المملكة العربية السعودية
الهيئة العامة للغذاء والدواء
Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication رسالة سلامة

Risk of a false positive result when using the Reagents for the BD MAX™ System.

Device/ Product Description:	SARS-CoV-2 Reagents
Brand:	BD MAX™ System
Affected product:	REFs: 445003 and 445003-01
Manufacturer:	Becton Dickinson (BD)
Problem:	The manufacturer has identified a potential for false positive results when using the Reagents for the BD MAX™ System. A false positive SARS-CoV-2 test result could lead to a delay in diagnosis and potentially cause the patient to be exposed to COVID-19 if they are isolated with an infected individual.
Recommendation /Actions:	**Recommendations for Health Care Providers and Facility Staff:** • Make sure that this document, with accompanying FSNs, are reached to the end-users. • The user Defined Protocol (UDP) threshold for the N2 target in the IFU needs to be revised from 50 RFU to 80 RFU . • Consider any positive result presumptive from tests using the BD SARS-CoV-2 Reagents for the BD Max System. Consider confirming with an alternate authorized test. 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:		
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