

## 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 Immunodiagnostic Products HIV Combo Reagent Pack (ROW) VITROS Immunodiagnostic Products HIV Combo Calibrators (ROW)
Device Model	6842779 6842780
Lot No.	0660 0670 0730 0740 0750 0760
Manufacturer	ORTHO DIAGNOSTIC CLINICS
Country of Origin	UK
Reference	<a href="https://ncmdr.sfda.gov.sa/FileDownload.ashx?f=ca&amp;fid=10777">https://ncmdr.sfda.gov.sa/FileDownload.ashx?f=ca&amp;fid=10777</a>
Reason of Recall	NHRA initiates this FSN due to potential for False Repeat Reactive Results and False Negative Results Reported Using VITROS® Immunodiagnostic Products HIV Combo Reagent Packs
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Gulf Corporation for Technology at <a href="mailto:quality@gctbahrain.com">quality@gctbahrain.com</a> to take the necessary action for recall.

For more information please contact [Medical\\_Devices@nhra.bh](mailto:Medical_Devices@nhra.bh)

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

**For more information please contact [Medical\\_Devices@nhra.bh](mailto:Medical_Devices@nhra.bh)**

Recall 2022 0039