



Circular No. 8 / 2025

بتقدم بثقة
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27 -07-1446 H

27 -01-2025

Field Safety Notice of HemosIL Heparin Calibrators from Werfen.

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| Source | SFDA- Saudi Food & Drug Authority https://ade.sfda.gov.sa/Fsca/PublishDetails/231 |
| Product | HemosIL Heparin Calibrators. |
| Manufacturer | Werfen. |
| Local agent | Muscat Pharmacy & Stores LLC. |
| The affected products | Part No. 0020300600. UDI-DI: 08426950472483. Please see Appendix A of the attachment for a list of in-date lots with corrected value assignments for the HEP CAL 2 and HEP CAL 3 levels. |
| Reason | The potential of heparin controls reporting low out of their assigned acceptance range with HemosIL Liquid Anti-Xa (Part Nos. 0020302600, 0020302602, 0020303600), leading to delays in patient testing. |
| Action | 1. Please follow "Mandatory Customer Actions" in the attachment. 2. Contact the local agent for remedial action. |
| comments | Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om |

Dr. Mohammed Hamdan Al Rubaie
Director General





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To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 8 dated 27/1/2025 Regarding SFDA Field Safety Notice of HemosIL Heparin Calibrators from (mfr: Werfen).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



URGENT FIELD SAFETY NOTICE

HemosIL Heparin Calibrators

Part No. 0020300600 – All In-Date Lots (See Appendix A)

December 18, 2024

Dear Valued HemosIL® Liquid Anti-Xa Customer:

This notification is intended to advise your facility regarding an unfractionated heparin (UFH) and low molecular weight heparin (LMWH) performance issue with HemosIL Liquid Anti-Xa (Part Nos. 0020302600, 0020302602, 0020303600) that is due to a bias against the WHO International Standards for UFH and LMWH with in-date lots of HemosIL Heparin Calibrators (Part No. 0020300600, UDI-DI 08426950472483).

See Appendix A at the end of this notification for a list of in-date calibrator lots with corrected values.

Issue Description and Impact

We have received customer complaints of heparin controls reporting low out of their assigned acceptance range with HemosIL Liquid Anti-Xa, leading to delays in patient testing. Our internal investigation has identified that the value assignment of the HemosIL Heparin Calibrators has shown a bias against the WHO International Standards for UFH and LMWH, potentially causing reduced recovery when measuring heparin on both controls and samples.

Note: Apixaban and rivaroxaban measurements with HemosIL Liquid Anti-Xa are unaffected as these tests use different calibrators.

To ensure accurate heparin reporting, customers must follow the instructions below to update the calibrator values for Heparin Calibrator 2 (HEP CAL 2) and Heparin Calibrator 3 (HEP CAL 3) in the ACL TOP test parameters (all instrument models: ACL TOP Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series) using the corrected values provided in Appendix A. The Heparin Calibrator 1 (HEP CAL 1) level remains unchanged as 0.00 IU/mL.

We will also verify the value assignments for on-market lots of HemosIL UF Heparin Controls (Part No. 0020300300) and HemosIL Low Molecular Weight Heparin Controls (Part No. 0020300200) using a representative reagent lot recalibrated based on the corrected HEP CAL 2 and HEP CAL 3 values. If needed, we will provide new acceptance ranges for these controls to you. Until then, perform quality control testing per labeled instructions for use. If the HemosIL UF Heparin Controls or HemosIL Low Molecular Weight Heparin Controls recover out of the lot-specific acceptance ranges, determine your own control ranges per your internal protocol.

werfen

Mandatory Customer Actions

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

- **Check** inventory for lots of HemosIL Heparin Calibrators (Part No. 0020300600). See Appendix A for a list of in-date lots with corrected value assignments for the HEP CAL 2 and HEP CAL 3 levels.
- **Follow** the instructions below to update the ACL TOP test parameters (same instructions for all models):
 - Select "Setup" from the menu bar and then select "Test List" from the dropdown menu.
 - From "Test List", double click on the Test Code "Anti-Xa" to open "Test Definition – Anti-Xa".
 - From "Test Definition – Anti-Xa, click on "Pre-diluted calibrators" under the header "Calibration". An editable table titled "Calibration points" will appear with HEP CAL 1, HEP CAL 2, and HEP CAL 3 and their predefined "Target Values IU/mL" of 0.00, 0.80 and 2.00, respectively.
 - In the "Calibration points" table, change the target values for HEP CAL 2 and HEP CAL 3 to the lot-specific calibrator values provided in Appendix A.
 - After entering the corrected HEP CAL 2 and HEP CAL 3 values, click on the save icon (picture of floppy disk) to save the changes.
- **Recalibrate** using the HemosIL Liquid Anti-Xa assay lot in use after making the test parameter update.
- **Run** quality controls per labeled instructions for use. **If needed, determine** control ranges for HemosIL UF Heparin Controls (Part No. 0020300300) and HemosIL Low Molecular Weight Heparin Controls (Part No. 0020300200) in accordance with your internal protocol until the new acceptance ranges are available.
- **Repeat the above test parameter update, recalibration, and quality control for all ACL TOP instruments.**
- **Share** this information with your laboratory staff.
- **Forward** this notification to all affected locations within your facility.
- **Retain** a copy of this notification for your records.

We appreciate your prompt attention to this Urgent Field Safety Notice.

Sincerely,



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



Appendix A

HemosIL Heparin Calibrators, Part No. 0020300600 (UDI-DI: 08426950472483)

In-date Lots with Corrected HEP CAL 2 and HEP CAL 3 Values

| Lot No. | Manufactured Date (YYYY-MM-DD) | Expiration Date (YYYY-MM-DD) | HEP CAL 2 Corrected Value (IU/mL) | HEP CAL 3 Corrected Value (IU/mL) |
|----------|--------------------------------|------------------------------|-----------------------------------|-----------------------------------|
| N0128933 | 2022-02-01 | 2025-01-31 | 0.88 | 2.15 |
| N0220450 | 2022-03-01 | 2025-02-28 | 0.90 | 2.31 |
| N0522479 | 2022-06-01 | 2025-05-31 | 0.91 | 2.12 |
| N0724070 | 2022-08-01 | 2025-07-31 | 0.86 | 2.21 |
| N1026509 | 2022-11-01 | 2025-10-31 | 0.90 | 2.18 |
| N0239584 | 2023-03-01 | 2026-02-28 | 0.89 | 2.24 |
| N0531891 | 2023-06-01 | 2026-05-31 | 0.88 | 2.23 |
| N0733658 | 2023-08-01 | 2026-07-31 | 0.90 | 2.24 |
| N0249207 | 2024-03-01 | 2027-02-28 | 0.89 | 2.22 |
| N0442161 | 2024-05-01 | 2027-04-30 | 0.87 | 2.24 |
| N0744673 | 2024-08-01 | 2027-07-31 | 0.90 | 2.30 |