

ООО "МЕЛОН"

Co Ltd "MELON"

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ИНН: 7801538989, КПП: 780101001, ОГРН 1117847032786

Фотографические изображения общего вида медицинского изделия

«БИОНИТ Экспресс-тест Helicobacter pylori UFT 300» в составе

«УТВЕРЖДАЮ»

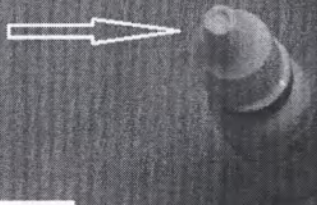
Генеральный директор
ООО «Мелон»

Побемянский Г.Э.

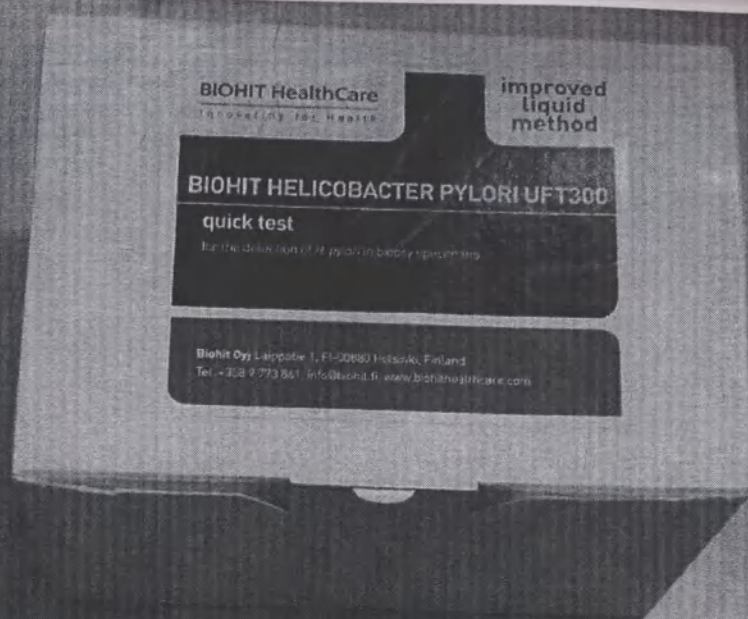
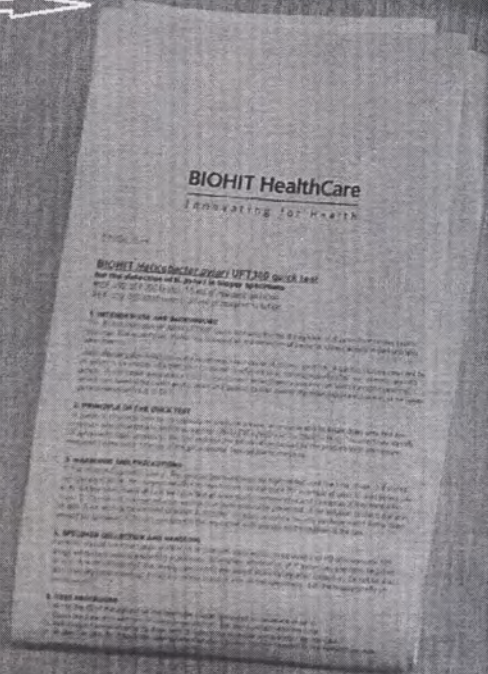


БИОНИТ Экспресс-тест Helicobacter pylori UFT 300»
в составе
Вариант исполнения 1 (REF:602005)

Флакон с реагентом 2,5 мл.



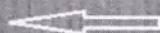
Инструкция по применению.



