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	C Reactive Protein Gen 3
Lot No.	452045 / 463518 / 479885 / 490025 / 21125 / 479882 / 490026 / 521123 / 452041 / 463515 / 479881 / 490027 / 521152
Manufacturer	Roche
Country of Origin	USA
Reference	https://www.sfda.gov.sa/sites/default/files/2021-01/%28SG-2101-293-H%29.pdf
Reason of Recall	NHRA initiates this FSN due to higher test imprecision at lower concentration on all cobas c systems. In addition specifically on cobas c 503, a higher frequency of calibration failures due to duplicate error (DUP.E) has been found.
Action should be taken	It is recommended by the manufacturer to switch to the Tina-Quanta C Reactive Protein IV (CRP 4) assay which is not affected. For more information please contact the authorized representative **General Medicals** at registration.medics@intercol.com

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

For more information please contact Medical_Devices@nhra.bh

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