

Kingdom of Saudi Arabia عند المملكة الصربية السعودية Saudi Food & Drug Authority

Medical Devices Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الادارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication

رسالة سلامة

Potential risk when using the system with specific software versions

Device/ Product Description:	In-vitro diagnostics - microbiological products		
Affected product:	Model Name:	Accelerate Pheno system.	
Affected product:	Catalogue No.:	10401008, 10301008	
Manufacturer:	Accelerate Diagnostics Inc		
Problem:	Potential risk of very major discrepancies, major discrepancies and/or essential agreement <90% with some organism-antimicrobial combinations as listed below, when using the Accelerate Pheno TM system with software versions 1.4.1 and later.		
Recommendation /Actions:	 Make sure that this document is reached to the end-users. Follow the instructions as indicated in the attached Field Safety Corrective Action. 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 report the problem to SFDA through: NCMDR Vigilance system (19999)unified call center		

SG-2106-334-H 08/06/2021



	Devices/Products photo:		
		AR name:	Creative Healthcare Establishment
F	Authorized	Assigned Contact Person:	Khaled Alressini
	Representative Details	Mobile/Phone:	+(966) 503478751

Email:

SFDA

info@chc.med.sa

SG-2106-334-H 08/06/2021