Declaration Ref No: DC22-0065

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

Atlas Medical GmbH
Head office: Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow, Germany.
Tel: +49 - 33708 – 3550 30
Email: info@atlas-medical.com

Manufacturing Site: Sahab Free Zone Area, P. O. Box 204, Amman 11512, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (AnnexI) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED:
  Certificate N^{0}.: 36655 rev 1
  Expiry Date: October 8 th.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And

Intended for In-Vitro Professional use only.

Manufacturer
Atlas Medical
Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow , Germany.

Atlas Medical
Quality Diagnostic Products

Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	May.2022	21.05.2022		

Digitally signed by Monastîrschii Viorica
Date: 2023.01.05 10:30:14 EET
Reason: MoldSign Signature
Location: Moldova

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

Item code	Product Description
8.00.01.0.0100	Atlas CRP Latex Kit with Buffer (100 Tests)
8.00.05.0.0100	Atlas RF Latex kit with Buffer(100 Tests)
8.00.11.0.0050	Atlas SLE Latex kit (50 Tests)
8.00.11.0.0100	Atlas SLE Latex kit (100 Tests)
8.00.12.0.0100	Atlas Staphylococcus Latex Kit (100 Tests)
8.00.17.0.0050	Atlas D-Dimer Latex Kit (50 Tests)
8.00.19.3.0100	Atlas TPHA Kit (100 Tests)
8.00.19.3.0200	Atlas TPHA Kit (200 Tests)
8.00.20.3.2500	Atlas VDRL Kit, 5ml+55ml buffer
8.04.38.0.0020	Atlas Fecal Occult Blood Test (FOB) Test Cassette , 20 Tests/Box
8.04.85.0.0050	Atlas Fecal Occult Blood Test (FOB) Test Strip, 50 Tests/Box
8.04.109.0.0020	Atlas Procalcitonin test (PCT) , 20 Tests/Box
8.16.78.0.0025	Atlas Calprotectin Test Cassette , 25 Tests/Box
8.04.45.0.0001	Atlas Troponin I Test Cassette, Bulk
8.04.45.0.0020	Atlas Troponin I Test Cassette , 20 Tests/Box.
8.04.45.0.0030	Atlas Troponin I Test Cassette , 30 Tests/Box.
8.04.46.0.0001	Atlas Myoglobin Test Cassette, Bulk
8.04.46.0.0020	Atlas Myoglobin Test Cassette , 20 Tests/Box.
8.04.46.0.0030	Atlas Myoglobin Test Cassette , 30 Tests/Box.
8.04.47.0.0001	Atlas CK-MB Test Cassette , Bulk.
8.04.47.0.0020	Atlas CK-MB Test Cassette , 20 Tests/Box.
8.04.47.0.0030	Atlas CK-MB Test Cassette , 30 Tests/Box.
8.04.48.0.0001	Atlas Cardiac Triple Tests Cassette (Troponin I, CK-MB, Myoglobin), Bulk.
8.04.48.0.0020	Atlas Cardiac Triple Tests Cassette (Troponin I, CK-MB, Myoglobin), 20 Tests/Box.
8.04.48.0.0030	Atlas Cardiac Triple Tests Cassette (Troponin I, CK-MB, Myoglobin), 30 Tests/Box.
8.14.19.1.0096	Helicobacter pylori Antigen ELISA, 96 Tests.
8.51.00.0.0096	25-OH VITAMIN D Elisa Kit, 96 Tests.
8.57.00.0.0096	Vitamin B12 Elisa Kit, 96 Tests

Declaration Ref No: DC21-0210

Date: 06.09.2021

CE Declaration of Conformity

Name and address of Manufacturer	**Atlas Medical GmbH** Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow Germany . Tel: +49(0)33708355030 Email: info@atlas-medical.com

Atlas Medical GmbH declared our his own responsibility that the following IVD medical devices:

Product Code	Product Name	GMDN code
8.04.23.1.0020	Atlas Helicobacter pylori Antigen Test Cassette, Individually pouched, 20 Tests/Box.	30825
8.04.23.1.0025	Atlas Helicobacter pylori Antigen Test Cassette, Individually pouched, 25 Tests/Box.	30825
8.04.23.1.0040	Atlas Helicobacter pylori Antigen Test Cassette, Individually pouched, 40 Tests/Box.	30825
8.04.24.1.0020	Atlas Helicobacter pylori Antigen Test Strip, Individually pouched, 20 Tests/Box.	30825
8.04.24.1.0025	Atlas Helicobacter pylori Antigen Test Strip, Individually pouched, 25 Tests/Box.	30825

Meets the essential requirments of In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I

And

EN ISO 13485 :2016 , EN 18113-1, -2,:2011, EN ISO 15223:2016
EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,
EN ISO 13612:2002, EN ISO 13641:2002 , EN ISO 62366-1+A1:2020.

