



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	Covid 19-Rapid Test	
Affected Devices	Name	Manufacturer
	HOPEGEN321	Gen Life
	SARS-CoV-2	TIB
	CHILL COVID-19 Antigen Rapid Test	CHIL
	TOP Rapid COVID 19	TOP Biotech
	HOPEGEN	Gen Life
	NowCheck COVID-19 AG Test	BIONOTE
Reference	NHRA	
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	COVID-19 Antigen Tout Kit TOP BIOTECH COVID-19 COVID-	apposable Sweb [(FU

For more information please contact Medical_Devices@nhra.bh

Reason of Recall	NHRA initiates this FSN due to the quality and efficacy of the mentioned rapid tests cannot be guaranteed because they were imported and distributed <u>without</u> NHRA approval and the results of these tests may be inaccurate.	
Action should be taken	Please stop using the above mentioned Rapid Tests and contact the authorized representative Happy	
	Pharmacy info@happypharmacybh.com to take the necessary action for recall.	

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