



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khouth & 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 133 dated 21/6/2023 Regarding NCMDR Field Safety Corrective Action of CALiaGold® Calibrator, CALiaGold® Control Set, CALiaGold® Sample Diluent from (mfr: Sentinel.CH.SpA).

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. 133/2023

تقدم بثقة
Going Forward
With Confidence



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21 -06-2023

Recall of CALiaGold® Calibrator, CALiaGold® Control Set, CALiaGold® Sample Diluent from Sentinel.CH.SpA.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19569
Product	CALiaGold® Calibrator, CALiaGold® Control Set, CALiaGold® Sample Diluent.
Description	IVD.
Manufacturer	Sentinel.CH.SpA.
The affected products	- CALiaGold® Calibrator; Reference number: 1151100; Lot Number: 20282, 20361, 20626, 21024; Expiration Date: 05/2023, 08/2023, 10/2023, 02/2024 - CALiaGold® Control Set; Reference number: 1151200; Lot Number: 20360, 20363, 20462, 20853, 30590; Expiration Date: 06/2023, 08/2023, 08/2023, 02/2024, 06/2024 - CALiaGold® Sample Diluent; Reference number: 1151400; Lot Number: 20137, 20362, 20627, 30591; Expiration Date: 05/2023, 08/2023, 10/2023, 06/2024 UDI: 08058056682734 SRN – Manufacturer: IT-MF-000012556
Reason	High recovery may be found due to an instability of the materials caused by some detergent lots used in the manufacturing of products mentioned above.
Action	1. Stop using the affected lots mentioned above. 2. 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