IVD Categorization	Directive 98/79, Other IVDs (Non-annex II, non-self-test).
Conformity Assesment Route	Directive 98/79/EC , Annex III.
Name , Address and Identification number of notified body	N/A

Date of issuance:	06.September.2021
Place	Atlas Medical GmbH
Signed by: **Position :**	Amani AL-Habahbeh Regulatory Affairs Manager

Atlas Medical GmbH
Ludwig - Erhard Ring 3
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MRXDO10F.11
11.08.2021

Atlas Medical

Declaration Ref No: DC21-0249

Date: 15.10.2021

CE Declaration of Conformity

Name and address of Manufacturer	**Atlas Medical GmbH** Ludwig-Erhard-Ring 3, 15827 Blankenefelde-Mahlow Germany . Tel: +49(0)33708355030 Email: info@atlas-medical.com

Atlas Medical GmbH declared our his own responsibility that the following IVD medical devices:

Product Code	Product Name	GMDN code
8.17.003.0300	Atlas Periodic Acid Schiff (PAS) Stain Kit, 3x100ml	43587
8.17.004.0300	Atlas Iron Stain Kit, 3x100ml	43587
8.17.009.1000	Atlas Gram Stain Kit	43733
8.17.010.0750	Atlas ZN (Kinyoun) stain pack , 3x250ml	43587
8.15.144.0250	Atlas ZN Decolouriser, 250 ml /Bottle	43587
8.17.015.0500	Atlas Diff-3 Stain.	43587
8.17.016.1000	Atlas Papanicolau Stain Pack.	43587
8.17.110.0250	Atlas Papanicolau Stain EA35, 250 ml /Bottle.	43587
8.17.111.0250	Atlas Papanicolau Stain EA36, 250 ml /Bottle	43587
8.17.112.0250	Atlas Papanicolau Stain EA65, 250 ml /Bottle.	43587
8.17.114.0250	Atlas Papanicolau Stain EA50, 250 ml /Bottle.	43587
8.17.115.0250	Atlas Papanicolau Stain OG6, 250 ml /Bottle.	43587
8.17.014.1000	Atlas Reticulocytes stain (Methylene Blue) , 1000 ml /Bottle	43587
8.15.037.0250	Atlas Eosin Y (1%) Stain, 250 ml/Bottle	43587
8.15.038.0250	Atlas Eosin Y (5%) Stain, 250 ml/Bottle.	43587
8.15.041.0250	Atlas Field Stain (Solution A), 250ml/Bottle	43587
8.15.042.0250	Atlas Field Stain (Solution B), 250ml/Bottle	43587
8.15.043.0750	Atlas Field Stain Kit 3x250ml (250ml Fixing Reagent , 250ml Eosin Reagent, 250ml Methylene Blue Reagent).	43587
8.15.047.0250	Atlas Giemsa Stain, 250 ml/Bottle.	43587
8.15.059.0250	Atlas Haematoxylin Harris Stain , 250 ml/Bottle	43587
8.15.069.0250	Atlas Leishman Stain , 250 ml/Bottle.	43587
8.15.069.1000	Atlas Leishman Stain , 1000 ml/Bottle.	43587
8.15.074.0250	Atlas Lugol's Iodine, 250 ml/Bottle.	43587
8.15.078.0250	Atlas May Grunwald Stain, 250 ml/Bottle.	43587
8.15.105.0250	Atlas New Methylene Blue for Reticulocytes, 250 ml/Bottle.	43587
8.15.143.0250	Atlas Wright's Stain, 250 ml/Bottle.	43587
8.15.146.0100	Atlas Immersion oil, 100 Bottle/Box	43587

Atlas Medical

Declaration Ref No: DC21-0249

Date: 15.10.2021

Meets the essential requirments of In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
And
EN ISO 13485 :2016 , EN 18113-1, -2,:2011, EN ISO 15223:2016
EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,
EN ISO 13612:2002, EN ISO 13641:2002 , EN ISO 62366-1+A1:2020.

