gabmed GmbH • Am Wassermann 28 • 50829 Köln

**Recipient:**
Users, operators, distributors
of the gabControl D-Dimer rapid test
(M09DD02)

gabmed GmbH
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# Urgent Field Safety Notice

## Medical Device Recall of gabControl D-Dimer rapid test (M09DD02) from the market

Cologne, October 18, 2016

Dear valued customer,

This Urgent Field Safety Notice of the gabmed GmbH concerns the gabControl D-Dimer rapid test (Product-ID: M09DD02).

**Details on affected devices:**

This notification relates to the subsequent batches of the test:

| Produkt-ID | Product name | Lot number | Expiry date |
|---|---|---|---|
| M09DD02 | D-Dimer rapid test | DIM16070008 | 04-2018 |
| M09DD02 | D-Dimer rapid test | DIM16070007 | 04-2018 |
| M09DD02 | D-Dimer rapid test | DIM16050005 | 04-2018 |
| M09DD02 | D-Dimer rapid test | DIM16050004 | 04-2018 |
| M09DD02 | D-Dimer rapid test | DIM16030006 | 03-2018 |
| M09DD02 | D-Dimer rapid test | DIM16030001 | 02-2018 |
| M09DD02 | D-Dimer rapid test | DIM16020004 | 12-2017 |
| M09DD02 | D-Dimer rapid test | DIM16010006 | 12-2017 |
| M09DD02 | D-Dimer rapid test | DIM16010003 | 11-2017 |
| M09DD02 | D-Dimer rapid test | DIM16010002 | 12-2017 |
| M09DD02 | D-Dimer rapid test | DIM15120003 | 11-2017 |
| M09DD02 | D-Dimer rapid test | DIM15100003 | 10-2017 |
| M09DD02 | D-Dimer rapid test | DIM15060002 | 05-2017 |
| M09DD02 | D-Dimer rapid test | DIM15060001 | 05-2017 |
| M09DD02 | D-Dimer rapid test | DIM15050008 | 05-2017 |
| M09DD02 | D-Dimer rapid test | DIM15050007 | 05-2017 |
| M09DD02 | D-Dimer rapid test | DIM15050006 | 05-2017 |
| M09DD02 | D-Dimer rapid test | DDI150303 | 03-2017 |
| M09DD02 | D-Dimer rapid test | DDI150302 | 03-2017 |
| M09DD02 | D-Dimer rapid test | DDI141202 | 12-2016 |

**Description of the problem:**

Due to weakly visible test lines in the said batches, it came to an increased amount of false-negative results.

Although the potential risk is considered to be minor with a test considered to be a pre diagnostic test, the product is being recalled from the European market by the gabmed GmbH as a precautionary measure to prevent false negative results. As the test is used as an aid in diagnosis, there is residual risk that additional

tests such as an ultrasound are not performed, particularly for patients considered to be at low risk. If you have performed this test recently consider the need to recall and retest patients with a laboratory based test. Production of new batches has been halted until further notice. **Please immediately discontinue use of the above-mentioned product; fill out the attached fax confirmation form and dispose of any remaining stocks in accordance with local regulations.**

**Action to be taken by the user/distributor:**

**REQUIRED MEASURES End Customer/Users**

- Please immediately discontinue use of all packages of the concerned batches, fill out the attached fax confirmation form and dispose of any remaining stocks in accordance with local regulations.
- Fill out the enclosed fax confirmation form and fax it to within 10 days to your invoice issuer/supplier in order to confirm receipt of this notice and communicate the number of destroyed single tests from your stocks/warehouse.
- If you acquired the product through a dealer, you should be sure to return the fax confirmation form to the invoice issuer/supplier. Only by doing so, proper processing and credit can be ensured. If you purchased the product from gabmed GmbH directly, please return the fax confirmation form to us.

**REQUIRED MEASURES Distributors/ Drug stores**

- Please immediately discontinue use of all packages of of the concerned batches, fill out the attached fax confirmation form and dispose of any remaining stocks in accordance with local regulations.
- Fill out the enclosed fax confirmation form and fax it to within 10 days to your invoice issuer/supplier in order to confirm receipt of this notice and communicate the number of destroyed single tests from your stocks/warehouse. **ONLY completely filled out fax confirmation forms are essential for problem-free processing and credit.**
- If you acquired the product through a dealer, you should be sure to return the fax confirmation form to the invoice issuer/supplier. Only by doing so can proper processing and credit be ensured. If you purchased the product from gabmed GmbH directly, please return the fax confirmation form to us.
- Please return the fax confirmation form along with the single tests destroyed by your customers to the invoice issuer/supplier with 30 days of receipt of this notice. You will then receive an appropriate credit.
- For purposes of providing absolutely necessary information to your customers, you can also request this letter in Word format e.g. so that you can modify it as needed. Simply send a brief e-mail to recall@gabmed.de. We will then send you the document without delay.

**Transmission of this Field Safety Notice**:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please send this notice to any other organisations or customers on which this action has an impact.

Please maintain awareness of this notice and resulting action to ensure effectiveness of the corrective action.

**Contact reference:**
All relevant National Competent Authorities have been advised of this field safety corrective action. If you have any further questions about the content of this Notice, please contact:

gabmed GmbH
Am Wassermann 28
50829 Köln
Tel. +49 221-569730
E-Mail: recall@gabmed.de

We sincerely regret any inconvenience, which may have been caused by the problem with the product quality. Please note that the competent authorities have received a copy of this Field Safety Notice and the recall measure.

We invite you to review the attached confirmation fax as soon as possible and to send it as soon as possible to the invoice issuer/supplier. **We may be required to notify competent authorities of all customers who do not respond to this FSN.**

Thank you very much for your cooperation.

Yours sincerely
gabmed GmbH

Dave Sieber
Safety officer

**Please fill out this form even when you do not have products left and fax it to your invoice party/supplier.**

# Confirmation fax
# Urgent Field Safety Notice

**gabControl D-Dimer rapid test**

1. I have read and understood the Urgent Field Safety Notice regarding the **gabControl D-Dimer rapid test.**
2. We confirm that all areas where the product could be located have been checked.
3. **PLEASE SELECT ALL STATEMENTS THAT APPLY, SIGN THIS FORM** and **FAX** to your distribution partner.

| | |
|---|---|
| ☐ | We do not have any affected product. If so, indicate zero on the form below. |
| ☐ | The notice was redistributed to other organization(s). We forwarded a copy of this field safety notice to this/these organization(s). We will ensure that the collected data of this/these organization(s) will be forwarded to our invoicing party/supplier. |
| ☐ | We have the affected product. We have read and understood the Urgent Field Safety Notice information. |
| ☐ | We discarded the products as mentioned in “Annex I” and expect a credit note: |

Date*

Authorized signature*

**Please complete in capital letters**

Name*

Company/Institution*

Address*

Phone*

**Field for company/organization stamp**

Please fill out this form and fax it within 10 working days after receipt to the invoicing party/your supplier to fulfill the global reporting obligation.

*) **Mandatory field**

ANNEX I

Please fill in lot number, expiry and number of used and discarded single tests as well as date of disposal:

| Product Name | Lot Number | Purchase Quantity (single tests) | Used Quantity (single tests) | Discard Quantity (single tests) | Date Discarded |
|---|---|---|---|---|---|
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