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Kunde
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E-Mail: info@gabmed.de
Internet: www.gabmed.de

URGENT MEDICAL DEVICE RECALL

Date: August XX, 2008

Re: **gabControl® Troponin I (M04K13) and gabControl® CardiaCombo Myoglobin/CK-MB/Troponin I (M05K47)**

Dear Valued Customer,

The purpose of this letter is to inform you that gabmed GmbH is initiating a voluntary recall of the following products: gabControl® Troponin I (M04K13) and gabControl® CardiaCombo Myoglobin/CK-MB/Troponin I (M05K47). Immediately discontinue all use and discard all affected product in accordance with your local regulations.

Internal investigations have revealed that the claimed limit of detection for Troponin I of 0.5 ng/ml has shifted since the initial development of the product. While heparinized human plasma had a minimum detection limit of 0.5 ng/ml, the results with human serum and heparinized human whole blood demonstrated a minimum detection limit of 1 ng/ml. Normal human plasma, normal human serum and normal human whole blood gave negative results as expected. Use of the affected devices may result in False Negative results with specimens containing Troponin I at levels between 0.5 ng/ml and 1 ng/ml, leading to missed or incorrect diagnosis.

As a result we have made the decision to discontinue the use of these products. Therefore, immediately discontinue all use and discard all affected product in accordance with your local regulations.

As was explained in the package inserts, the gabControl® Troponin I Rapid Test Devices (Whole Blood/Serum/Plasma) and gabControl® Myoglobin/CK-MB/Troponin I Combo Test Devices (Whole Blood/Serum/Plasma) provided a qualitative result of cTnI in the specimen and would not have been used as the sole criteria for the diagnosis of myocardial infarction. A negative result at any time does not preclude the possibility of myocardial infarction. Additionally, as with all diagnostic tests, all results should have been interpreted together with other clinical information available to the physician. If you have any questions regarding previously reported results from any of the above tests we recommend that you consult your resident clinical expert or cardiologist.

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END USER/CUSTOMER REQUIRED ACTION

- **Discontinue the use of all kits of the gabControl® Troponin I (M04K13) and gabControl® CardiaCombo Myoglobin/CK-MB/Troponin I (M05K47)**
- **Discard in accordance with your local regulations all kits of the gabControl® Troponin I (M04K13) and gabControl® CardiaCombo Myoglobin/CK-MB/Troponin I (M05K47)**
- **Complete and FAX the enclosed Verification Form within 10 days to confirm your receipt of this notice and to indicate the number of kits discarded from your inventory.**

Once we receive your completed form, we will start crediting the listed items and quantities.

We have recently included a new Troponin I test to our product range that works with a buffer solution and is not affected by the recall. This test was clinically evaluated with great success and is available for you now. The catalogue number is M06K14.

We sincerely regret any inconvenience this product performance issue may have caused. Please note that the relevant National Competent Authorities have been advised of this Field Safety Corrective Action.

Sincerely,

[redacted]
Quality Management
gabmed GmbH

Please complete this form even if you do not have any involved product and
Fax Back to gabmed GmbH, +49-2153-9597-17

End User/Customer Verification Form
Urgent Medical Device Recall

1. We acknowledge receipt of the gabmed GmbH Product Recall notice dated, August XX, 2008 for the gabControl® Troponin I (M04K13) and gabControl® CardiaCombo Myoglobin/CK-MB/Troponin I (M05K47)
2. We confirm that all areas where the product could be located have been checked.
3. **SELECT ALL STATEMENTS THAT APPLY***, **SIGN THIS FORM** and **FAX** to +49-2153-9597-17

   ☐ We do not have any affected product.

   ☐ Product was redistributed to another facility (please forward the information you have received to any other facilities that have received this product)

   ☐ We are destroying/discarding the following product(s) (confirm the product, lot number(s), the quantity destroyed and date destroyed).

Product Name	Part Number	Lot Number(s) (please list below)	Kit Quantity Discarded

Date*: _____

Authorized Signature*: _____

Print Name*: _____

Tlitle*: _____ Department: _____

Institution*: _____

Address*: _____

City*: _____ State*: _____ Country*: _____

Phone*: _____

To satisfy global requirements for regulatory reporting, please complete and return this form within 10 business days of receipt to gabmed GmbH, +49-2153-9597-17

*** Mandatory field**