

5/29/2018

**RE: Medical Device Recall: Accu-Chek® Aviva Plus Test Strips**

***Affected strips may have an increased number of strip errors prior to applying a blood sample, or strips not detected once inserted, or wrong results.***

**In support of safe, informed prescribing, Neighborhood Health Plan of Rhode Island is sharing information about this Medical Device Recall with you.** As you are aware, Accu-Chek® is Neighborhood's preferred test strip for diabetics. This major recall is due to the potential for inaccuracy of readings from affected strips.

On May 7, 2018, Roche Diabetes issued a medical device correction of ACCU-CHEK® Aviva Plus Test Strips. This medical device correction was issued because the affected strips may have an increased number of:

- Strip errors prior to applying a blood sample, or
- Strips not detected once inserted or
- Wrong results.

**This may represent a potential health hazard or safety risk to plan members who may be using the product affected by this medical device correction.**

**Affected Products:**

Product Name	NDC #	Affected Lots
ACCU-CHEK Aviva Plus Test Strips 50 count	65/02-0407-10	497325 exp. 05/31/19, 496947 exp. 10/31/18
ACCU-CHEK Aviva Plus Test Strips 100 count	65/02-0408-10	497291 exp. 04/30/19
ACCU-CHEK Aviva Plus Health Network Test Strips 50 count	65/02-0438-10	497296 exp. 04/30/19

**Manufacturer Recommendations:**

All users should see if they have the affected product by checking the lot number. The lot number is on the top flap of the manufacturer's box and on the label on the test strip vial.

If the product is not from one of the affected lot numbers, it is not affected by this correction. If the product is from one of these affected lot numbers, users should stop using it and contact Roche Diabetes Care to get replacement product by one of the following options:

- For fastest replacement, submit a request at <https://notices.accu-chek.com>.
- E-mail Accu-Chek Customer Care at [accu-chek.care@roche.com](mailto:accu-chek.care@roche.com) and include users name, full mailing address, phone number, test strip lot number and number of affected test strips.



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- Call Accu-Chek Customer Care toll-free at 1-800-358-4866, Monday through Friday, 8:00 am to 8:00 pm (ET).

Please evaluate your potentially affected patients medical history and medications with respect to this new information.

For more information on this drug safety communication, please refer to:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=164224>

For questions or more information, please call Accu-Chek Customer Care toll-free at 1-800-358-4866, Monday through Friday, 8:00 am to 8:00 pm (ET) or visit [www.accu-chek.com](http://www.accu-chek.com). You may also call the United States Food and Drug Administration toll-free at 1-888-INFO-FDA (1-888-463-6332) or visit [www.fda.gov](http://www.fda.gov).