Urgent Field Safety Notice

For attention of: **Consumer**

Manufacturer's reference: SB_RDC_2021_03 SRN number: DE-MF-000006276

From,
Roche Diabetes Care India private limited,
146-B, 166A, Unit No. 7,8 & 9, 8th Floor,
R City Offices, R City Mall, Lal Bahadur Shastri Marg,
Ghatkopar, Mumbai -400086

Location/Date: India, 19th Jul, 2021

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

Dear valued customers,

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 should be made aware. This is why we would like to inform you today about the rare occurrence of Accu-Chek® Aviva / Accu-Chek® Performa test strip vials which have opened while still in a sealed carton. If you have a test strip vial that has opened while still in a sealed carton, you 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.

This could happen to Accu-Chek® Aviva / Accu-Chek® Performa test strips, when they are shipped at elevated temperature (≥45°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

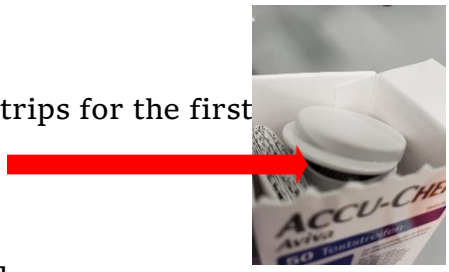
- Accu-Chek® Aviva
- Accu-Chek® Performa

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 users of Accu-Chek® Aviva / Accu-Chek® Performa test strips

- Users are advised to always inspect vials of Accu-Chek® Aviva / 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
    - 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.
- 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 our Roche Diabetes Care Customer Care line (Toll free)as shown below:

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Table 1 - List of Call Centre Numbers within India

Country	From	Hotline Number
India	Landline/Mobile	18001206020

Communications of this Field Safety Notice

Your national competent authority, healthcare professionals, distributors and retailers and users of the Accu-Chek® Aviva / Accu-Chek® Performa test strips have been informed about this field action.

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

We appreciate your time and attention to this important notification.

Sincerely,
For and on behalf of
Roche Diabetes Care India Private India