



Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details		
Device Name	CALiaGold® Calibrator	
	CALiaGold® Control Set	
	CALiaGold® Sample Diluent	
Device Model	1151100	
	1151200	
	1151400	
Lot No.	20137	20362
	20282	20462
	20360	20853
	20361	
Manufacturer	Sentinel.CH.SpA	
Country of Origin	Italy	
Reference	<u>Link</u>	
NHRA initiates this FSN due to an instability of the materials caused by some deter		e materials caused by some detergent lots used
Reason of Recall	in the manufacturing of CALiaGold®	
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative	
	General Medical W.L.L at <u>registration.medics@intercol.com</u> to take the necessary action for recall	

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

Recall 2023 0016 07/Jul/2023