



**UPDATED-URGENT FIELD SAFETY NOTICE**

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

November 2022

Dear Valued HemosIL AcuStar ADAMTS13 Activity Customer:

This updated notification is to advise your facility regarding additional actions we are taking for a potential performance issue identified with HemosIL AcuStar ADAMTS13 Activity (Part No. 0009802048) that may affect all currently released product lots.

Your Werfen Representative will apply a comment to your instrument, that will flag all results  $\leq 10\%$  with the following notification "Assay intended for diagnosis and monitoring of TTP. Check sample integrity and verify results against other clinical and laboratory findings prior to reporting".

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	B34776	2022-02-18	2023-02-01
		B34881	2022-03-28	2023-03-16
		B35222	2022-10-07	2023-08-01
		B35406	2022-10-28	2023-10-16

**• Issue Description and Impact**

We have received customer complaints of patient sample results reporting below the normal range (with a subset < 10% activity) with HemosIL AcuStar ADAMTS13 Activity 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, HemosIL AcuStar ADAMTS13 Activity 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.

**• Mandatory Actions**



**Werfen:** A Werfen Representative will apply a comment to your instrument, that will flag all results  $\leq 10\%$  with the following notification **“Assay intended for diagnosis and monitoring of TTP. Check sample integrity and verify results against other clinical and laboratory findings prior to reporting”**.

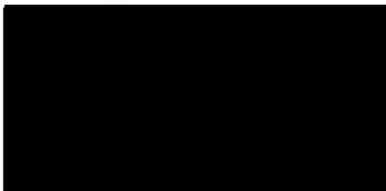
**Customer:** Based on the potential performance issue the initial notification requested the following **immediate** actions for HemosIL AcuStar ADAMTS13 Activity (Part No. 0009802048):

- **Evaluate** patient sample results using the HemosIL AcuStar ADAMTS13 Activity 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** patient samples that may be discordant from other clinical and laboratory findings.
- **Share** this information with your laboratory staff and follow your internal procedures.
- **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,



Instrumentation Laboratory Co.