

2nd of May 2018

Urgent IVD Recall (Class 11, Type B)

Dear Customer

RE: Important information on selected lots of Accu-Chek® Performa blood glucose test strips showing an increased number of strip errors prior to dosing or biased results.

Roche Diabetes Care South Africa (Pty) Ltd hereby wish to notify you of the urgent IVD recall, in cooperation with the South African Health Products Regulatory Authority pertaining to the following product and recalling of specific lot numbers:

The recall only affects the following TWO lot numbers:

Name of Product	Lot numbers	Expiry date
Accu-Chek® Performa test strips	476258	12/2018
Accu-Chek® Performa test strips	476295	12/2018

Reason for recall:

Ongoing quality monitoring and market surveillance processes, have identified certain test strip lots that potentially show an increase in strip errors prior to dosing. Due to the designed fail-safe in the blood glucose meter, the issue can be identified by the error message on the meter upon strip insertion or through the device not recognizing the test strip, respectively. In a very limited number of cases the test strip can produce a biased result i.e. falsely too high or too low value, which might not be detected easily and which could lead to erroneous therapy adaptations. As patient safety is our first priority, kindly take the note of the following actions:

1. Check the lot numbers of your test strip supply. You can find the lot number on the top flap of the vial packaging as well as on the label of each test strip vial as shown in the picture below:



2. Discontinue using strips from the affected lots immediately.
3. Contact the Accu-Chek Diabetes Care line at 080-34-22-38-37 or email us at info@accu-chek.co.za if you have the affected strip supply to obtain instructions on how to receive your replacement products.
4. If your strip supply is not from the lots affected , you can continue using these test strips and no additional action is required.

We have thoroughly investigated this issue to identify the root cause of this potential error and have already started to implement the appropriate corrective measures. Please be assured that this issue only affects the Accu-Chek® Performa test strips. Other Accu-Chek blood glucose strips available in the market are not impacted by this issue.

Your national competent authority, healthcare professionals, hospitals, distributors and retailers have been informed about this field action.

Please contact the Accu-Chek Diabetes Care line at 080-34-22-38-37 or email us at info@accu-chek.co.za if you need any additional advice on the operation of your Accu-Chek Blood glucose meter and test strips or have any further questions or concerns. It is through careful monitoring of customer reports that we are able to identify issues and implement solutions. We appreciate your time and attention to this important notification.

Your sincerely,



Dr. Mary Atkinson
General Manager



Corine Verwey
Authorized Representative