IVD Categorization	Directive 98/79, Other IVDs (Non-annex II, non-self-test).
Conformity Assesment Route	Directive 98/79/EC , Annex III.
Name , Address and Identification number of notified body	N/A

Date of issuance:	15. October.2021
Place	Atlas Medical GmbH
Signed by: **Position :**	Amani AL-Habahbeh Regulatory Affairs Manager

Atlas Medical GmbH
Ludwig - Erhard Ring 3
15827 Blankenfelde - Mahlow
Tel. (0049) 33708 - 355030

Atlas Medical

Date: 15/Jan/2022

STATEMENT

We, ATLAS MEDICAL having a registered office at Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

On behalf of manufacturer:-

General Manager

Haya Amawi

Signature: _____

Date: 15.01.2022

Atlas Medical
Quality Diagnostic Products

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.1

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

pour les activités
for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485: 2016

Début de validité */ Effective date* **October 9th, 2020 (included)**
Valable jusqu'au */ Expiry date :* **October 8th, 2023 (included)**
Etabli le */ Issued on :* **October 8th, 2020**

DocuSigned by:
Beatrice Lys
EE33BDA9BAA04A3...

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED N° 36655–1
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 36655-0

GMED_SQ_plus3sites-F-V0-07-2018

Addendum au certificat n° 36655 rev. 1 page 1/1
Addendum of the certificate n° 36655 rev. 1
Dossier / *File* N°P601408

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites:

French version :
Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.

English version:
Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for self-testing, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
GERMANY

French version:
Siège social, responsable de la mise sur le marché
English version:
Headquarter, legal manufacturer

****

Sahab Industrial Zone Area
King Abdullah II Industrial City
Amman 11512
JORDAN

French version:
Conception, fabrication et contrôle final
English version:
Design, manufacture and final control

****

William James House
Cowley Road,
Cambridge, CB OWX
United Kingdom

French version:
Contact réglementaire
English version:
Regulatory Administration

****

3 sites / 3 *sites*

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Atlas Medical CE

Fecal Occult Blood Test Strip (Feces)

A rapid, one step test for the qualitative detection of human occult blood in feces.

IVD *For In-Vitro diagnostic and professional use only*

Store at 2-30°C

INTENDED USE

The FOB One Step Fecal Occult Blood Test Strip (Feces) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces.

INTRODUCTION

Most of diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based method lacks sensitivity and specificity, and has diet-restriction prior to the testing.

The FOB One Step Fecal Occult Blood Test Strip (Feces) is a rapid test to qualitatively detect low levels of fecal occult blood in feces. The test uses double antibody sandwich assay to selectively detect as low as 50ng/mL of hemoglobin or 6µg hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

The FOB One Step Fecal Occult Blood Test Strip (Feces) is a qualitative, lateral flow immunoassay for the detection of human occult blood in feces. The membrane is pre-coated with anti-hemoglobin antibody on the test line region of the Strip. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibody on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

MATERIALS PROVIDED

- Test Strip(contains anti-hemoglobin antibody particles and anti-hemoglobin antibody coated on the membrane).
- Specimen collection tube with extraction buffer.
- Package insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container.
- Timer.
- Pipette.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test Strip is stable through the expiration date printed on the sealed pouch.
- The test Strip must remain in the sealed pouch until use.
- Do not freeze.
- Do not use beyond the expiration date.

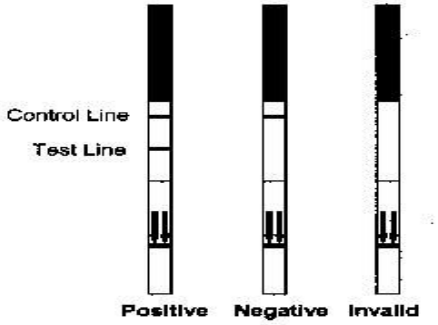
PATIENT PREPARATION

- Specimen should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemmorhoids or blood in the urine.
- Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.
- Dietary restrictions are not necessary.

