

Urgent Medical Device Correction

18-002

May 07, 2018

Important information on select lots of Accu-Chek® Aviva Plus test strips potentially showing an increased number of strip errors, strips not detected, or inaccurate results.

Issue:

As part of our ongoing quality monitoring and marketing surveillance processes, Roche has identified four test strip lots that are out of specification. 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.

It was found that the affected strips had cracked reagent, which may lead to the issues described above.

Affected Product:

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 |

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

Actions Required: Check the lot numbers of your test strip supply against the lot numbers above. You can find the lot number on the top flap of the vial packaging as well as on the label of each test strip vial as shown in the example below.





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Actions Required Continued:

- **Immediately discontinue using test strip lots 496947, 497291, 497296, and 497325. Affected test strips must be discarded.**
- To get replacement test strips, use **one** of the following options:
 - **For fastest replacement of your product, please submit your request at <https://notices.accu-chek.com>**
 - Email Accu-Chek Customer Care at accu-chek.care@roche.com and include the following information: your name, full mailing address, phone number, test strip lot number and number of affected test strip vials.
 - For questions regarding this letter, contact our 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.
- Please keep this notification for future reference.

This notification is being made with the knowledge of the Food and Drug Administration (FDA). You may also report adverse events or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Events Reporting Program online at www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or call the FDA 1-800-FDA-1088.

Roche Diabetes Care, Inc.

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