Recipient:
Users, operators, distributors
of the below named rapid test

November 7, 2018

Important Field Safety Note

Affected product

Product name	Ratiomed H.pylori (whole blood/serum/plasma)
Product-ID:	MEG 254085, MEG 254086, MEG 254087
Lot number:	all
Type of action	Correction of the product insert

Dear valued customer,

In this field safety note gabmed GmbH provides **important information regarding an updated product insert** for the **Ratiomed H. pylori rapid test (whole blood/serum/plasma)** and all variants:

Description of issue

An internal investigation confirmed that invalid results may be obtained with serum or plasma specimens due to an incorrect description of the test procedure in the product insert of the above-named products. The product insert was corrected accordingly. Changes are stated below:

Section	Current product insert (Rev. 003, 2015-04-15 (FAM))	Correction of product insert (Rev. 005, 2018-10-22 (FAM))
Material provided	• ,**H. pylori Test** separately packed • Disposable dropper • Dilution buffer (for whole blood only) • Package insert	• ,**H. pylori Test** separately packed • Disposable dropper • Dilution buffer • Package insert
Test procedure	**3. Serum or Plasma specimens** Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50 µl) to the specimen well of the test device. **Venipuncture whole blood** Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50 µl) to the specimen well of the test device. **Fingerstick whole blood specimen** **Use capillary tube:** Fill the capillary tube and transfer approximately 50 µl of fingerstick whole blood to the specimen well (S) of the test device **4. Dilution buffer (for whole blood only)** Add drop of dilution buffer (approximately 40 µl) to the same sample well. Avoid adding any solution to the rectangular result window. Start the timer immediately.	**3. Serum or Plasma specimens** Hold the dropper vertically and transfer **2 drops of serum or plasma** (approximately 50 µL) to the specimen well (S) of the test device, then add **1 drop of dilution buffer** to the specimen well. Start the timer. **Venipuncture whole blood specimens** Hold the dropper vertically and transfer **2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the test device, then add **1 drop of buffer**. Start the timer. **Fingerstick whole blood specimen** **Use capillary tube:** Fill the capillary tube and transfer approximately 50 µL of fingerstick whole blood to the specimen well (S) of the test device**.** Add **1 drop of buffer** and start the timer.

Note: Additionally, graphics were updated and minor changes to wording added.

Health risk evaluation

The Ratiomed H. pylori Test (and variants) contains a procedural control (control line) to verify correct procedural technique, usage of sufficient sample volume, and adequate membrane wicking. Usage of insufficient sample volume due to lack of buffer for serum and plasma samples will be displayed as an invalid result (no control line visible) and is readily identifiable to users. An invalid test must then be repeated with a new test. A residual risk remains that patients might face further testing in the laboratory/clinic and diagnosis could be delayed. This risk does not affect users of the test using whole blood samples (fingerstick or venous).

The H. pylori test for whole blood, serum, or plasma specimens is intended for the qualitative detection of antibodies to *H. pylori* to aid in the diagnosis of *H. pylori* infection. Stated limitations of the product include that all results must be interpreted together with other clinical information available to the physician. The H. pylori test only detects the presence of antibodies against *Helicobacter pylori* and should not be used as the sole criteria for the diagnosis of *H. pylori* infection. The test should be used only to evaluate patients with clinical signs and symptoms suggestive of gastrointestinal disease. For these reasons the health risk for patients was evaluated as low.

The competent national authority BfArM has been notified of this field safety corrective action.

Customer actions

1. To be carried out by the end user / user

- Please forward this information to all persons using the test within your organization or to any organization where the affected products have been transferred.
- Please check your records for the H. pylori test kit IFU (rev. 003, 2015-04-15 (FAM)). Destroy this IFU and replace with the included IFU (rev. 005, 2018-10-22 (FAM)). Use only the correct product insert that is transmitted with this field safety notice.
- To comply with regulatory requirements, please complete the attached confirmation fax and mail or fax it to E-mail-address: alongi@megro.de or Fax-No. 0049-281-9899-55 within 10 days to confirm the receipt of this message and the correct product insert.

2. To be carried out by the distributer / pharmacy

- Please forward this safety notice and the updated insert to all affected customers and those within your facility who need to be aware of the situation and confirm this on the confirmation form.

Please allow for awareness and the resulting actions to ensure the effectiveness of this corrective action.
There is no requirement to stop using the product or to return goods. You may contact our customer support (E-mail-address: alongi@megro.de or Tel-No. 0049-281-9899-854) in case a return is required.

Contact:

megro GmbH & Co. KG
Am Schornacker 30
46485 Wesel
Phone: 0049-281-9899-854
E-Mail: alongi@megro.de

We sincerely regret any inconvenience, which may have been caused. If you have any further questions or concerns, please contact us at any time.

Thank you very much for your cooperation.

Yours sincerely

megro GmbH & Co. KG

Attachment
Confirmation form
Product insert Ratiomed H. pylori test

Confirmation form

Ratiomed H. pylori test device (whole blood/serum/plasma)

Please fill out this form and fax or email it within 10 business days of receipt to E-mail-address:alongi@megro.de or Fax-No. 0049-281-9899-55 **to meet the worldwide reporting requirements. Please fill out this form even when you do not have products left.**

1. I have read and understood the important Safety Notice of megro GmbH & Co. KG regarding the Ratiomed H. pylori test.
2. We confirm that all sites where the product could be located have been checked.
3. Please select all statement below that apply and provide your contact data.

☐ We do not work with this product.

☐ I am working for a distributer and have forwarded the safety notice to all persons in my organization who need to be aware of it, as well as to all affected customers.

☐ I am an end user of the affected product and I have received the notice and the correct product insert (rev 005, 2018-10-22 (FAM)) for this test. I confirm the exclusive use of this product insert by all persons in my organization and destroyed all inserts with rev. 004, 2015-04-14 (FAM).

CONTACT		
Name in capital letters*:		Address/stamp:
Company*:		
Phone*:		
Email*:		
Product was purchased by this distributor:		

Date and authorized signature*:

_____

*** required**