gabmed GmbH • Am Wassermann 28 • 50829 Cologne

gabmed GmbH
Praxis- & Drogendiagnostik
[Surgery & Drug Diagnostics]
Am Wassermann 28
D-50829 Cologne

Telephone: 02 21 – 56 97 3 - 0

E-mail: info@gabmed.de
Internet: www.gabmed.de

Urgent Medical Device Recall

Cologne, 6 October 2011

Affected Product:	PZN: [Central Pharmaceutical Product no.]:	Product ID:
gabControl® Strep A TEST CARD	4766124	M04K09-05
	4766176	M04K09-10
	2929786	M04K09-20

Nota Bene: gabControl® Strep A **TEST STRIPS** are **NOT** affected!

Dear Valued Customer,

the purpose of this letter is to notify you that gabmed GmbH has initiated a voluntary recall of the following product: gabControl® Strep A **TEST CARD**.
The reason for this recall is as follows: in the course of regular quality inspections, it was determined that false positive results may occasionally be generated.

Although the potential risk is considered to be minor, the product is being recalled by gabmed GmbH as a precautionary measure to prevent false positive results. Production of new batches has been halted until further notice, until such time as product quality can be guaranteed with absolute certainty.

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.

The strip test version of the gabControl® Strep A test is NOT affected by this recall and may continue to be used as an alternative without limitation.

Fax confirmation forms can only be processed if they are sent to the appropriate **invoice issuer or supplier**.
Thank you for your comprehension.

Whilst it is regrettable that recalls may occasionally arise in instances such as this one, this measure also clearly shows the high standards we place - and must place - on our product quality, standards from which you as our customer benefit in the long run.

Please note that the competent national authorities have been notified of this recall.

Please be so kind as to return the attached fax confirmation form to us as soon as possible. We are obligated to report all customers who have not responded to our letter to the Federal Institute for Drugs and Medical Devices (BfArM).

Sincerely,

[redacted]

Required Steps End Customer/Users:

- **Please immediately discontinue use of all packages of gabControl® Strep A test cards, 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 kits from your stocks/warehouse. 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.**

Required Steps Dealers/Chemists:

- **Please immediately discontinue use of all packages of gabControl® Strep A test cards, 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 kits from your stocks/warehouse. 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 kits 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 info@gabmed.de. We will then send you the document without delay.**

Please fill out this form even if you no longer have any of the aforementioned products and fax it to the invoice issuer/supplier.

Fax Confirmation Form
Urgent Medical Device Recall

1. We acknowledge receipt of the product recall of 6 October 2011 for the gabControl® Strep A test cards.
2. We confirm that all potential warehouse and storage locations for the product have been checked.
3. **PLEASE TICK ALL APPROPRIATE STATEMENTS***, **SIGN THIS FORM**, and fax it back to the invoice issuer/supplier

   ☐ We do not have any supplies of the aforementioned product.

   ☐ The product has been despatched to another institution
   (please follow the procedures regarding notification of your customers).

   ☐ We have destroyed the following products
   (please provide LOT numbers, expiry and where applicable number of kits disposed of):

Product/VE	PZN [Central Pharmaceutical Product no.]/ Product ID	LOT/Expiry	Disposed of
Strep A Card 5 pack	4766124 M04K09-05		
Strep A Card 10 pack	4766176 M04K09-10		
Strep A Card 20 pack	2929786 M04K09-20		

Date*

Responsible Individual's Signature*

Please fill out in block letters

Name*

Institution*

Address*

Telephone*

Space for Company/Surgery Stamp

Fill out this form and fax it to the **invoice issuer/supplier** within 10 working days of receipt in order to comply with internationally applicable notification requirements.

***) Mandatory fields**