

Field Safety Notice**Product: Quo-Test A1C Test Kit**
FSN reference: EKF122018Date: 19th December 2018

Dear valued customer,

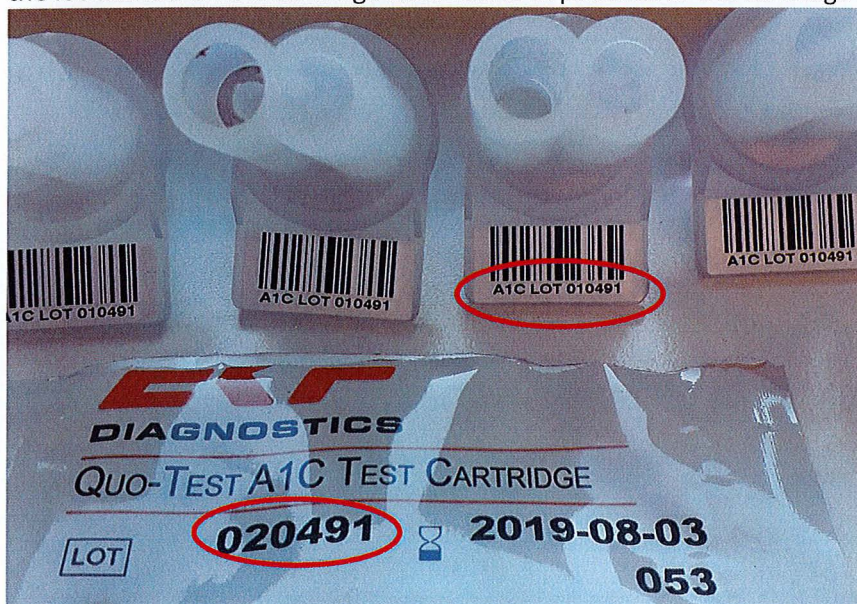
This letter is to inform you that one lot of the Quo-Test A1C Test Kit (REF 0031) may contain single cartridges that are marked with an incorrect barcode on the cartridge and will not produce a result when used for measurement.

Details of Affected Devices:

Quo-Test A1C Test Kit (REF 0031) LOT: 020491 expiry date: 03.08.2019

Description of the Problem:

EKF-diagnostic GmbH has become aware of a manufacturing issue that can result in cartridges marked with the lot 010491 on the cartridge itself found in pouches of the cartridge lot 020491.



The barcode on the cartridge is identified by the analyzer during measurement and is used to link the measured cartridge to the calibration barcode which is scanned from the cartridge box.

It is possible to start the measurement using a cartridge carrying the incorrect lot information. As there is no calibration barcode recognized by the analyzer for the incorrectly marked lot (010491), no measurement result will be displayed when using an affected cartridge.

The root cause for this issue is under investigation and actions have been taken to prevent recurrence. Only the lot number listed above is potentially impacted by this issue.



General Terms and Conditions of EKF-diagnostic GmbH, which you can view at any time in our offices, shall apply. We would also send it to you upon your request.

EKF-diagnostic GmbH
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Patient Impact:

There is no impact on the patient as no result can be generated. There may be a potential delay in generating results because of the failure to produce a result using an affected cartridge.

Actions to be taken by the Customer:

We recommend to check the barcode on the cartridges of the affected lot 020491 prior to use and discard the cartridge if the lot number 010491 is displayed on the cartridge itself.

Cartridges showing the correct lot number 020491 can be used without restrictions.

Please inform EKF-diagnostic GmbH about your need for replacement of the discarded material.

Please confirm receipt and acknowledgement of this information by sending back the attached response form.

Transmission of this Field Safety Notice:

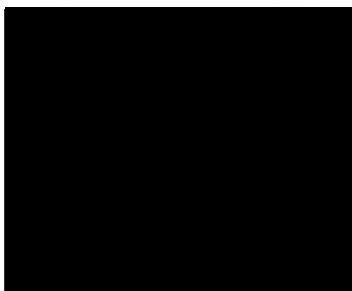
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the affected products have been transferred.

Contact:

Technical Support
EKF-diagnostic GmbH
Ebendorfer Chaussee 3
39179 Barleben
Germany
+49 (0) 39203 511 414
support@ekf-diagnostic.de

We apologize for the inconvenience this issue has caused and thank you for your assistance.

The undersigned confirms that this notice has been notified to the appropriate regulatory agency.



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FSN RESPONSE FORM

Product: Quo-Test A1C Test Kit
FSN reference: EKF122018

This response form is to confirm receipt of the enclosed Field Safety Notice dated 19th December 2018 regarding the Quo-Test A1C Test Kit.

Please fax or email a scanned copy of this completed form to EKF-diagnostic GmbH until 31st March 2016.
Fax: +49 (0) 39203 511 171
Email: support@ekf-diagnostic.de

I have read and understood the Field Safety Notice instructions provided in this letter.

Please mark as applicable

Please create a credit for Quo-Test A1C Test Kits.

Please replace Quo-Test A1C Test Kits.

We need no credit or replacement.

Signature	
Date	
Name	
Company name	
Address	