

المملكة الصربية السحودية Saudi Food & Drug Authority

Medical Devices Sector Surveillance & Biometrics Executive Department قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication

رسالة سلامة

Important information about open vials of Accu-Chek Inform II test strips

Device/ Product Description:	Accu-Chek Inform II test strips		
Affected product:	Part No. 05942861		
Manufacturer:	Roche Diagnostics GmbH.		
Problem:	It is possible that a vial can open in a sealed carton due to the influence of high temperature and humidity; this failure might affect the accuracy of the blood glucose measurement. This may lead unexpected results (such as positively biased, or falsely too high, results).		
Recommendation /Actions:	 Make sure that this document is reached to the end-users. Users are advised to always check vials of test strips before use. Please, do not use the test strips if; Vial is open or damaged before using the test strips for the first time, The cap is not fully closed If you see any damage to the cap or vial, or Anything prevents the cap from closing properly. Please do not perform control testing as instructed in the meter manual. If you have any affected product, please dispose of the test strips immediately. Roche Diagnostics will provide test strip replacements to users who have purchased vials that were open within the sealed carton. 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-2108-344-H 08/08/2021



Image:	ACCU-CHEK® Inform II TESTS CODE 2011-0 47001 REF 05942 GLICOSE CONTROL LEVEL 1 LEVEL 2 14.5	ACCU-CHEK Strips 150 TEST STRIPS 1 CODE CHIP ACCU-CHEK ACCU-CHEK Strips 1 Only for: ACCU-CHEK Inform II ACCU-CHEK Performa Roche Roche
Authorized Representative Details	AR name:	Roche Diagnostics Saudi Arabia Limited
	Assigned Contact Person:	Turki Bin Juraid
	Mobile/Phone:	+(966) 545673111
	Email:	Rdsa.regulatory@roche.com

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