



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. 44..... dated 28/2/22. Regarding NCMDR recall of Thermo Scientific QMS Tacrolimus Calibrator from (mrf: Thermo Fisher Scientific O).

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. 44 / 2022

27-07-1443 H

28 -02-2022

بمقدم بثقة
Moving Forward
with Confidence



Recall of Thermo Scientific QMS Tacrolimus Calibrator from Thermo Fisher Scientific O.

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=16038
Product	Thermo Scientific QMS Tacrolimus Calibrator.
Description	In-vitro diagnostics - equipment / products for clinical chemistry
Manufacturer	Thermo Fisher Scientific O.
Affected	Catalog number 10015573, lot number 74085025 (expired), 74175462 or 74267412.
Local Agent	National Pharmacy LLC.
Reason	Thermo Scientific™ QMS® Tacrolimus Calibrator, catalog number 10015573, lot numbers 74175462, 74267412, and 74085025 (expired) are recovering between 82 – 94% of their target values, resulting in over-quantitation in patient result values.
Action	<ol style="list-style-type: none">1. Call Technical Service, if assistance is needed for lot replacement (free of charge).2. Discontinue use of affected in-date lots, and transition to new lot(s) where corrections have been made. Lot 74395275 and Lot 74459127 have had the testing correction applied and are currently available in stock to replace any of your remaining inventory of lots 74175462 or 74267412.3. Dispose of the effected lots.4. Contact the local agent for remedial action.
Product Image	
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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

