

Dear Patient,

**Please can you kindly see the attached letter about your blood glucose test strips from Roche.**

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 and 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 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 your patients might not be able to detect easily and which could lead to erroneous therapy adaptations.

The affected UK products are:

Accu-Chek Aviva 50s

Accu-Chek Aviva 10s (Sold in retail only)

Accu-Chek Performa 10s (Sold in retail only)

As patient safety is our first priority, we would therefore like to ask you to advise your patients to:

- **Check the lot numbers of their test strip supplies against the complete list of lot numbers in Appendix A. You can also do this online by visiting [www.accu-chek.co.uk/customer-service/field-safety-notices](http://www.accu-chek.co.uk/customer-service/field-safety-notices). They 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 them to the pharmacy or store where they obtained the strips for a replacement pack at no charge.**

**Partners**

**Dr Kristina King** BM BCh MRCGP

**Dr Kirsteen Fraser** MBBS MRCGP

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.**

***Should you have any queries about this, please can you ask your local pharmacy for advice or alternatively speak to our Clinical Pharmacist Rimple Patel at the surgery.***

Kind regards,  
Rimple Patel  
Clinical Pharmacist

## **APPENDIX A: AFFECTED LOTS 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

LOT information can be found here,  
represented either way as shown below.

**LOT** 490366

Lot No.: 490366



LOT information can be found here,  
represented either way as shown below.

**LOT** 490366

Lot No.: 490366

