21-001 July 28, 2021

URGENT MEDICAL DEVICE CORRECTION

Accu-Chek® Aviva Plus and Accu-Chek® SmartView Test Strips – Potential for Open Vials

This Urgent Medical Device Correction (UMDC) only applies to the following products:

Product	Catalog No.	NDC Number	UPC Number
Accu-Chek Aviva Plus 10ct test strips	06908152001	65702-0405-10	3-65702-40510-3
Accu-Chek Aviva Plus 50ct test strips	06908217001	65702-0407-10	3-65702-40710-7
Accu-Chek Aviva Plus 100ct test strips	06908268001	65702-0408-10	3-65702-40810-4
Accu-Chek Aviva Plus 50ct Health Network strips	06908349001	65702-0438-10	3-65702-43810-1
Accu-Chek Aviva Plus 50ct Mailorder strips	06908373001	65702-0436-10	3-65702-43610-7
Accu-Chek SmartView 50ct test strips	06337538001	65702-0492-10	3-65702-49210-3
Accu-Chek SmartView 100ct test strips	06337546001	65702-0493-10	3-65702-49310-0
Accu-Chek SmartView 50ct Mailorder strips	06337562001	65702-0495-10	3-65702-49510-4

Issue:

Roche has received complaints about test strip vials opening while still inside a sealed carton during shipment. An open vial might expose the test strips to humidity, which might damage the strips and could result in inaccurate results (such as positively biased or falsely too high results). Inappropriate therapy decisions based on inaccurate results could lead to adverse health consequences.

This could happen to Accu-Chek Aviva Plus and Accu-Chek SmartView test strips when they are shipped at elevated temperatures (≥45°C or 113°F) and when the carton is dropped or handled roughly during transit and the distribution process. It is only when these two conditions occur in combination that the failure mode has been observed.

Risk to Health:

If you have a test strip vial that has opened while still in a sealed carton, you may not be able to perform a valid blood glucose measurement on your meter, because an open vial may expose the test strips to humidity which damages the strips. This could lead to inaccurate results (such as positively biased, or falsely too high, results). Inappropriate therapy decisions based on inaccurate results could lead to adverse health consequences.

Actions Required for Distributors/Retailers

- Read this UMDC (21-001).
- No product returns are required as part of this notification.
- If you have distributed the products noted on the previous page to other suppliers, provide a copy of this UMDC to those suppliers whom you have shipped these products within the last 18 months.
- If you have distributed the products noted on the previous page to consumer customers, make the UMDC available to those customers who have received these products from you in the last 18 months.
- Complete all sections of the enclosed distributor faxback form (21-001) and fax or email it according to the instructions on the form.
- Contact your Roche Account Manager if you have questions regarding the information in this UMDC.
- Please keep this UMDC for future reference.

Actions Required by Users

- Check vials of Accu-Chek Aviva Plus and Accu-Chek SmartView test strips before use. **DO NOT** use the test strips if:
  - the vial is open or damaged before using the test strips for the first time,
  - the cap is not fully closed,
  - you see any damage to the cap or vial, or
  - anything prevents the cap from closing properly.

- **DO NOT** perform control testing if you open a sealed carton and any of the vials inside meet the criteria listed above.
- Contact Accu-Chek Customer Care for product replacement if you open a sealed carton and any of the vials inside meet the criteria listed above by phone at 1-866-805-5919 or on our website at Accu-Chek.com under "Contact Us" for email or chat. Please have the affected products available.
- Complete and return the enclosed business reply letter per the provided instructions.
- Dispose of the affected test strips and vial according to your local guidelines.
- Contact Accu-Chek Customer Care if you have questions regarding the information in this Urgent Medical Device Correction (UMDC) by phone at 1-866-805-5919 or on our website at Accu-Chek.com under "Contact Us" for email or chat.
- Please keep this UMDC for future reference.

Reason for the Notification:
Investigations have revealed that, in rare circumstances, it is possible that a vial can open in a sealed carton while in transit. This could happen to Accu-Chek Aviva Plus and Accu-Chek SmartView test strips when they are shipped at elevated temperatures (≥45°C or 113°F) and when the carton is dropped or handled roughly during transit and the distribution process. It is only when these two conditions occur in combination that the failure mode has been observed.

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.