Safety Communication رسالة سلامة

Potential for invalid or false positive results.

Device/ Product Description:	Analyzers, Laboratory, Immunoassay	
Brand:	Cobas z 480 Analyzer	
Affected product:	GMMI	05200881001
	Device Identifier	04015630929016
Manufacturer:	Roche Diagnostics GmbH.	
Problem:	Potential for false positive/invalid results due to dirty lenses. Factors that may contribute to dirty lenses are: improper sealing of the AD-plate, age and usage of the instrument, and laboratory environmental conditions.	
Recommendation /Actions:	• Make sure that this document, with accompanying FSNs, are reached to the end-users. • The end-user should follow laboratory standards operation procedure to investigate the potential for false positive results for assays where a change in a result reporting could impact patient management. • Contact the Authorized Representative for required corrective action. For more information, Please click here. If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center	

Devices/Products photo:		
Authorized Representative Details	AR name:	Roche Diagnostics Saudi Arabia Limited
	Assigned Contact Person:	Turki Abdulaziz Bin Juraid
	Mobile/Phone:	0555443544
	Email:	turki.juraid@roche.com