



URGENT FIELD SAFETY NOTICE

**HemosIL® AcuStar ADAMTS13 Activity, Part Number 0009802048,
All Product Lots**

February 4th, 2022

Dear Valued HemosIL AcuStar ADAMTS13 Activity Customer:

This notification is issued to advise your facility regarding a potential performance issue identified with HemosIL AcuStar ADAMTS13 Activity assay (Part No. 0009802048) that may affect all currently released product lots.

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

Product Name	Part Number	Lot Number	Manufacture Date (YYYY-MM-DD)	Expiration Date (YYYY-MM-DD)
HemosIL AcuStar ADAMTS13 Activity	0009802048	B33919	2021-03-12	2022-03-01
		B34173	2021-06-21	2022-06-16
		B34353	2021-09-03	2022-09-01
		B34520	2021-11-09	2022-11-01

• Issue Description and Impact

We have received customer complaints of patient sample results reporting below the normal range (with a subset < 10% activity) with the HemosIL AcuStar ADAMTS13 Activity assay and, in some cases these same patient samples were later tested with FRET or ELISA assays, with results reporting higher percent activity.

As indicated in the instructions for use, the HemosIL AcuStar ADAMTS13 Activity assay is labeled as an aid in the diagnosis and monitoring of Thrombotic Thrombocytopenic Purpura (TTP). The assay results should be used in conjunction with other clinical and laboratory findings.

<ul style="list-style-type: none">• Mandatory Customer Actions

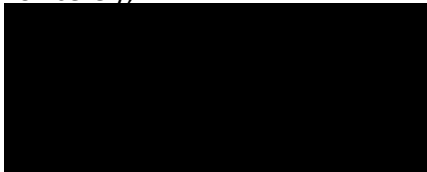
Based on the potential performance issue with HemosIL AcuStar ADAMTS13 Activity assay (Part No. 0009802048), please take the following **immediate** actions:

- **Evaluate** patient sample results using the HemosIL AcuStar ADAMTS13 Activity assay in conjunction with other clinical and laboratory findings prior to taking clinical action. Refer to current guidance for recommendations on diagnosis and management of TTP for additional information. See references below.
- **Assess** the need to perform additional testing for patient samples that may be discordant from other clinical and laboratory findings.
- **Share** this information with your laboratory staff and follow your internal procedures.
- **Forward** this notification to all affected locations within your facility.
- **Retain** a copy of this notification for your records.

We are actively investigating this potential performance issue and will provide follow-up guidance when additional information is available.

We appreciate your prompt attention to this important Field Safety Notification.

Sincerely,



Regulatory Affairs Manager II
Instrumentation Laboratory Co.

References:

Scully M, Hunt BJ, Benjamin S, *et al.* Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies. *Br J Haematol.* 2012; 158: 323-335.

Zheng XL, Vesely SK, Cataland SR, *et al.* ISTH guidelines for the diagnosis of thrombotic thrombocytopenic purpura. *J Thromb Haemost.* 2020;18:2486-2495.

Zheng XL, Vesely SK, Cataland SR, *et al.* ISTH guidelines for treatment of thrombotic thrombocytopenic purpura. *J Thromb Haemost.* 2020;18:2496-2502

Mackie I, Mancini I, Muia J, *et al.* International Council for Standardization in Haematology (ICSH) recommendations for laboratory measurement of ADAMTS13. *Int J Lab Hematol.* 2020;42:685-696.

Mingot Castellano ME, Pascual Izquierdo C, González A, *et al.* Recommendations for the diagnosis and treatment of patients with thrombotic thrombocytopenic purpura. *Med Clin (Barc).* 2021;S0025-7753(21)00332-8