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	LeadCare® Test Kits					
Affected Devices	**Catalog No.**	**Product**	**Lot No**			
	70-6762	LeadCare® II Blood Lead Test Kit	2012M sub-lots***	2018M	2107M**	2114M
			2013M*	2101M**	2109M	7114M
			2014M*	2102M	2110M	2115M
			2015M*	2103M**	2111M	
			2016M*	2105M**	2112M	
			2017M*	2106M**	2113M	
	82-0004 70-8098	LeadCare Plus® Blood Lead Test Kit LeadCare Ultra® Blood Lead Test Kit	2011MU*			
			2104MU**			
			2108MU**			
Manufacturer	**Meridian Bioscience, Inc./ Magellan Diagnostics, Inc**					
Reference	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/magellan-diagnostics-inc-expands-voluntary-recall-leadcarer-test-kits?utm_medium=email&utm_source=govdelivery					

For more information please contact Medical_Devices@nhra.bh

Recall 2021 0054

Device picture	
Reason of Recall	NHRA initiates this FSN due to a significant risk of falsely low results, Obtaining falsely low results may lead to patient harm including delayed puberty, reduced postnatal growth, decreased IQ, and inattention and behavior problems in children.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative to take the necessary action for recall.

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

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