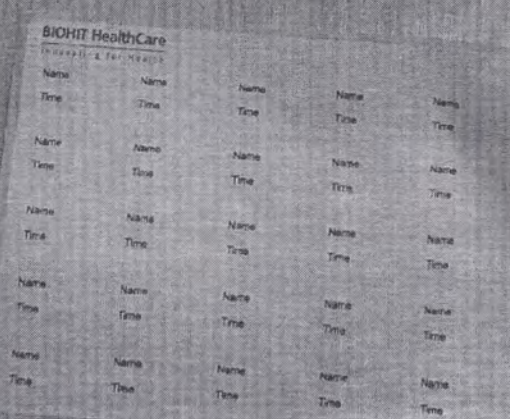
Пробирки конические



Крышки для конических пробирок



Этикетки для конических пробирок



«BIOHIT Экспресс тест Helicobacter pylori UFT 300» в составе
Вариант исполнения 2 (REF:602019)

BIOHIT HealthCare
Improved liquid method
BIOHIT HELICOBACTER PYLORI UFT 300
quick test

Флакон с реагентом 15 мл.

Крышки для конических пробирок

Инструкция по применению

Этикетки для конических пробирок

Пробирки конические

«БИОНИТ» экспресс-тест Helicobacter pylori UFT 300» в составе
Варианты экспресс-тестов 3 (REF:602021)

БИОНИТ
HELICOBACTER PYLORI UFT300
quick test

Флакон с реагентом 30 мл.

