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	PreWash failure after Preparation in Quick Start mode on cobas® e 801 and e 402
Affected Devices	cobas pure e 402 and cobas e 801 analytical unit , cobas pure and cobas pro sample supply unit , cobas pro SSU , cobas 8000 core unit
Manufacturer	Roche Diagnostics
Country of Origin	Germany
Reference	https://laegemiddelstyrelsen.dk/da/nyheder/senest-opdaterede-indhold/~/media/098A21D936F945CC90CB037B3E6832F5.ashx
Reason of Alert	NHRA initiates this FSN due to software issue affecting cobas pure e 402 and cobas pro/cobas 8000 e 801 analytical units. With Quick Start Mode active, the issue may occur when "Rinse Pre-wash Sipper Flow Path" or "Wash Sippers Flow Path"option "Pre-Wash" is performed and the system starts afterwards. It may also occur when "Finalization", "System Wash" or "Wash Sippers Flow Paths" option "All" is performed, and the "Prime System Reagents Flow Path" option "Reagent Probe" is executed later and the system starts afterwards. This may lead to a Pre-Wash assay being washed with PreClean II M diluted with system water at run start and to potentially affected results of some Pre-Wash assays.
Action should be taken	For more information about software update, please contact the authorized representative **General Medical W.L.L** at registration.medics@intercol.com ; meher.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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