



لتقدم بثقة
Moving Forward
with Confidence



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 281 dated 25/12/23 Regarding NCMDR Field Safety Notice of ACL TOP® Family 50 Series Testing Systems 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



بتقدم بثقة
Moving Forward
with Confidence



Circular No. 281 / 2023

11 -06-1445 H

25-12-2023

FSN of ACL TOP® Family 50 Series Testing Systems 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=19819
Product	ACL TOP® Family 50 Series Testing Systems.
Description	Analyzer for in vitro diagnostic clinical use in hemostasis laboratory for coagulation
Manufacturer	Instrumentation Laboratory SpA, a Werfen Company.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	ACL TOP® Family 50 Series Testing Systems.
Reason	Potential for sample misidentification.
Action	<ol style="list-style-type: none">1. Users should not attempt to change any samples in the sample rack that have been properly identified by the ACL TOP.2. If the user must remove a sample from a sample rack that has been entered on the ACL TOP, they may do so only after the bar code reader has returned to the home position or all the samples on that sample rack have completely resulted.3. Alternatively, if user removes a properly identified sample from a sample rack they must leave that sample rack position empty.4. A future software update will correct this rare potential sample misidentification possibility.5. 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

