

Urgent Field Safety Notice

For attention of: **Consumer**

Manufacturer's reference: SB_RDC_2021_03

SRN number: DE-MF-000006276

Burgess Hill, 22 July 2021

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

Dear valued Accu-Chek customers,

At Roche Diabetes Care, 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 should be made aware. This is why we would like to inform you today about the rare occurrence of Accu-Chek Aviva / test strip vials which have opened while still in a sealed carton. If you have a test strip vial that has opened while still in a sealed carton, you may observe the inability to perform a valid blood glucose measurement on your 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 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 Aviva / 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 the 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 Aviva

Actions taken by Roche Diabetes Care

Roche Diabetes Care is updating product labelling 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 users of Accu-Chek Aviva test strips

- Users are advised to always inspect vials of Accu-Chek Aviva 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 Diabetes Care will provide test strip replacements to users who have purchased vials that were open within the sealed carton. To obtain replacement from Roche Diabetes Care, please call our Roche Diabetes Care Customer Careline in Ireland on 1 800 709 600*



Communication of this Field Safety Notice

Your national competent authority, healthcare professionals, distributors, retailers and users of the Accu-Chek Aviva test strips have been informed about this field action.

We sincerely apologise for any inconvenience this may cause and hope for your understanding and cooperation. Please call our Roche Diabetes Care Customer Careline in Ireland: 1 800 709 600*, if you need any additional advice on the handling of the Accu-Chek Aviva / test strips or have any further questions or concerns. We appreciate your time and attention to this important notification.

Kind regards,

Roche Diabetes Care

* Some mobile phone operators may charge or restrict access for calls to these numbers.

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Roche Diabetes Care Limited, Charles Avenue, Burgess Hill, RH159RY, UK
Company registration number: 9055599
For use in the UK and Ireland only
Date of Preparation: July 2021
www.accu-chek.ie

Urgent Field Safety Notice

For attention of: **Safety Officers / Practice Managers**

Manufacturer's reference: SB_RDC_2021_03
DE-MF-000006276
Burgess Hill, 22 July 2021

SRN number:

Important information about open vials of Accu-Chek® Aviva / test strips

Dear Safety Officer / Practice Manager,

At Roche Diabetes Care, 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 Aviva / test strip vials which have opened while still in a sealed carton.

If your patients 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 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 Aviva 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 the 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 Aviva

Actions taken by Roche Diabetes Care

Roche Diabetes Care is updating product labelling 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 healthcare professional

Please inform your patients about the following warnings and instructions mentioned below and acknowledge receipt of this letter by completing and returning the enclosed acknowledgement form.

Actions to be taken by users of Accu-Chek Aviva / test strips

- Users are advised to always check vials of Accu-Chek Aviva / 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 Diabetes Care will provide test strip replacements to users who have purchased vials that were open within the sealed carton. To obtain replacement from Roche Diabetes Care, please call our Roche Diabetes Care Customer Careline on: 1 800 709 600*.



Communication of this Field Safety Notice

Your national competent authority, healthcare professionals, distributors, retailers and users of the Accu-Chek Aviva test strips have been informed about this field action.

We sincerely apologise for any inconvenience this may cause and hope for your understanding and cooperation. Please advise your patients to call our Roche Diabetes Care Customer Careline on: 1 800 709 600*, if they need any additional advice on the handling of the Accu-Chek Aviva test strips or have any further questions or concerns. We appreciate your time and attention to this important notification.

Kind regards,

Roche Diabetes Care

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Company registration number: 9055599

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Date of Preparation: July 2021 www.accu-chek.ie



URGENT FIELD SAFETY NOTICE

PLEASE COMPLETE AND RETURN BY POST IN THE ENCLOSED PRE-PAID ENVELOPE

Roche Diabetes Care Reference:	SB_RDC_2021_03	
Medical Device:	Accu-Chek® Aviva Test Strips	
Manufacturer:	Roche Diabetes Care	
Issue:	Important information about open vials of Accu-Chek Aviva test strips	

Acknowledgement Form

Please submit this acknowledgement form to Roche Diabetes Care:

Via post	Using the enclosed pre-paid envelope
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<input type="checkbox"/>	I confirm I have received, read and understood the information in this Field Safety Notice of 22 Jul 2021 for the above-mentioned medical devices and will perform the requested actions.
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Form completed and returned by:

Name (CAPITAL LETTERS):	
Position/Title of Person completing this Form:	
Company Name:	
Phone Number:	
E-mail:	
Address:	
Date (dd-mmm-yyyy):	

Signature

Roche Diabetes Care Account number: _____

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Date of Preparation: July 2021

www.accu-chek.co.uk www.accu-chek.ie

Urgent Field Safety Notice

For attention of: **Distributor / Retailer**

Manufacturer's reference: SB_RDC_2021_03

SRN number: DE-MF-000006276

Burgess Hill, 22 July 2021

Important information about open vials of Accu-Chek® Aviva / Accu-Chek® Performa test strips

Dear Distributors,

At Roche Diabetes Care, 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 customers should be made aware. This is why we would like to inform you today about the rare occurrence of Accu-Chek Aviva / Accu-Chek Performa test strip vials which have opened while still in a sealed carton. If your customer or a patient 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 your 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 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 Aviva / Accu-Chek Performa 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 the 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 Aviva
- Accu-Chek Performa

Actions taken by Roche Diabetes Care

Roche Diabetes Care is updating product labelling 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 and acknowledge receipt of this letter by completing and returning the enclosed acknowledgement form.

Actions to be taken by users of Accu-Chek Aviva / Accu-Chek Performa test strips

- Users are advised to always check vials of Accu-Chek Aviva / Accu-Chek Performa 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 Diabetes Care will provide test strip replacements to users who have purchased vials that were open within the sealed carton. To obtain replacement from Roche Diabetes Care, please call our Roche Diabetes Care Customer Careline at UK: 0800 701 000* or Ireland: 1 800 709 600*



Communication of this Field Safety Notice

Your national competent authority, healthcare professionals, distributors, retailers and users of the Accu-Chek Aviva /Accu-Chek Performa test strips have been informed about this field action.

We sincerely apologise for any inconvenience this may cause and hope for your understanding and cooperation. Please inform your customer that users should call our Roche Diabetes Care Customer Careline at UK: 0800 701 000* or Ireland: 1 800 709 600*, if they need any additional advice on the handling of the Accu-Chek Aviva / Accu-Chek Performa test strips or have any further questions or concerns. We appreciate your time and attention to this important notification.

Kind regards,

Roche Diabetes Care

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Date of Preparation: July 2021

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URGENT FIELD SAFETY NOTICE

PLEASE COMPLETE AND RETURN BY E-MAIL

Roche Diabetes Care Reference:	SB_RDC_2021_03	
Medical Device:	Accu-Chek® Aviva and Accu-Chek® Performa Test Strips	
Manufacturer:	Roche Diabetes Care	
Issue:	Important information about open vials of Accu-Chek Aviva and Performa test strips	

Acknowledgement Form

Please submit this acknowledgement form to Roche Diabetes Care:

via e-mail:	<u>burgesshill.dcsafety@roche.com</u>
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<input type="checkbox"/>	I confirm to have received, read and understood the information in this Field Safety Notice of 22 Jul 2021 for the above-mentioned medical devices and will perform the requested actions.
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Form completed and returned by:

Name (CAPITAL LETTERS):	
Position/Title of Person completing this Form:	
Company Name:	
Phone Number:	
E-mail:	
Address:	
Date (dd-mmm-yyyy):	

Signature

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