

Field safety notice

Singapore, 3rd May 2018

Important information on selected lots of Accu-Chek® Aviva and Accu-Chek® Performa test strips potentially showing an increased number of strip errors prior to dosing or biased results

Dear Customer,

At Roche Diabetes Care we hold our products to the highest standards of quality and are committed to communicating any issues impacting the operation of our products. This is why we would like to inform you today about an issue that might occur in certain lots of the Accu-Chek Aviva and Accu-Chek Performa test strips. As part of our ongoing quality monitoring and market surveillance processes, we have identified certain test strip lots that potentially show an increase in strip errors prior to dosing. Due to the designed fail-safe in the blood glucose meter, the issue can be identified by the error message displayed on the meter upon strip insertion or through the device not recognizing the test strip, respectively. However, in a very limited number of cases the test strip can produce a biased result i.e. a falsely too high or too low value, which you might not be able to detect easily and which could potentially lead to erroneous therapy adaptations.

As patient safety is our first priority, we would therefore like to ask you to

- check the lot numbers of your test strip supply against the complete list of lot numbers in the attachment. You can find the lot number on the top flap of the vial packaging as well as on the label of each test strip vial as shown in the picture below.



- discontinue using strips from the affected lots immediately and
- contact our Accu-Chek ExtraCare line at 6272 9200 if you have affected test strip supply to obtain instructions on how to receive your replacement products at no charge.

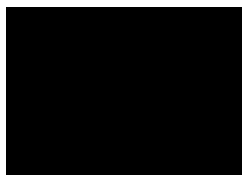
If your test strip supply is not from the lots affected, you can continue using these test strips and no additional action is required.

We have thoroughly investigated this issue to identify the root cause of this potential error and have already started to implement the appropriate corrective measures. Please be assured that this issue only affects the Accu-Chek Aviva and Accu-Chek Performa test strips of the specific lots. Other lots of Accu-Chek Aviva and Accu-Chek Performa test strips and other Accu-Chek blood glucose test strips available in your market are not impacted by this issue.

Health Science Authority (HSA), healthcare professionals, hospitals, distributors and retailers have been informed about this field action.

Please call our Accu-Chek ExtraCare line at 6272 9200, if you need any additional advice on the operation of your Accu-Chek blood glucose meter and test strips or have any further questions or concerns. It is through the careful monitoring of customer reports that we are able to identify issues and implement solutions. We appreciate your time and attention to this important notification.

Kind regards,



Jean Koh
Head of Diabetes Care Singapore

Appendix A: List of affected lot numbers

Appendix A

List of affected lot numbers:

Accu-Chek Aviva test strips 50s
496915

Accu-Chek Performa test strips 10s
476238

Accu-Chek Performa test strips 50s
476258
476295

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Dear Healthcare Professional,

At Roche Diabetes Care we hold our products to the highest standards of quality and are committed to communicating any issues impacting the operation of our products. This is why we would like to inform you today about an issue that might occur in certain lots of the Accu-Chek Aviva and Accu-Chek Performa test strips. As part of our ongoing quality monitoring and market surveillance processes, we have identified certain test strip lots that potentially show an increase in strip errors prior to dosing. Due to the designed fail-safe in the blood glucose meter, the issue can be identified by the error message displayed on the meter upon strip insertion or through the device not recognizing the test strip, respectively. However, in a very limited number of cases the test strip can produce a biased result i.e. a falsely too high or too low value, which your patients might not be able to detect easily and which could potentially lead to erroneous therapy adaptations.

As patient safety is our first priority, we would therefore like to ask you to advise your patients to

- check the lot numbers of their test strip supply against the complete list of lot numbers in the attachment. They can find the lot number on the top flap of the vial packaging as well as on the label of each test strip vial as shown in the picture below.



- discontinue using strips from the affected lots immediately and
- contact our Accu-Chek ExtraCare line at 6272 9200 if they have affected test strip supply to obtain instructions on how to receive the replacement products at no charge.

Please also check, if you have testing supply from the affected product lots in your professional setting. In this case, please use other testing supplies and equipment to monitor your patients' glucose levels and contact our Accu-Chek ExtraCare line at 6272 9200 to receive instructions on how to replace the products at no charge.

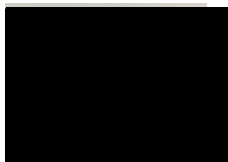
We have thoroughly investigated this issue to identify the root cause of this potential error and have already started to implement the appropriate corrective measures. Please be assured that this issue only affects the Accu-Chek Aviva and Accu-Chek Performa test strips of the specific lots. Other lots of Accu-Chek Aviva and Accu-Chek Performa test strips and other Accu-Chek blood glucose test strips available in your market are not impacted by this issue.

Health Science Authority (HSA), users of the affected blood glucose monitoring systems, distributors and retailers have been informed about this field action.

This notice must be passed on to all those who need to be aware within your organization or to any other organization/individual where the potentially affected devices have been distributed/supplied. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA.

Please call our Accu-Chek ExtraCare line at 6272 9200, if you need any additional advice on the operation of Accu-Chek blood glucose meters and test strips or have any further questions or concerns. It is through the careful monitoring of customer reports that we are able to identify issues and implement solutions. We appreciate your time and attention to this important notification.

Kind regards,



Jean Koh
Head of Diabetes Care Singapore

Appendix A: List of affected lot numbers

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Dear Retailer,

At Roche Diabetes Care we hold our products to the highest standards of quality and are committed to communicating any issues impacting the operation of our products. This is why we would like to inform you today about an issue that might occur in certain lots of the Accu-Chek Aviva and Accu-Chek Performa test strips. As part of our ongoing quality monitoring and market surveillance processes, we have identified certain test strip lots that potentially show an increase in strip errors prior to dosing. Due to the designed fail-safe in the blood glucose meter, the issue can be identified by the error message displayed on the meter upon strip insertion or through the device not recognizing the test strip, respectively. However, in a very limited number of cases the test strip can produce a biased result i.e. a falsely too high or too low value, which your customers might not be able to detect easily and which could potentially lead to erroneous therapy adaptations.

As patient safety is our first priority, we would therefore like to ask you to advise your customers to

- check the lot numbers of their test strip supply against the complete list of lot numbers in the attachment. They can find the lot number on the top flap of the vial packaging as well as on the label of each test strip vial as shown in the picture below.



- discontinue using strips from the affected lots immediately and
- contact our Accu-Chek ExtraCare line at 6272 9200 if they have affected test strip supply to obtain instructions on how to receive replacement products at no charge.

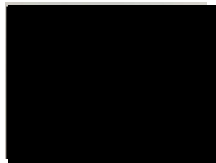
Please also check, if you have testing supply from the affected product lots on stock. In this case, please contact our Accu-Chek ExtraCare line at 6272 9200 to receive instructions on the replacement procedure for the affected quantities.

We have thoroughly investigated this issue to identify the root cause of this potential error and have already started to implement the appropriate corrective measures. Please be assured that this issue only affects the Accu-Chek Aviva and Accu-Chek Performa test strips of the specific lots. Other lots of Accu-Chek Aviva and Accu-Chek Performa test strips and other Accu-Chek blood glucose test strips available in your market are not impacted by this issue.

Health Science Authority (HSA), users of the affected blood glucose monitoring systems, healthcare professionals and hospitals have been informed about this field action.

Please call our Accu-Chek ExtraCare line at 6272 9200, if you need any additional advice on the operation of Accu-Chek blood glucose meters and test strips or have any further questions or concerns. It is through the careful monitoring of customer reports that we are able to identify issues and implement solutions. We appreciate your time and attention to this important notification.

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