

Roche – Recall of Accu-Chek® Aviva Plus

 On December 11, 2019, <u>Roche Diabetes Care announced</u> a voluntary, consumer-level recall of two lots of <u>Accu-Chek Aviva Plus</u> test strips due to the inability to perform a valid blood glucose measurement on a patient's meter with multiple strips in a given strip vial.

Product Description	NDC #	Lot #
Accu-Chek Aviva Plus Health Network Strips	65702-0438-10	497864
Accu-Chek Aviva Plus Retail Strips 50 ct	65702-0407-10	498315

- Accu-Chek Aviva Plus test strips are used to measure and monitor blood sugar levels in people with diabetes.
- When using the recalled test strips, patients may experience errors such as blood application not detected, test strip defective, E-4 + Drop symbol flashing, M-54, and E-54 errors.
- The Accu-Chek Aviva Plus 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 the affected test strips will not produce inaccurate results due to this issue.
 However, inability to dose the Accu-Chek Aviva Plus test strips may result in a temporary inability to
 get a result that could lead to a delay in treatment and/or therapy decisions. Such a failure could
 cause a delay in therapy decisions that may potentially contribute to health effects requiring
 assistance to resolve.
- To date, Roche Diabetes Care has not received any reports of adverse events related to this issue.
- Patients should immediately discontinue using the affected Accu-Chek Aviva Plus test strips.
 Affected test strips should be discarded.
- Anyone with an existing inventory of the recalled product should stop use and destroy any remaining product immediately.
- For more information regarding this recall, contact Accu-Chek Customer Care at **1-800-358-4866** or e-mail **accu-chek.care@roche.com**.



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