

Urgent Field Safety Notice

epoc BGEM Test Card, Catalogue No. CT-1004-00-00

FSCA-identifier: 28 March 2013

Type of action: Device Destruction

[\[Click here and type the date\]](#)

[\[Click here and type the contact name\]](#)

[\[Click here and type the facility's name\]](#)

[\[Click here and type the mailing address\]](#)

[\[Click here and type the mailing address\]](#)

Dear Valued Customer,

The purpose of this letter is to inform you that Epocal Inc. is initiating a voluntary recall of the following lots of epoc[®] BGEM Test Card.

| Product Description: | Product Number: | Lot Number: |
|----------------------------------|------------------------|---------------------|
| epoc [®] BGEM Test Card | CT-1004-00-00 | Refer to Appendix 1 |

Our records indicate that you have received one or more of the referenced lots of epoc[®] BGEM Test Cards from Alere International Limited.

Epocal has determined that the referenced lots of this product may yield results that are not consistent with stated precision performance criteria at concentration values at the high-end range of the Glucose test sensor. Specifically, in some test cards aged to within 2.5 months (75 days) of their expiration date, a negative bias of 15 - 30% has been observed in samples with glucose levels greater than 400 mg/dl (22 mmol/L). All glucose measurements between the low end of the reportable range and 400 mg/dL are accurately reported, as are all other assay results in the affected cards.

Please discontinue use of the referenced lots of product and dispose of them in accordance with your local requirements.

The epoc Blood Analysis System is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders, including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell tumors.

We have not had any reports of adverse events associated with this issue. This issue impacts only the Glucose sensor and only samples with glucose levels greater than 400 mg/dl; all other assays for other analytes are performing as expected.

The relevant National Competent Authorities have been advised of this field safety corrective action (FSCA) through our EU Authorized Representative, Emergo Europe, Molenstraat 15, 2513 BH The Hague, The Netherlands, Telephone: +31.70.345.8570.

CUSTOMER REQUIRED ACTION

- Discontinue use and/or sale of epoc[®] BGEM Test Card for the lot numbers identified in Appendix 1.
- If you have remaining inventory of the affected lot numbers, please discard all units of these lot numbers in accordance with your local regulations.
- If you have consumed all product for the lot numbers listed in Appendix 1, please indicate that you have no remaining inventory on the attached Field Safety Notice Reply form.
- If you have forwarded product lots listed in Appendix 1 to another customer or laboratory, please provide a copy of this letter to them.
- Whether you have remaining inventory or not, please complete and FAX or e-mail the enclosed Field Safety Notice Reply Form within 10 days to confirm your receipt of this notice. Once the completed Field Safety Notice Reply Form is received, credits or replacement orders for quantities specified will be processed.

Please FAX or e-mail the completed Field Safety Notice Reply form to your local Alere Distributor:

**<INSERT LOCAL DISTRIBUTOR NAME>
<INSERT LOCAL DISTRIBUTOR FAX #>
<INSERT LOCAL DISTRIBUTOR E-MAIL ADDRESS>**

We apologize for any inconvenience that this may cause you and your patients. We appreciate your attention and cooperation in this matter.

If you have any questions relating to this Field Safety Notice please call Alere Technical Support at **<INSERT DISTRIBUTOR CUSTOMER SERVICE PHONE NUMBER>** or email **<INSERT DISTRIBUTOR CUSTOMER SERVICE EMAIL>**.

Sincerely,



Vice President, Quality Assurance and Regulatory Affairs
Epocal Inc.

Field Safety Notice Reply Form

- [\[Click here and type the contact name\]](#)
- [\[Click here and type the facility's name\]](#)
- [\[Click here and type the mailing address\]](#)
- [\[Click here and type the mailing address\]](#)

I have been notified by Epocal, Inc. to discontinue use / sale / distribution of the following products:

| Product Description: | Product Number: | Lot Number: |
|----------------------------------|-----------------|---------------------|
| epoc [®] BGEM Test Card | CT-1004-00-00 | Refer to Appendix 1 |

Please check those that apply:

- I have remaining inventory and will destroy the quantities indicated in the table below:

| Product Number: | Lot Number(s): | Quantity Destroyed: | Unit of Measure: (Please circle one) | Credit or Replacement (Please circle one) |
|-----------------|----------------|---------------------|---|--|
| CT-1004-00-00 | | | EACH BOX | CREDIT REPLACEMENT |

- I have no remaining inventory of these lot numbers.
- I have no record of receipt of this product or these lot numbers and therefore have no product to destroy.
- I have forwarded this notification to our consignees.

Please complete the following information:

| | |
|---------------|---------|
| Signature: | Title: |
| Printed Name: | Date: |
| Telephone: | E-mail: |

Please FAX the completed form to [<Insert Local Distributor Fax #>](#) or email a PDF to [<Insert Local Distributor email>](#).

To satisfy global requirements for regulatory reporting, please complete and return this form within 10 business days of receipt.

Appendix 1: List of Lot Numbers Included in Field Safety Notice

| <u>LOT #'s</u> | <u>EXP. DATE</u> | | <u>LOT #'s</u> | <u>EXP. DATE</u> |
|----------------|------------------|--|----------------|------------------|
| 07-12283-00 | 2013-03-26 | | 07-12331-00 | 2013-05-13 |
| 07-12284-00 | 2013-03-27 | | 07-12333-00 | 2013-05-15 |
| 07-12285-00 | 2013-03-28 | | 07-12335-00 | 2013-05-17 |
| 07-12289-00 | 2013-04-01 | | 07-12338-00 | 2013-05-20 |
| 07-12290-00 | 2013-04-02 | | 07-12340-00 | 2013-05-22 |
| 07-12292-00 | 2013-04-04 | | 07-12341-00 | 2013-05-23 |
| 07-12293-00 | 2013-04-05 | | 07-12345-00 | 2013-05-27 |
| 07-12296-00 | 2013-04-08 | | 07-12346-00 | 2013-05-28 |
| 07-12297-00 | 2013-04-09 | | 07-12347-00 | 2013-05-29 |
| 07-12298-00 | 2013-04-10 | | 07-12349-00 | 2013-05-31 |
| 07-12300-00 | 2013-04-12 | | 07-12352-00 | 2013-06-03 |
| 07-12303-00 | 2013-04-15 | | 07-12354-00 | 2013-06-05 |
| 07-12305-00 | 2013-04-17 | | 07-12355-00 | 2013-06-06 |
| 07-12306-00 | 2013-04-18 | | 07-12362-00 | 2013-06-13 |
| 07-12307-00 | 2013-04-19 | | 07-12363-00 | 2013-06-14 |
| 07-12310-00 | 2013-04-22 | | 07-13002-00 | 2013-06-19 |
| 07-12312-00 | 2013-04-24 | | 07-13003-00 | 2013-06-20 |
| 07-12313-00 | 2013-04-25 | | 07-13004-00 | 2013-06-21 |
| 07-12314-00 | 2013-04-26 | | 07-13007-00 | 2013-06-24 |
| 07-12317-00 | 2013-04-29 | | 07-13008-00 | 2013-06-25 |
| 07-12320-00 | 2013-05-02 | | 07-13009-00 | 2013-06-26 |
| 07-12321-00 | 2013-05-03 | | 07-13010-00 | 2013-06-27 |
| 07-12324-00 | 2013-05-06 | | 07-13014-00 | 2013-07-01 |
| 07-12325-00 | 2013-05-07 | | 07-13015-00 | 2013-07-02 |
| 07-12327-00 | 2013-05-09 | | 07-13017-00 | 2013-07-04 |