



**IMPORTANT PRODUCT NOTICE**

**MANDATORY TEST PARAMETERS UPGRADE ON ACL TOP FAMILY, ACL TOP FAMILY 50 Series, ACL TOP FAMILY 70 Series**

April 28, 2025

Dear Valued Customer:

This notification is to advise your facility about a reagent carryover issue on the ACL TOP Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series systems from the HemosIL D-Dimer HS 500 (Part No. 0020500100/0020500300; UDI-DI 8426950485605/08426951391615) into the HemosIL Free Protein S assay (Part No. 0020002700, UDI-DI 08426950070320). Mandatory Parameters released through this notification are to mitigate the carryover from D-DimerHS500 (DDHS500) assay into the Free Protein S (Free PS) assay.

**Mandatory Parameters**

Mandatory Parameters P-16.8.03 for the ACL TOP Family (SW 5.2.0), P-18.8.04 (SW 6.4.2) and P-18.6.07 (SW 6.5.3) for the ACL TOP Family 50 Series and P-22.1.02 (SW 1.4.0) or a higher version for the ACL TOP Family 70 Series contain the final mitigations to address this carryover issue.

The following instrument models are included under each Family of Instruments:

The **ACL TOP Family**: includes the ACL TOP, ACL TOP CTS, ACL TOP 700, ACL TOP 700 CTS, ACL TOP 700 LAS, ACL TOP 500 CTS, ACL TOP 300 CTS models.

The **ACL TOP Family 50 Series**: includes the ACL TOP 750; ACL TOP 750 CTS; ACL TOP 750 LAS; ACL TOP 550 CTS; ACL TOP 350 CTS models.

The **ACL TOP Family 70 Series**: includes the ACL TOP 770, 770s, 770 LAS, 570 and 370 models.

**Reason for the Mandatory Parameter Upgrade**

We have become aware of a potential carryover issue that may cause elevated quality control and sample results when HemosIL Free Protein S (Part No. 0020002700) is tested in the same run as HemosIL D-Dimer HS 500 (Part No. 0020500100/0020500300). The reagent carryover may result in a falsely higher Free Protein S result increasing the risk of excluding a protein S deficiency. However, a misclassification is not likely to result in harm to the patient that requires medical or surgical intervention.



### **Mandatory Customer Actions**

Customers are requested to take the following action:

- **Share** this information with your laboratory staff and update your internal procedures, as needed.
- **Forward** this notification to all affected locations in your facility.
- **Post** this notification on all affected systems in your facility.
- **Contact** your local Werfen Representative to install the Mandatory Test Parameters at your next service or applications visit, no later than December 30, 2026
- **Retain** a copy of this notification for your records.

We appreciate your prompt attention to this Important Product Defect Correction notice.

Sincerely,

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Anuja Khan  
Regulatory Affairs Manager II  
Instrumentation Laboratory Company  
A Werfen Company