

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:	<ul style="list-style-type: none"> • 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; <ul style="list-style-type: none"> - 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. <p>For more information, please click here.</p> <p>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</p>



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