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.** 52 **dated** 21/3/12 **regarding recall of In-vitro diagnostics - microbiological products from Siemens Healthcare**

**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**

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

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**Circular No.** 52 **/ 2020**

07 -07-1441 H

02 -03-2020

Ref: 40/2020

## Recall of In-vitro diagnostics - microbiological products from Siemens Healthcare

| | |
|---|---|
| **Source of Recall** | **NCMDR National Centre for Medical Devices Reporting, SFDA**<br>https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=15061 |
| **Product** | IMMULITE 2000/IMMULITE 2000 XPi EBV-VCA IgM-In-vitro diagnostics - microbiological products |
| **Manufacturer** | Siemens Healthcare Diagnostics Product |
| **Local Agent** | New Source |
| **The affected products** | Test Code: ECM<br>Catalog: L2KEM2<br>SMN: 10488005<br>Lot: 355 |
| **Reason for Recall** | Siemens Healthcare Diagnostics Inc. has confirmed the potential for an increase in within run and within laboratory imprecision on Siemens' EBV-VCA IgM Control Module quality control material and patient samples with EBV-VCA IgM on the IMMULITE® 2000/IMMULITE® 2000 XPi Systems<br>These samples may exhibit higher percent coefficient of variation (%CV) than the precision performance data published in the Instructions For Use across nonreactive, indeterminate and reactive S/CO ratios. The imprecision is especially evident on quality control material and samples that are close to the indeterminate range (0.9 to 1.0 S/CO ratio) of the assay. The imprecision may cause the interpretation of a sample that is nonreactive to be indeterminate or reactive and a sample that is reactive to be nonreactive or indeterminate. |
| **Action** | 1. Kindly check your stock, contact your 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 Director of Medical Device Control<br>contact E-mail dg-padc@moh.gov.om |

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

**Dr. Mohammed Hamdan Al Rubaie**

**DIRECTOR GENERAL**

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