

# **URGENT MEDICAL DEVICE RECALL**

## **(Accu-Chek® Aviva test strips - dosing issues)**



**TGA Reference No.: RC-2019-RN-01825-1**

Product Description	Catalogue Number	Lot Number	ARTG No.
Accu-Chek Aviva test strips	06453970020	498287	190251

Dear Valued Customer,

As part of our ongoing quality monitoring and market surveillance processes, it has recently come to our attention that a may have observed the inability to perform a valid blood glucose measurement with multiple strips in a given strips vial. This is because of dosing issues with specific lot of Accu-Chek Aviva test strips.

### **Description of the Situation:**

Roche Diabetes Care received customer feedback related to specific lots of the Accu-Chek Aviva test strips which could not be dosed as intended. The Accu-Chek Aviva test strips consist of several material layers. During the manufacturing process, one of these layers was not assembled correctly, resulting in the inability to dose the test strips.

Please note that this failure mode **does not** affect the accuracy of the blood glucose measurement.

### **What to do if you notice this dosing issue**

1. Please check if you have Accu-Chek Aviva test strips from an impacted lot. You can find the lot number and catalogue number on the label of each test strip vial, as shown in the photo. Please note that the lot number on this photo is for illustration purposes ONLY and NOT impacted by this recall.
2. If you have the impacted lot/batch number, please **discontinue** using the strips from the impacted lot.
3. Please go to our website, [www.accu-chek.com.au](http://www.accu-chek.com.au) to find out if your product is impacted or not or call our **Roche Diabetes Care Enquiry line at 1800 800 535** to obtain further support.



We have thoroughly investigated this issue and implemented the appropriate corrective measures. The Therapeutic Goods Administration (TGA) has been notified of this action.

Your healthcare professionals, distributors and retailers have been informed about the dosing issue. Additionally, we are placing notifications on the following webpages: Australian Diabetes Society (ADS), Australian Diabetes Educator Association (ADEA), Australian Practice Nurse Association (APNA), Diabetes Australia (DA)

This information is also available on our website, [www.accu-chek.com.au](http://www.accu-chek.com.au).

We sincerely apologise for any inconvenience this may cause you.

Please call our **Roche Diabetes Care Enquiry line at 1800 800 535**, if you need any additional advice on the operation of Accu-Chek Aviva system 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 Australia Pty Limited**