



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 217 dated 23/10/2023 Regarding NCMDR recall of Specific Lots of VENTANA anti-ALK (D5F3) Antibody from (mfr: Roche Diagnostics GmbH).

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





Circular No. 217 / 2023

نتقدم بثقة
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2040
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23 -10-2023

Recall of Specific Lots of VENTANA anti-ALK (D5F3) Antibody from Roche Diagnostics GmbH

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19724
Product	Specific Lots of VENTANA anti-ALK (D5F3) Antibody.
Description	An in vitro diagnostic medical device (IVD).
Manufacturer	Roche Diagnostics GmbH.
Local Agent	National Pharmacy LLC.
The affected products	Product name (part number): - VENTANA ALK (D5F3) CDx Assay (06687199001 / 790-4796); - VENTANA anti-ALK (D5F3) Rabbit Monoclonal Primary Antibody (06679072001 / 790-4794). Lot numbers: H35641, H36978, J01547, J06534 and J11153 Please refer to the attachment for manufacturing, labeled expiration & 14 month short dates.
Reason	It has been observed light staining during routine internal Stability & Surveillance monitoring by the manufacturer of above products.
Action	1. Customers should discontinue use and discard any remaining inventory of lots Mentioned above. 2. It is recommended that customers review patient samples tested after the shortened expiry date and retest any clinically diagnosed negative VENTANA anti-ALK (D5F3) results, especially where only appendix is being utilized as a positive tissue control. 3. 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

