

# URGENT NOTIFICATION

## Accu-Chek Aviva Test Strips potentially showing an increased number of strip errors prior to dosing or biased results

According to Health Canada Medical Device Regulation, we are required to provide the following information to all potential users.

At Roche Diabetes Care we hold our products to the highest standards of quality and are committed to communicating any issues impacting our products. This is why we would like to inform you about issues that might occur in the Accu-Chek Aviva Test Strip lots mentioned below (Format of 10 and 100). There are two potential issues that could occur under rare circumstances.

- An increase in strip error messages prior to dosing. Due to the fail-safe design 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 Accu-Chek Aviva test strip.
- Also, in a very limited number of cases (0.017%) the Accu-Chek Aviva test strip can produce a biased result i.e. a false high or a false low value, which patients might not be able to detect easily and which could lead to erroneous therapy adaptations.

## [d-012\\_accu-chek\\_aviva\\_test\\_strips\\_product\\_shot\\_600x200\\_en\\_v7\\_bigger.jpg](#)




Information appearing on impacted products

Product Name	Product Reference N°.	Impacted Lot	Expiry Dates
Accu-Chek Aviva Test Strips (100 Format)	06453988164	497377 497380 497392	2019-06-30
Accu-Chek Aviva Test Strips (10 Format)	06453953164	497356	2019-06-30

## Required Action

- If you have a vial of the **impacted lot of the 10 strips format:**
  - Destroy any remaining test strips of the impacted lot
- If you have a vial of the **impacted lots of the 100 strips format:**
  - Bring back to your local pharmacy to exchange.

## Questions

Should you need more information, please do not hesitate to contact Accu-Chek Customer Care at 1-800-363-7949  and also by e-mail at [laVal.info\\_line@roche.com](mailto:laVal.info_line@roche.com). Please use reference number RRDC201801-WEBPAGE.

Thank you for your continued support of Roche Diabetes Care.