PROCEDURE

1. Allow the test strips and samples to reach room temperature (15-30ºC) prior to testing. Do not open the package until ready to perform the assay.
2. Using the applicator stick of the provided sample diluent vial, transfer a small portion (5mm diameter) of stool specimen into the sample diluent.
3. Shake gently in order to unstuck and facilitate the sample dispersion.
4. Hold the vial and break the tip off.
5. Dispense 10 drops (approximately 0.5 ml) of the sample extract in a test tube.
6. Immerse the test strip in the liquid prepared in step 5. Do not exceed the line shown on the strip.
7. Read the result 5 minutes after the immersion of the strip. Do not read result after 10 minutes.

INTERPRETATION OF RESULTS (Please refer to the illustration below)



POSITIVE:*

Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

***NOTE:**

The intensity of the red color in the test line region (T) will vary depending on the concentration of hemoglobin present in the specimen. Therefore, any shade in the test region indicates positive result.

NEGATIVE:

One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID:

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

EXPECTED VALUES

The FOB One Step Fecal Occult Blood Test Strip (Feces) has been compared with another leading commercial rapid test. The correlation between these two systems is 98%.

QUALITY CONTROL

- A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
- Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATION

- The FOB One Step Fecal Occult Blood Test Strip (Feces) is for *in vitro* diagnostic use only.
- The FOB One Step Fecal Occult Blood Test Strip (Feces) will only indicate the presence of human hemoglobin in the specimen and the presence of blood in feces may be other than colorectal bleeding.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- Other clinically available tests are required if questionable results are obtained.

PERFORMANCE CHARACTERISTICS

Sensitivity

The FOB One Step Fecal Occult Blood Test Strip (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or around 2µg hemoglobin/g feces.

Specificity

The FOB One Step Fecal Occult Blood Test Strip (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration were tested on both positive and negative controls with no effect on test results.

Substances	Concentrations (Diluted with the extraction buffer)
Bovine hemoglobin	1 mg/mL
Chicken	1 mg/mL
Pork hemoglobin	1 mg/mL
Goat hemoglobin	1 mg/mL
Horse hemoglobin	1 mg/mL
Rabbit hemoglobin	1 mg/mL
Turkey hemoglobin	1 mg/mL

REFERENCES

1. Simon J.B. *Occult Blood Screening for Colorectal Carcinoma: A Critical Review,* Gastroenterology, Vol. 1985; 88: 820.
2. Blebea J. and Ncpherson RA. *False-Positive Guaiac Testing With Iodine, Arch Pathol Lab Med,* 1985;109:437-40

ATLAS MEDICAL
William James House, Cowley Rd,
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Tel: ++44 (0) 1223 858 910
Fax: ++44 (0) 1223 858 524
PPI589A01
Rev C (23.04.2015)

REF	**Product Reference No.**	IVD	**For in-vitro diagnostic use.**
	Caution.		**Store at 2 - 30°C.**
	Read product insert before use.		**Number of tests in the pack.**
LOT	**Lot (batch) number.**		**Manufacturer.**
	Expiry date.		**Manufacturer telephone number.**
	Manufacturer fax number.		

Atlas Medical

CE

Helicobacter pylori Antigen Test

IVD *For in- vitro diagnostic use only*

2°C 8°C Store at (2-8º C)

INTENDED USE

A rapid one step test for the detection of H.pylori antigen in stool samples.

PRINCIPLE

The Helicobacter pylori antigen reacts with the conjugate-Red latex particles sensibilized with anti-H.pylori monoclonal antibody coated to the membrane of the test. The formed H.pylori-conjugate complex, which migrates upward the membrane by capillarity, binds to the specific antibody molecules fixed to the reaction zone. The excess of complex keeps migrating through the membrane until reaching the C zone of control, where will bind to another specific antibody coated to the membrane forming a green band. The green band presence confirms the functionality of the test.

MATERIALS

MATERIALS PROVIDED

- Test Cassette
- Sample diluent in extraction tubes.
- H.pylori Positive Control.
- Package insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Tubes or vials.
- Disposable gloves.
- Shaker/vortex.
- Timer.

