

18-016 QA PRODUCT RECALL ACCU-CHEK AVIVA PLUS TEST STRIPS DUE TO POTENTIAL FOR INACCURATE RESULTS

Date: 11 MAY 2018
016

Recall: # 18-

Scope: WORLDWIDE RETAIL FACILITIES

With the knowledge of the Food and Drug Administration (FDA), Roche Diagnostics Corps is conducting a voluntary withdrawal for specific lots of the Accu-Chek Aviva Plus Test Strips due to the potential for inaccurate test results.

Hazard: Affected test strips show an increased potential for strip errors prior to applying a blood sample, or strips not detected once inserted or in a very limited number of cases, an inaccurate result may occur, which may not be detectable.

Incidents/Injuries: If a defective strip is used for blood glucose testing and produces an inaccurate result, incorrect action could be taken by the user.

Description: The following product lots are affected. The lot number is printed on the top flap of the box and on the label of each test strip vial.

Product	Catalog Number	Lot Number	Expiration Date
Accu-Chek Aviva Plus Strips	06908217001	496947	10/31/2018
Accu-Chek Aviva Plus Strips	06908268001	497291	04/30/2019
Accu-Chek Aviva Plus Health Network Strips	06908349001	497296	04/30/2019
Accu-Chek Aviva Plus Strips	06908217001	497325	05/31/2019

Remedy: Consumers should immediately discontinue using test strip lots 496947, 497291, 497296, and 497325. Affected test strips must be discarded. To get replacement test strips please submit your request at <https://notices.accu-chek.com> or Email Accu-Chek Customer Care at accu-chek.care@roche.com and include your name, full mailing address, phone number, test strip lot number and number of affected test strip vials.

Consumer Contact: Consumers can contact Accu-Chek Customer Care line at 1-800-358-4866 Monday through Friday between the hours of 8:00 am and 8:00 pm Eastern Standard Time.

Sold at: Worldwide Exchange facilities and other retailers.

Manufacturer(s): Roche Diabetes Care, Inc.