

Urgent Field Safety Notice

FSN- RDC-2021-003



RDC

Version1

25 July 2021

Dear Valued Customer,

Please find here attached a Field Safety Notice (FSN) related to FSN-RDC-2021-003:

“Important information about open vials of Accu-Chek® Inform II test strips”

We kindly ask you to acknowledge receipt of the attached FSN by completing the relevant details and signing where indicated.

Finally, please forward the attached FSN to your customers having purchased and utilizing the related products and collect their required information and signature.

We thank you for your understanding and collaboration and apologize for any inconvenience.

Yours sincerely,

For on behalf of
Roche Diagnostics Middle East FZCO

Marie McMahon
Head of Quality, Regulatory & SHE

Venkatesan Veeraraghavan
Regional Product Safety & Quality Lead, RDME

Important information about open vials of Accu-Chek® Inform II test strips



Product Name	Accu-Chek® Inform II test strips
Product Line	Accu-Chek® Inform II
Part No	05942861
SW Version	N/A
Type of Action	Field Safety Corrective Action (FSCA)

Description of Situation

Roche Diabetes Care has received complaints from one hospital in the United States alleging unexpected results (such as positively biased, or falsely too high, results) when using test strip vials which have opened while still in a sealed carton.

The Roche investigation showed 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 test strips, when they are shipped at elevated temperature ($\geq 45^{\circ}\text{C}$ or 113°F) AND when the carton is dropped or handled roughly during transit and distribution process. It is only when these two conditions occur in combination that the failure mode has been observed.

Due to the influence of high temperature and humidity this failure might affect the accuracy of the blood glucose measurement.

Details on affected test strips

The potentially affected test strips are

- Accu-Chek® Inform II

Important information about open vials of Accu-Chek® Inform II test strips



Actions taken by Roche Diabetes Care

Roche Diabetes Care is updating product labeling to clarify instructions for handling vials that have opened within sealed cartons. Roche Diabetes Care will provide test strip replacements to users who have purchased test strip vials which have opened while still in a sealed carton.

Actions to be taken by the distributors and retailers

Please inform your customers about the below mentioned instructions for users.

Actions to be taken by users of Accu-Chek® Inform II test strips

- Users are advised to always check vials of Accu-Chek® Inform II test strips before use. Please, do not use the test strips if:
 - 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.
- Please do not perform control testing as instructed in the meter manual.
- If you have any affected product, please dispose of the test strips immediately.
- Roche Diagnostics will provide test strip replacements to users who have purchased vials that were open within the sealed carton.



Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied. (If appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact. (If appropriate).

Please maintain awareness of this notice and the resulting action for an appropriate period to ensure the effectiveness of the corrective action. (If appropriate).

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Important information about open vials of Accu-Chek® Inform II test strips



Local authorized distributor's Details:

Facility Name: Contact Name: Position: Phone: Date: Signature and Stamp:

I have received the FSN and read/understand its content.

Customer Details:

Facility Name: Contact Name: Position: Phone: Date: Signature and Stamp:
