

Consumer Letter **(Accu-Chek Aviva,** **Accu-Chek Performa)**



Urgent field safety notice

May, 2018

Important information on selected lots of Accu-Chek® Aviva and 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 Aviva , Accu-Chek Performa test strips, and Accu-Chek Performa strips that have been included in Accu-Chek Performa Nano meter kits.

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 an error message displayed on the meter upon strip insertion or through the device not recognising the test strip. 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 incorrect 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 supplies against the complete list of lot numbers in Appendix A.
- You can find the lot number on the top flap of the vial carton 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 please return to the pharmacy or store where you obtained the strips for a replacement pack



If your test strip supply is not from the affected lots, 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 specific lots of the Accu-Chek Aviva and Accu-Chek Performa test strips. Other Accu-Chek blood glucose test strips available in your market are not impacted by this issue.

The MHRA, users of the affected blood glucose monitoring systems, healthcare professionals, hospitals, distributors and retailers will all be informed about this field action.

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, please call our Accu-Chek Customer Careline on 0800 701 000 or visit the www.accu-chek.co.uk website. If you are a pump user please contact the Accu-Chek Pump Careline on 0800 731 2291. 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

Appendix A: List of affected lot numbers

APPENDIX A: LOT NUMBERS UK

ACCU-CHEK AVIVA STRIPS (50s)

- 497392
- 497391
- 496915
- 496809
- 496802
- 496807

ACCU-CHEK AVIVA STRIPS (10s)

- 497344
- 497392

ACCU-CHEK PERFORMA STRIPS (10s)

- 476597
- 476646

Accu-Chek Performa Nano mmol Kit. [Please note that the FSN only applies to the pack of Performa 10 test strips contained within the kit]

- 10153116
- 10153114
- 10153115
- 10153112
- 10153111