

Urgent Medical Device Correction

19-003

December 11, 2019

Roche

Accu-Chek® Aviva Plus test strips with lot numbers 497864 and 498315

Purpose of this Notification:

Roche Diabetes Care has identified an issue with the Accu-Chek Aviva Plus test strips from lot numbers 497864 and 498315. This notification provides guidance to customers with affected test strips who may observe the inability to perform a valid blood glucose measurement on his/her meter with multiple strips in a given strip vial.

Reason for the Notification:

As part of our ongoing quality monitoring and market surveillance processes, Roche Diabetes Care received customer feedback related to specific lots of the Accu-Chek Aviva Plus test strips which could not be dosed as intended. The customer may experience this 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.

Risk to Health:

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.

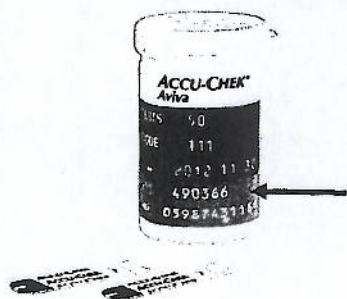
To date, no adverse events have been reported for this issue.

Affected Product:

The following product is affected:

| Product | Catalog Number | Lot Number | NDC Number | UPC |
|--|----------------|------------|---------------|-----------------|
| Accu-Chek Aviva Plus Health Network Strips | 06908349001 | 497864 | 65702-0438-10 | 3-65702-43810-1 |
| Accu-Chek Aviva Plus Retail Strips 50 ct | 06908217001 | 498315 | 65702-0407-10 | 3-65702-40710-7 |

For location of lot number, please see example picture below:



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This notice only applies to Accu-Chek Aviva Plus test strips with the lot numbers noted above.

Actions to be taken by the user:

- **Immediately discontinue using test strip lots 497864 and 498315. Affected test strips must be discarded.**
- To get replacement test strips, or for questions regarding this notification, 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.
 - 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.
- If a Business Reply Form was included with this notification, please complete and return it by U.S. mail using the provided postage paid envelope.
- Please keep this notification for future reference.

Actions to be taken by Distributors who receive product directly from Roche:

- **Discontinue distribution and destroy any remaining stock of the affected lots (497864 and 498315) immediately.**
- If you have distributed affected product to other suppliers, provide a copy of this UMDC to those suppliers who have purchased affected test strip lots from you. Have those customers report the quantity of product destroyed to you.
- If you have distributed affected product to consumer customers, make the notification available to those customers. It is not necessary to obtain quantity destroyed from your consumer customers.
- Complete the enclosed faxback form indicating the total number of test strip vials destroyed by you and your supplier customers and email or fax it per the directions on the form.
- If you have questions about impacted product you have received or information in this notification, please contact your Roche Account Manager.
- Please keep this notification for future reference.

Actions to be taken by Suppliers who receive product from other distributors:

- **Discontinue the sale or distribution and destroy any remaining stock of the affected lots (497864 and 498315) immediately.**
- Please make this notification available to consumer customers to whom you distributed affected product.
- If you have distributed affected product to other suppliers, provide a copy of this UMDC to those suppliers. Have those suppliers report the quantity of product destroyed to you.
- Please note quantity destroyed by you and your supplier customers. **To arrange for credit, contact your Supplier.**
- For questions please contact your wholesaler or contact Accu-Chek Customer Care by email at accu-chek.care@roche.com or by phone 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.

ACCU-CHEK Aviva Plus is a trademark of Roche.

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.

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