

Urgent field safety notice

Petaling Jaya, 11 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

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 Care line at 1-800-88-1313 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.

The Malaysia Medical Device Authority, healthcare professionals, hospitals, distributors and retailers have been informed about this field action.

Please call our Accu-Chek Customer Care line at 1-800-88-1313 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,

Roche Diabetes Care

A handwritten signature in black ink, appearing to read "Lim Chun Khoo".

Lim Chun Khoo
Marketing Manager

A handwritten signature in blue ink, appearing to read "Lee Chor On".

Lee Chor On
Local Safety Officer

Appendix A: List of affected lot number:

No.	Product description	Lot number
1	Accu-Chek Performa MMOL FC-Kit	200990
2	Accu-Chek Performa FC Promo Kit	476238
3	Accu-Chek Performa 10 strips	476238
4	Accu-Chek Performa 50 strips	476295 & 476375