

# Field Safety Notice

## SB-RDC-2018-02

Version 1  
02-May-2018

### Accu-Chek® Inform II test strips

#### Issue: Increase in Strip Errors due to reagent and electrode cracking

<b>Product Name</b>	Accu-Chek® Inform II Strips
<b>GMMI / Part No</b> <b>Device Identifier</b>	05942861022 <i>Note: There may be other affected identifiers that are affected globally. Please contact the product owner if the device is obtained from an overseas dealer.</i>
<b>Production Identifier</b> <b>(Lot No./Serial No.)</b>	Lot No.: 476638 <i>Note: There may be other affected lot no. that are affected globally. Please contact the product owner if the device is obtained from an overseas dealer.</i>
<b>Type of Action</b>	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

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

At Roche Diagnostics 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 Inform II 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 might not be detected easily and which could lead to erroneous therapy adaptations.

# Accu-Chek® Inform II test strips

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

- check the lot numbers of the test strip supply against the affected lot number mentioned (Lot no 476638). The lot number can be found 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 please use different lot of Accu-Chek blood glucose test strips to monitor your patients' glucose levels
- contact our Roche representative, Francis at 98175522 should you have the affected test strip supply to advise you on how to receive the replacement 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 particular lot of Accu-Chek Inform II test strips. Other Accu-Chek Inform II test strips available in your market are not impacted by this issue.

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.

### Communication of this Field Safety Notice

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 maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action

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

Sincerely,

# **Accu-Chek® Inform II test strips**

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**Roche Diagnostics Asia Pacific Pte Ltd**

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