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	Alinity i HIV Ag/Ab Combo Calibrator
Device Model	List No. 08P0701
Lot No.	21292BE00
Manufacturer	Abbott GmbH
Country of Origin	Germany
Reference	https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75019r-eng.php
Reason of Recall	NHRA initiates this FSN due to a manufacturing issue where individual vials of the Alinity i HAVAb IgG Calibrator were mislabeled as Alinity i HIV Ag/Ab Combo Calibrator lot number 21292BE00. Impacted vials can cause invalid calibrations due to low RLU (Relative Light Units) calibrator signals.
Action should be taken	Please stop using the defected product and contact the authorized representative **Wael Pharmacy** at vincent@waelpharmacy.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