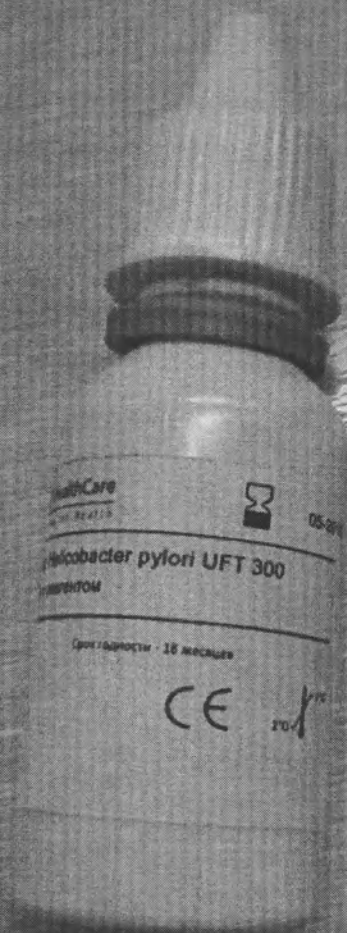
Пробирки конические

Крышки для конических пробирок

Инструкция по применению

Этикетки для конических пробирок

Флакон с реагентом

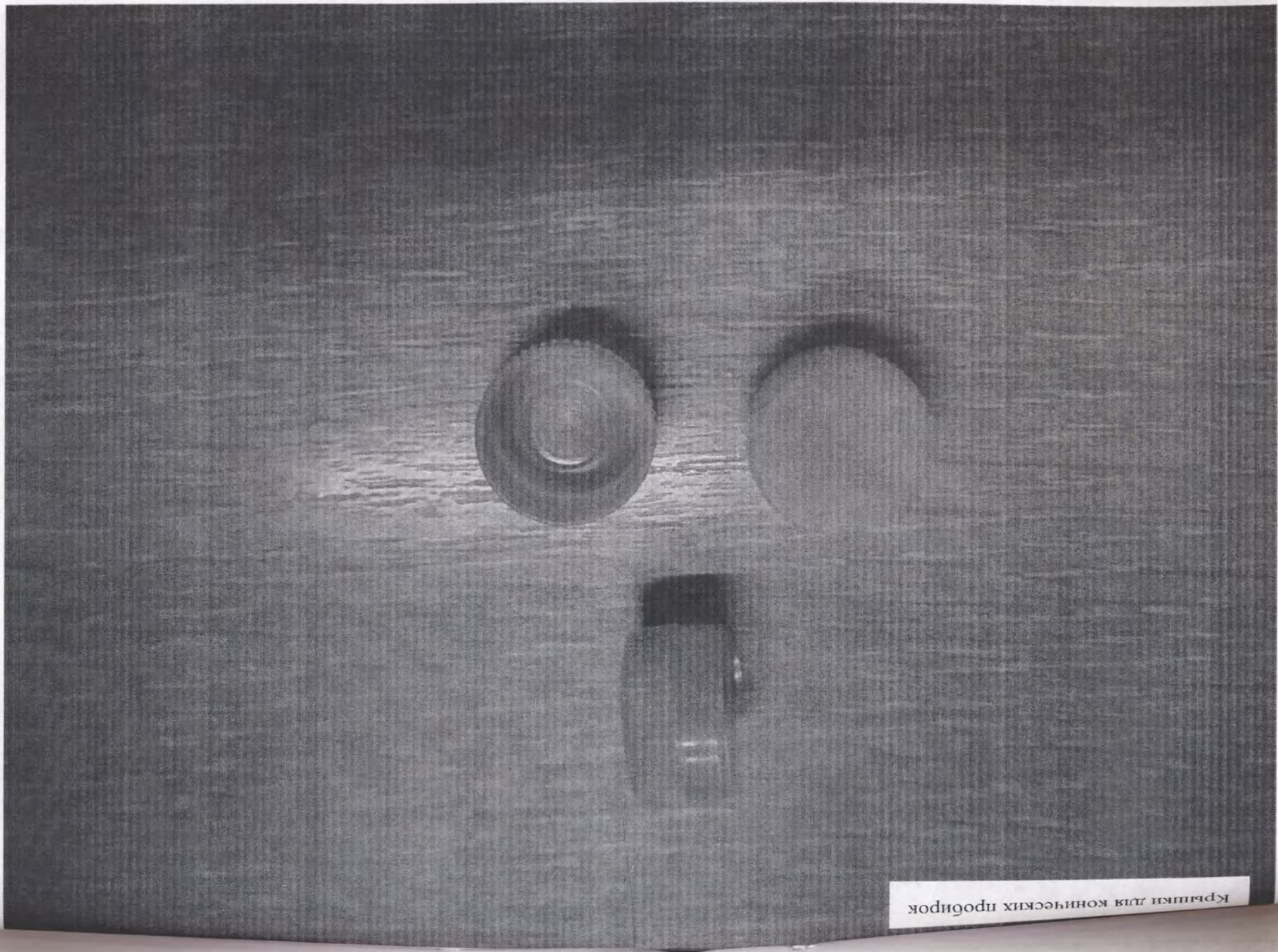


BIOHIT HealthCare

IMPROVING THE QUALITY

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Этикетки для конических пробирок



Крышки для конических пробонок

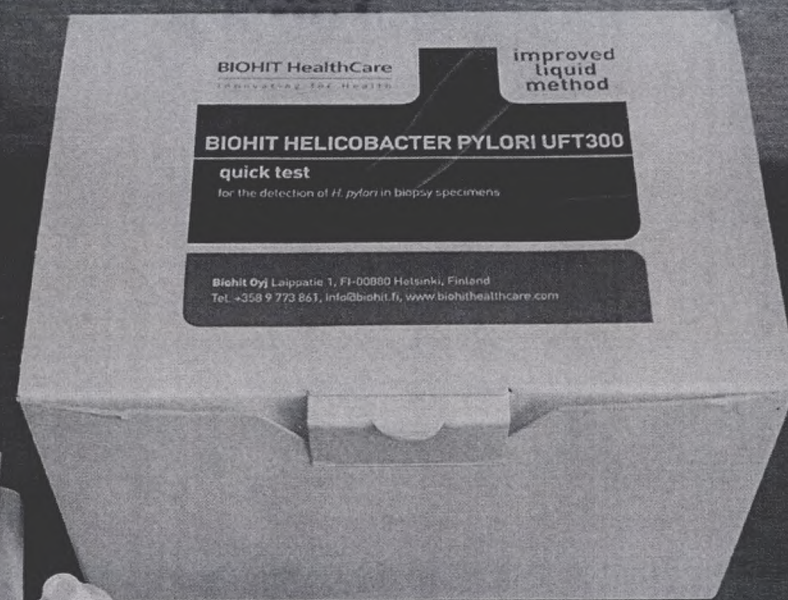


Пробирки конические

Принимая, прошу проверить
и подтвердить наличие
в (Фонд) акк тов
Генеральный директор
Подпись: П.П.



