

URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Ref No: PFSN Accu-Chek® Inform II test strips Issue: Positively biased results due to Open Vials within sealed cartons SB_RDC_2021_03
Date: 22/07/21
Type of Action: Field Safety Corrective Action (FSCA)

Product Affected: Accu-Chek® Inform II test strips

System Affected: Accu-Chek® Inform II
Accu-Chek® Performa
Accu-Chek® Performa Nano

Software Version: N/A

Product No	Material No	Lot No
Accu-Chek® Inform II	05060303001	N/A
Accu-Chek® Performa	05894999018	N/A
Accu-Chek® Performa Nano	06454364190	N/A
Accu-Chek® Inform II test strips	05942861018	N/A

Summary of Issue

Accu-Chek® Inform II test strips Issue: Positively biased results due to Open Vials within sealed cartons

Reason for Notice

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

Dear healthcare professionals,

At Roche Diagnostics, we strive for the highest quality of products and services and are committed to keeping you informed as soon as there is a potential issue of which you and your patients should be made aware. This is why we would like to inform you today about the rare occurrence of Accu-Chek® Inform II test strip vials which have opened while still in a sealed carton.

✓	Immediate Action Required
	Action Required
	Information Only

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If your users have a vial that has opened while still in a sealed carton, they may observe the inability to perform a valid blood glucose measurement on their meter, because an open vial would expose the test strips to humidity which damages 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.

Description of Situation and Rationale giving rise to this corrective measure

Roche Diagnostics 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 ($\geq 45^{\circ}$ 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

Actions taken by Roche Diagnostics

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

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Actions to be taken by the healthcare professional

Please inform your users about the following warnings and instructions mentioned below.

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. To obtain replacement from Roche Diagnostics, please call our Roche Technical Support Hotline at UK: 0808 100 19 20 or Ireland: 1800 40 95 64.

Please complete and return the [Acknowledgement Form](#) which accompanies this [Field Safety Notice](#) by 5th August 2021.

Please bring this notice to the attention of all personnel in your hospital or Health Care facility who need to be aware of this safety issue.

If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.

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Attachments

PFSN Accu-Chek® Inform II test strips Issue: Positively biased results due to Open Vials within sealed cartons SB_RDC_2021_03 Acknowledgment Form

This action is being conducted with the knowledge of the Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

Roche Diagnostics operates a vigilance system that complies with the IVD Directive 98/79 EC

A copy of this notice can also be found on the [Roche Dialog Portal](#)

If you require any further information please contact our

Technical Support Hotline

UK: 0808 100 19 20

Ireland: 1800 40 95 64

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ACKNOWLEDGEMENT

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Please kindly return this acknowledgment form by Thursday 5th August 2021 to the email address given in the footer

Product Catalogue No:	Accu-Chek® Inform II test strips
System:	Accu-Chek® Inform II Accu-Chek® Inform II Performa

Name:

Position/Title of Person completing this Form:

Company Name:

Phone Number:

E-mail address:

Address:

Please acknowledge receipt of information and awareness of any required actions described within the accompanying **Field Safety Notice**.

Please bring this notice to the attention of all personnel in your hospital or healthcare facility who need to be aware of this safety issue.

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ACKNOWLEDGEMENT

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Date: 22/07/21

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I acknowledge receipt of this Field Safety Notice and have read, understood and implemented its content.

Form completed and returned by:

Name:

Signed:

Date:

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