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

سلطنة عمان
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.2.4**... dated** 29/01/26 **Regarding NCMDR recall Giemsa Solution Biological stain IVD from of (Mfr: RAL dagnostics)**

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**

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

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

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

Circular No. 24 / 2020

04 -06 1441 H

29 -01-2020

Ref: 15/2020

Recall of Giemsa Solution Biological stain IVD from RAL diagnostics

Source of Recall	NCMDR National Centre for Medical Devices Reporting, SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=15029
Product	Giemsa Solution-Biological stain IVD
Manufacturer	RAL Diagnostics SAS
Local agent	ASTON MEDICAL SUPPLIES L.L.C
The affected products	Lot: I88021, I97523, I63818 sold in 1 Litre bottles under reference Model: 75030SX1000
Reason for Recall	These affected lots has a staining defect which could appear depending on the method used and result in staining that may be either too dark or too pale
Action	1. Kindly check your stock, contact your local agent for remedial action 2. withdrawn and destroyed your stock
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical Device to Director of Medical Device Control contact E-mail dg-padc@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

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

RAL
DIAGNOSTICS

Martillac, 06 December 2019

Subject : Security information n°R1916718 ANSM

Dear Madam, Dear Sir,

We hereby confirm that the Giemsa Solution lot I88021, lot I97523 and lot I63818 has a staining defect which could appear depending on the method used and result in stainings that may be either too dark or too pale.

These lots of Giemsa have been sold in 1 Litre bottles under the reference 75030SX1000 and are being recalled.

Therefore, all bottles that you have in stock must be withdrawn and destroyed.
You will find below a destruction certificate to be filled in and sent to your distributor. The products will be replaced as soon as possible.

The ANSM (French National Authority) has been informed of this communication.

Be assured of our total commitment in solving this problem and in the satisfaction of our clients.

Sandrine SAUVIGNON
Quality, Health, Safety and Environment Director

RAL DIAGNOSTICS
RAL Diagnostics
Site Montesquieu 33650 Martillac
www.ral-diagnostics.fr
T +33 (0)5 57 96 04 04
F +33 (0)5 57 96 04 05
Siret 449 261 403 000 41 | Code APE 2059 Z
TVA intracommunautaire : FR67449261403