Sultanate of Oman Ministry of Health Drug Safety Center Muscat



سلطنة عُمـان وزارة الصحـة مركز سلامة الـدواء 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 14 dated 10 16 2025 Regarding SFDA Recall of Access Testosterone Reagent Kit from (mfr: Beckman Coulter Inc).

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





Sultanate of Oman Ministry of Health Drug Safety Center Muscat



سلطنة عُمان وزارة الصحة مركز سلامة الدواء مسقط

Circular No.

114/2025 / Double of Moving Forward with Confidence

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Recall of Access Testosterone Reagent Kit from Beckman Coulter Inc.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/375
Product	Access Testosterone Reagent Kit.
Manufacturer	Beckman Coulter Inc.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	REF: 33560 Lot: 538081 Expiry Date: 31-Jan-2026.
Reason	The affected products may have experienced cross-contamination between reagent pack wells during manufacturing.
Action	 Discontinue using and discard all remaining Access Testosterone reagent packs from the lot listed above. Beckman Coulter recommends performing a retrospective review on patient results generated with the Access Testosterone lot listed above and assessing the need for retesting. Contact your local Beckman Coulter distitubutor for replacement product requests.
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

Ph. Ibrahim Nasser Al Rashdi OMAN Director General





