

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	VITROS® Chemistry Products Calibrator Kit 20
Device Model	6801704
Lot No.	2022
Manufacturer	QuidelOrtho
Country of Origin	US
Reference	Link
Reason of Recall	NHRA initiates this FSN due to a Potential biased results; Level 5 calibrator exhibited vial to vial variability which may cause a bias for all six affected assays, although to varying magnitudes.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Gulf Corporation for Technology at quality@gctbahrain.com 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