EKF-diagnostic GmbH • Ebendorfer Chaussee 3 • 39179 Barleben

FSN Reference Number: FSNEKF022024 Monday, 4th March 2024

# URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

**Dear Valued Customer,**

Product quality and safety are the main priorities at EKF-diagnostic GmbH (EKF).
The purpose of this letter is to advise you that EKF has issued a Field Safety Notice (FSN) in relation to the below product(s);

**Details of affected products:**

| | |
|---|---|
| Impacted Products: | Quo-Lab A1C Test Kit / REF 0055<br>PocketChem™ A1c HbA1c Test Kit / REF 0130 |
| Impacted Product Lots: | 026246 to 026403 |

Please be further advised that to date EKF is not aware of any serious injuries and/or deaths occurring due to the failure mode associated with this FSN.

Our records indicate that you purchased one or more of the identified lots (listed in Attachment 1).

**Description of the problem:**
During routine internal testing of retention samples, EKF identified failures to meet the product's stability specification in samples stored beyond six months, nine months, and the end of shelf life resulting in possible false low measurements.

Due to the deterioration of the stability in the lots indicated above, we request that you immediately **discontinue the use** of any remaining affected product beyond a 6 month shelf life from the date of manufacture (see Attachment 1) and follow the **customer-required action** as detailed in this notification. Please complete the attached 'Customer Response Form' and return it to EKF without delay.

**Risk to health:**
An A1C level just below the recommended 7% (53 mmol/mol) based on a false too-low A1C test result might prevent the physician from changing therapy.
The product is unlikely to give assurance as to whether a result is 50 or 60 mmol/mol when stored beyond six months and consequently has the potential for causing patient harm.
This risk is significantly higher for patients who are treated with oral medication and/or non-insulin injectable alone since, for these patients, a regular (self-) measurement of the blood glucose level is not recommended.

**Action taken by EKF:**
EKF has identified all impacted customers and product lots placed on the market.
EKF has quarantined any remaining product held in the inventory.
Product currently being produced by EKF pending investigation will be assigned a six-month shelf life in the interim.
EKF are able to offer the Quo-Test analyzer and A1C Test Kit as an alternative.

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Deutsche Bank Magdeburg
IBAN DE80 8107 0000 0118 6253 00
BIC DEUTDE8MXXX
Commerzbank Magdeburg
IBAN DE42 8104 0000 0209 6006 00
BIC COBADEFFXXX

Until the investigation is finalized, if you have further questions and/or would like to discuss possible alternative products, please contact Technical Support at;
+49 39203 511 414 or support@ekf-diagnostic.de.

## CUSTOMER REQUIRED ACTION

1. Please immediately discontinue use, quarantine, and dispose of any remaining inventory beyond the indicated validity period of 6 months.
2. Please ensure this information is shared with your laboratory staff and other pertinent personnel.
3. If you are a distributor, please complete and return the 'Customer Response Form' enclosed herein. Please also forward this FSN to your end user(s) without delay for completion and return.
4. If you are the end user in receipt of this FSN from the distributor, please complete the 'Customer Response Form' and return it to the distributor.
5. If you are an end user in receipt of this FSN directly from EKF, please complete the 'Customer Response Form' and return it to EKF.
6. The enclosed 'Customer Response Form' must be returned via fax or email within 10 business days.
7. Please ensure a copy of this notification is retained as part of your Quality System records.
8. Upon receipt of the fully completed and signed 'Customer Response Form', we will contact you to process the product replacement or refund.

Your cooperation is appreciated and we sincerely apologize for any inconvenience this issue may cause.

Sincerely,

EKF-diagnostic GmbH
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CIC 287282
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**CUSTOMER RESPONSE FORM**

**MEDICAL DEVICE FIELD SAFETY NOTICE FSN Reference Number: FSNEKF022024**

**Response is Required**

To satisfy regulatory requirements for reporting, please complete this 'Customer Response Form' and return it to EKF using one of the below methods.
Please enter the following in the subject: RESPONSE TO FSNEKF022024 - <COMPANY NAME >

FAX +49 (0) 39203 511 171
E-Mail support@ekf-diagnostic.de

**Return Response:**

We acknowledge receipt of the URGENT MEDICAL DEVICE FIELD SAFETY NOTICE dated, Monday, 4th March, 2024 for the Quo-Lab A1C Test Kit / REF 0055 and PocketChem A1c Test Kit / REF 0130 and confirm we have read and understand the instructions provided therein.

☐ Yes / ☐ No

Are you aware of any adverse events or quality issues associated with recalled product?

☐ Yes / ☐ No

If yes, please provide further information:

The following has been verified (SELECT ALL THAT APPLY):
We attest that;

☐ We confirm that all areas where the product could be located have been identified and checked.

☐ We do not have any affected product.

☐ We do have affected product and have quarantined the product. **Indicate lots and quantities below**.

☐ We have appropriately disposed of the product. **Indicate lots and quantities below**.

☐ Product was redistributed to another facility; and the notice was forwarded.

Please provide any additional information below, (if applicable).

Date: _____ Signature of Receipt _____

Print Name: _____ Title: _____

Institution Name: _____

Address: _____

City, State: _____ Postal Code: _____

Country: _____ Phone: _____

Email: _____