

Urgent field safety notice

Hong Kong, 3 May 2018

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

Affected lots available in Hong Kong

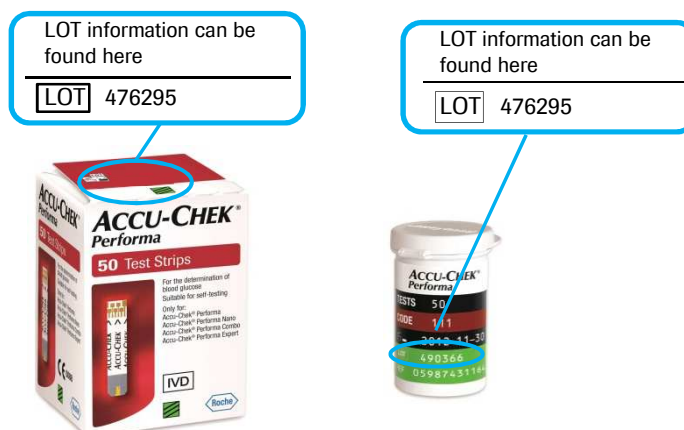
Description	Affected Lots
Accu-Chek Performa 50's strip	476295, 476258
Accu-Chek Performa 10's strip included in Accu-Chek Performa Meter Kit with Fastclix Device* * Only the 10's strip in the meter kit is the affected lot. The Accu-Chek Meter is not affected.	476238, 476568

Dear Customer,

At Roche Diabetes Care we hold our products to the highest standards of quality and are committed to communicating any issues impacting the operation of our products. This is why we would like to inform you today about an issue that might occur in certain lots of the Accu-Chek Performa test strips. As part of our ongoing quality monitoring and market surveillance processes, we 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 displayed on the meter upon strip insertion or through the device not recognizing the test strip, respectively. However, in a very limited number of cases the test strip can produce a biased result i.e. a falsely too high or too low value, which you might not be able to detect easily and which could lead to erroneous therapy adaptations.

As patient safety is our first priority, we would therefore like to ask you to

- check the lot numbers of your test strip supply against the complete list of lot numbers in the attachment. 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.





- discontinue using strips from the affected lots immediately and
- contact our Accu-Chek Customer Service Hotline at 2485 7512 / 2485 7517 if you have affected test strip supply to obtain instructions on how to receive your replacement products at no charge.

If your test 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 test strips available in your market are not impacted by this issue.

Hospital Authority, Department of Health, healthcare professionals, distributors and retailers have been informed about this field action.

Please call our Accu-Chek Customer Service Hotline at 2485 7512 / 2485 7517 during office hours (Mon-Fri 9:00am-12:00pm, 1:30pm-5:30pm), 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 the 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.

Kind regards,

Diabetes Care
Roche Diagnostics (Hong Kong) Limited