 2/29/2024 | 2/28/2026 |
| N0441745 | 5/1/2024 | 4/30/2026 |
| N0643232 | 7/1/2024 | 6/30/2026 |
| N0743954 | 8/1/2024 | 7/31/2026 |
| N0743976 | 9/1/2024 | 8/31/2026 |
| N0946184 | 10/1/2024 | 9/30/2026 |
| N1046534 | 11/1/2024 | 10/31/2026 |
| N1147340 | 12/1/2024 | 11/30/2026 |
| N1248401 | 1/1/2025 | 12/31/2026 |
| N1248443 | 1/1/2025 | 12/31/2026 |
| N0159332 | 2/1/2025 | 1/31/2027 |
| N0259994 | 3/1/2025 | 2/28/2027 |