



Urgent Field Safety Notice

For attention of: **Nampharm**

Manufacturer's reference: SB_RDC_2021_03

SRN number: DE-MF-000006276

From,

Roche Diabetes Care South Africa (Pty) Ltd

Hertford Office Park

90 Bekker Road, Midrand,

South Africa, 1686

Location/Date: South Africa, 21 Jul, 2021

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

Dear Margareth,

At Roche Diabetes Care, we strive for the highest quality of products and services and are committed to keeping you informed as soon as there is a potential issue of which you and your customers should be made aware. This is why we would like to inform you today about the rare occurrence Accu-Chek® Performa test strip vials which have opened while still in a sealed carton. If your customer or a patient have a vial that has opened while still in a sealed carton, they may observe the inability to perform a valid blood glucose measurement on your meter, because an open vial would expose the test strips to humidity which damages the strips and could result in inaccurate results (such as positively biased, or falsely too high, results). Inappropriate therapy decisions based on inaccurate results could lead to adverse health consequences.

Description of Situation and Rationale giving rise to this corrective measure

Roche Diabetes Care has received complaints from one hospital in the United States alleging unexpected results (such as positively biased, or falsely too high, results) when using test strip vials which have opened while still in a sealed carton.

The Roche investigation showed that, in very rare circumstances, it is possible that a vial can open in a sealed carton while in transit.

We have not had such complaints in the Middle East & Africa region.



Urgent Field Safety Notice

For attention of: **Nampharm**

Manufacturer's reference: SB_RDC_2021_03

SRN number: DE-MF-000006276

This could happen to Accu-Chek® Performa test strips, when they are shipped at elevated temperature ($\geq 45^{\circ}\text{C}$ or 113°F) AND when the carton is dropped or handled roughly during transit and distribution process. It is only when these two conditions occur in combination that the failure mode has been observed.

Due to the influence of high temperature and humidity this failure might affect the accuracy of the blood glucose measurement.

Details on affected test strips

The potentially affected test strips are

- Accu-Chek® Performa

Actions taken by Roche Diabetes Care

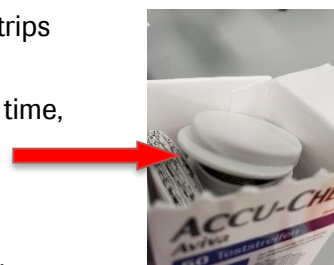
Roche Diabetes Care is updating product labelling to clarify instructions for handling vials that have opened within sealed cartons. Roche Diabetes Care will provide test strip replacements to users who have purchased test strip vials which have opened while still in a sealed carton.

Actions to be taken by the distributors and retailers

Please inform your customers about the below mentioned instructions for users.

Actions to be taken by users of Accu-Chek® Performa test strips

- Users are advised to always check vials of Accu-Chek® Performa 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
 - 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





Urgent Field Safety Notice

For attention of: **Nampharm**

Manufacturer's reference: SB_RDC_2021_03

SRN number: DE-MF-000006276

call our Roche Diabetes Care Customer Care line as shown below:

Country	From	Hotline Number
South Africa	Landline	+2780 34 22 38 37

Communications of this Field Safety Notice

As our local authorized distributor we would require you to inform your healthcare professionals, customers, retailers and users of the Accu-Chek® Performa test strips about this field action and assure them that this is a rare occurrence and has only been identified in a hospital in the United States.

Additionally, as the local authorized distributor of Roche Diabetes Care products, you are also required to check the local regulations and accordingly inform the relevant national competent authorities, if there is a need to do so. Please also send us a copy of the communication to the authorities for our reference in case we need to support you further with any requests, and for record keeping.

We sincerely apologize for any inconvenience this may cause and hope for your understanding and cooperation. Please inform your customer that users should call our Roche Diabetes Care Customer Care line as mentioned above, if they need any additional advice on the handling of the Accu-Chek® Performa test strips or have any further questions or concerns.

Kindly find here attached an acknowledgment form that you need to sign & stamp and send back to us as acknowledgment of receipt of the FSN.

In addition, we would also request you to provide us with a list of all the customers you reach out to informing them of this FSN and, if possible, also collect the acknowledgement form (or confirmation email) from them as far as possible and send a copy back to Roche Diabetes Care to Ms. Batabile Sililo <batabile.sililo@roche.com> by August 31st, 2021 the latest.



Urgent Field Safety Notice

For attention of: **Nampharm**

Manufacturer's reference: SB_RDC_2021_03

SRN number: DE-MF-000006276

We appreciate your time and attention to this important notification.

Sincerely,

For and on behalf of
Roche Diabetes Care South Africa

A handwritten signature in blue ink, appearing to be "Thomas Roex", written over a horizontal line.

Thomas Roex
Head of Finance, Sub Region MEA

DocuSigned by:
A handwritten signature in blue ink, appearing to be "Susan Snell", written over a horizontal line.
01114EE0589B41E...

Susan Snell
Head of DC Cluster MEA3