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	LIAISON® Biotrin Parvovirus B19 IgM
Device Model	317010
Lot No.	129080
Manufacturer	Diasorin Italia S.P.A
Country of Origin	Italy
Reference	Link
Reason of Recall	NHRA initiates this FSN due to decreased reactivity in the LIAISON® Biotrin Parvovirus B19 IgM assay (affected lot), which may lead to false negative results—posing a significant risk to vulnerable patients such as pregnant women, immunocompromised individuals, or those with hemolytic conditions
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Gulf corporation for Technology W.L.L 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

Recall 2025 0023

02/Jul/2025