Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

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 231 **dated** 29/10/2023 **Regarding NCMDR Field Safety Notice of ACL TOP Family / ACL TOP Family 50 Series from (mfr: Instrumentation Laboratory SpA, a Werfen Company).**

Copy to:

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

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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سلطنة عُمان
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Circular No. 231 / 2023

13 -04-1445 H

29 -10-2023

FSN of ACL TOP Family / ACL TOP Family 50 Series from Instrumentation Laboratory SpA, a Werfen Company.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19743
Product	ACL TOP Family / ACL TOP Family 50 Series.
Description	IVD.
Manufacturer	Instrumentation Laboratory SpA, a Werfen Company
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	ACL TOP FAMILY MODELS: ACL TOP, ACL TOP CTS, ACL TOP 700, ACL TOP 700 CTS, ACL TOP 700 LAS, ACL TOP 500 CTS, ACL TOP 300 CTS; FAMILY 50 SERIES MODELS: ACL TOP 750, ACL TOP 750 CTS, ACL TOP 750 LAS, ACL TOP 550 CTS, ACL TOP 350 CTS
Reason	Mandatory Parameters P-16.8.00 for the ACL TOP Family, and P-18.6.03 and P-18.8.00 for the ACL TOP Family 50 Series, contain the final mitigations to address the following field actions: Reduction of on-board stability claim from 7 days to 4 days for HemosIL® Liquid Anti-Xa. Reduction of on-board stability claim from 3 days to 24 hours for HemosIL® Homocysteine Controls. Updated test definitions to mitigate carryover for HemosIL® Liquid Anti-Xa.
Action	1. Please share this information with your laboratory staff and update your internal procedures, as needed. 2. All customers with ACL TOP Family 50 Series systems with software (SW) versions 6.1.0, 6.2.0, 6.3.0 (Windows 7 OS) must be upgraded to SW 6.4.1 prior to installation of above parameters. For ACL TOP Family 50 Series systems with Windows 10 OS, you must be at SW version 6.5.2 prior to installation of above parameters. All ACL TOP Family customers need to be at a minimum of SW version 5.2.0 to install the Mandatory Test Parameters. 3. Your local Werfen distributor will install the applicable Mandatory Test Parameters at your next scheduled preventative maintenance or service applications visit. 4. 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: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

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