

Safety Notice

Medical Devices

Accu-Chek® Aviva and Inform II test strips

Priority 2 – Warning



HPRA Safety Notice: SN2021(07)

Issue Date: 24th August 2021

| MANUFACTURER / SUPPLIER | HPRA CASE REFERENCE |
|--------------------------|---------------------|
| Roche Diabetes Care GmbH | V46991 |

ISSUE

The Health Products Regulatory Authority (HPRA) is issuing this Safety Notice to raise awareness of an issue with Accu-Chek® Aviva and Inform II test strips.

Roche have determined that, in very rare circumstances, it is possible that a test strip container (sometimes known as a vial) can open within the box while in transit. An open container could expose the test strips to humidity, which can damage the strips and could result in inaccurately high blood glucose results (known as positively biased results).

For example, a patient with a low blood glucose could get a result indicating that their blood glucose is normal or high. If a patient is not aware of the symptoms associated with a low blood glucose, they may not take the appropriate steps to raise their blood sugar. If left untreated a low blood sugar can lead to adverse health consequences such as confusion, visual disturbances, seizure or collapse.

It is important to be aware that if the test strips are affected, an error message may not appear on the glucometer and the control test will not identify the issue.

Please read the action section below for instructions from Roche if, when opening the box for the first time, you notice the container is open.

ACTION OR RECOMMENDATIONS

The HPRA advises that **users**:

- 1 Refer to the accompanying FSNs and follow the instructions provided by the manufacturer.
- 2 Always inspect containers of Accu-Chek Aviva and Inform II test strips before use.
- 3 Do not use the test strips if :
 - the container 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 container, or
 - anything prevents the cap from closing properly
- 4 Report any adverse incidents/concerns regarding these devices to the manufacturer and the HPRA as soon as possible.
- 5 The manufacturer will provide test strip replacements to users who have purchased containers that were open within the sealed box. To obtain replacement for Accu-Chek Aviva test strips from Roche Diabetes Care they have advised customers to call the Roche Diabetes Care Customer Care line, Ireland on 1800 709 600. To obtain replacement for Accu-Chek Inform II test strips from Roche Diagnostics they have advised customers to call the Roche Technical Support Hotline, Ireland on 1800 40 95 64.
- 6 Contact your healthcare professional with any health concerns.

The HPRA advises that **healthcare professionals**:

- 1 Refer to the accompanying FSNs and follow the instructions provided by the manufacturer.
- 2 Where possible inform all end-users of this issue.
- 3 Forward a copy of this Safety Notice and the accompanying FSNs to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred.
- 4 Report any adverse incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

| | |
|----------------------------|-------------------------------|
| Carers | Outpatient clinics |
| Community care managers | Paediatricians |
| Community nurses | Pharmacists |
| Diabetes clinics | Practice nurses |
| Diabetes nurse specialists | Private medical practitioners |
| Endocrinologists | Pump Users |
| Endocrinology units | Risk managers |
| General practitioners | School nurses |
| Nursing homes | Supplies/purchasing managers |

BACKGROUND

This issue can happen to Accu-Chek® Aviva and Accu-Chek® Inform II test strips when they are shipped at elevated temperatures ($\geq 45^{\circ}\text{C}$) and when the box 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.

It was determined by Roche that the labelling for these products is inadequate as there are no instructions on what a customer should do if the test strip container is open when they initially open a test strip box. Roche will be updating the product labelling to clarify the instructions for handling containers that have opened within a sealed box.

Please refer to the accompanying FSNs for further details.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

To Contact Roche Diabetes Care, please call the Roche Diabetes Care Customer Care line, Ireland on 1800 709 600.

To Contact Roche Diagnostics, please call the Roche Technical Support Hotline, Ireland on 1800 40 95 64.

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie