

Safety Communication

رسالة سلامة

Important information about open vials of Accu-Chek Performa test strips

Device/ Product Description:	Accu-Chek Performa test strips
Manufacturer:	Roche Diabetes Care
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 refrain from using the concerned test strips. • Roche Diabetes Care will provide test strip replacements to users who have purchased vials that were open within the sealed carton. To obtain replacement from Roche Diabetes Care, please call Roche Diabetes Care Customer Care line: 8008500829 <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>

<p>Image:</p>		
<p>Authorized Representative Details</p>	<p>AR name:</p>	<p>FAROUK, MAAMOUN TAMER & COMPANY</p>
	<p>Assigned Contact Person:</p>	<p>AHMED ELMADHOUN</p>
	<p>Mobile/Phone:</p>	<p>+966) 503015881</p>
	<p>Email:</p>	<p>Ahmed.madhoun@Roche.com</p>