TP-01353
07/28/21

URGENT MEDICAL DEVICE CORRECTION

For Healthcare Professionals (HCPs)
Accu-Chek® Inform II and Accu-Chek Performa Test Strips – Potential for Open Vials

Affected Products

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

Product	Catalog Number
Accu-Chek Inform II test strips	05942861001
Accu-Chek Performa test strips	07299702001

Issue

Roche has received a complaint 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 elevated results). Inappropriate therapy decisions based on inaccurate results could lead to adverse health consequences.

This could happen to Accu-Chek Inform II and Accu-Chek Performa test strips when they are subjected to elevated temperatures (≥45°C or 113°F) during shipping **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.

Clinical Significance

A remote but important medical risk exists for patients whose glucose testing is performed using strips that have been damaged due to humidity exposure. Although very rare in frequency, a positive bias (e.g., falsely elevated test results) may be observed due to damage to the test strip occurring during shipping whereby vials exposed to extreme heat and rough physical handling may open within their sealed carton. When damaged test strips are used for patient testing, individuals who are highly insulin sensitive, those with brittle diabetes, individuals who are unaware of their hypoglycemia, and those with an inability to recognize or communicate symptoms of low blood glucose, **especially neonates**, might be at an increased risk for adverse health consequences. Diagnosis of hypoglycemia may be delayed or missed due to positive bias of blood glucose testing results.

Collectively, the patient risk associated with using damaged strips range from no risk up to serious adverse health consequences depending on the patient's actual blood glucose value, physiologic status, and level of medical supervision. Consult with a physician and/or neonatologist at your facility to determine any clinical implications specific to your patients.

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☑ Accu-Chek Inform II
☑ Accu-Chek Performa

Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457
USA

Actions Required

- Check vials of Accu-Chek Inform II and Accu-Chek Performa 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 using a vial of test strips that has opened during shipment if you open a sealed carton and any of the vials inside meet the criteria listed above.
- Contact Accu-Chek Customer Care at 1-800-440-3638 for product replacement if you open a sealed carton and any of the vials inside meet the criteria listed above. Please have the affected products available.
- Complete all sections of the enclosed HCP faxback form (TP-01355) and fax or email it according to the instructions on the form.
- Dispose of the affected test strips and vial according to your local guidelines.
- Contact Accu-Chek Customer Care at 1-800-440-3638 if you have questions regarding the information in this UMDC.
- Consult with a physician and/or neonatologist at your facility to determine any clinical implications specific to your patients. (See the *Clinical Significance* section on the prior page.)
- File this UMDC for future reference.

Root Cause

Investigations have revealed that, in very rare circumstances, it is possible that a vial can open in a sealed carton while in transit. This could happen to Accu-Chek Inform II and Accu-Chek Performa 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.

Enclosure

Faxback form, TP-01355

Questions

Please contact the Accu-Chek Customer Care Support Center, 24 hours a day, seven days a week at 1-800-440-3638 if you have questions about the information contained in this UMDC.

This UMDC is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Events Reporting Program: Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form is available to fax or mail), or call FDA 1-800-FDA-1088.