Инструкция по применению.



BIOHIT HealthCare
Innovating for Health

ENGLISH

BIOHIT Helicobacter pylori UFT300 quick test
for the detection of *H. pylori* in biopsy specimens
REF: 602 217 520 (small), 15 mm of reagent solution
REF: 602 221 7150 (small), 30 ml of reagent solution

1. INTENDED USE AND BACKGROUND
The BIOHIT Helicobacter pylori UFT300 quick test is used for the rapid diagnosis of *H. pylori* from human gastric mucosa. The qualitative result is based on the detection of the urease activity of gastric mucosa.

Helicobacter pylori infection is the most important cause of chronic gastritis. A gastric mucosa infected by *H. pylori* is characterized by a chronic inflammation. This condition is referred to as chronic gastritis or non-atrophic gastritis, which is characterized by the presence of *H. pylori*. The chronic inflammatory process can lead to atrophic gastritis, which has been linked with gastric ulcer and gastric cancer, both of the most important causes of the upper gastrointestinal tract (UGT).

2. PRINCIPLE OF THE QUICK TEST
H. pylori is characterized by its capacity to produce urease, an enzyme able to break down urea into ammonia and to participate with the reaction: $\text{NH}_4\text{CO}_2 + \text{H}_2\text{O} \rightarrow \text{NH}_3 + \text{CO}_2$. To identify *H. pylori* with high sensitivity, the test exploits the permeability caused by the production of ammonia, measured by the color change of the pH indicator from yellow to magenta.

3. WARNINGS AND PRECAUTIONS
1. For in vitro diagnostic use. 2. The sample test tube must be kept closed until the time of use. 3. It should be refrigerated. Allow the reagent solution to reach room temperature before the sample of urea. 4. Do not use after the expiration date. 5. All biopsy specimens should be requested as endoscopically obtained and treated as if they were infectious. 6. Contact of the test tube with skin or eyes should be prevented. 7. The solution reacts with the skin. 8. Contact of the test tube with skin or eyes should be prevented. 9. The solution reacts with the skin. 10. Do not use beyond the expiration date printed on the inside of the box.

4. SPECIMEN COLLECTION AND HANDLING
Helicobacter pylori should not have taken antibiotics or bismuth salts within three weeks, or H2-reducers and PPIs within four weeks, preceding endoscopic biopsies. Incomplete eradication of *H. pylori* can give false negative results. It is recommended that biopsy specimens are tested as quickly after collection. Do not let the specimen dry before testing. If there is a doubt about the quality of the specimen, due to the biopsy being on gastric juice.

5. TEST PROCEDURE
1. Break the test tube and place on the test tube's label (provided on separate sheet).
2. Open the tube and add one or more biopsies from the gastric mucosa into the tube.
3. Add reagent solution (BIOHIT UFT300) until it covers the specimen completely. Cap the tube.
4. Shake the tube for 5 minutes, taking care that the specimen remains covered by the reagent solution.
5. Wait 10 min.

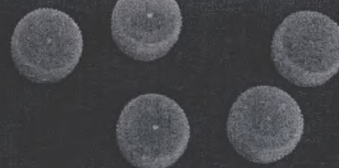
Флакон с реагентом 2,5 мл.



Пробирки конические 5 шт.



Крышки для конических пробирок 5 шт.

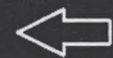


Этикетки для конических пробирок 5 шт.

BIOHIT HealthCare
Innovating for Health

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ОБЩЕСТВЕННАЯ ОТВЕТСТВЕННОСТЬ



«BIOHIT Экспресс-тест Helicobacter pylori UFT 300»,
в составе

Вариант исполнения 1 (REF:602005)

Генеральный директор ООО «Мелон»

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Побелянский Г.Э.