STORAGE AND STABILITY

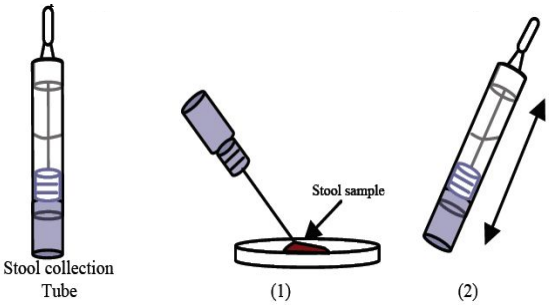
- Store at 2-8ºC.
- The reagents are stable until the expiry date stated on the label.

SAMPLES PREPARATION

- Stool: Do not use watery or diarrhoeal samples.
- Collect the stool sample in a clean container and use as soon as possible.
- The samples can be stored at 2-8ºC for a longer period of time.

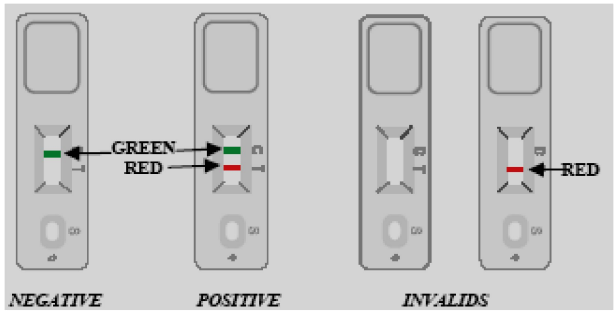
PROCEDURE

a. Allow the test device, control and samples to reach room temperature (15-30ºC) prior to testing. Do not open the package until ready to perform the assay.
b. Using the applicator stick of the provided sample diluent vial, transfer a small portion (5mm diameter) of stool specimen into the sample diluent. (Refer to the illustration bellow)
c. Shake gently in order to unstuck and facilitate the sample dispersion.
d. Hold the vial and break the tip off.
e. Add 4 drops to the sample well in the test device.
f. For positive control: add 75µL of the control to the sample well in the test device.
g. Read the result after 5 minutes.



READING THE RESULTS

Look at the colored bands in the test device



Negative: only one GREEN band (Control Line) appears in the white central zone of the reaction strip (Control zone)

Positive: 2 bands appear; in addition to the GREEN control band, a RED band in the zone marked with T (Result Line) also appears.

Invalid: No colored bands appear or only one band appears in the T zone. If an incolcusive result is obtained, re-assay the sample again with a new strip.

QUALITY CONTROL

Internal procedural controls are included in the test. A green band appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

CLINICAL SIGNIFICANCE

Helicobacter Pylori (H.Pylori) is a spiral-shaped bacterium that is found in the gastric mucous layer or adherent to the epithelial lining of the stomach. H.Pylori cause more than 90% of duodenal ulcers and up to 80% of gastric ulcers.

ANALYTICAL PERFORMANCE

- Sensitivity:The minimum detectable unit of H.Pylori Antigen is of 4-8ng/ml.
- Comparison of methods: the comparison of Helicobacter pylori one step with a commercial ELISA assay shows a concordance level of 95%.
- Specificity: agnostic specificity. The monoclonal antibodies used in the manufacturing of

Helicobacter pylori one step. The antibodies used to elaborate the H.Pylori device + recognise epitopes present in the antigen found in stool of patients, as well as in preparations from the bacteria cultures in vitro. Sonicated Helicobacter pylori extract from different commercial samples react with H.Pylori device+.

- The possibility for interference by human anti-mouse antibodies (HAMA) or high levels of RF in the stools sample have not been evaluated. Some stool samples could produce control lines with a light green color.

LIMITATIONS

- The test must be carried out within 2 hours of opening the dealed bag.
- The clinical diagnosis must not be done with the results of an loy assay, the clinical bachground of the patient must also be taken in account.

NOTES

- An excess of sample can lead to an inconclusive result, brown colored low defined lines with no diagnostic values may appear. The sample should be diluted again with the diluent and the test should be repeated.
- Some samples may diminish the intensity of the green control band.
- If the assay is inconclusive as a result of solid particles in the reaction zone, take them out and add a drop of diluent, until migration of the reaction mix is observed.
- The intensity of the red colored band in the result line region (T) will vary depending on the concentration of antigens present in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be detemined by this qualitative test.
- The most common causes of an inconclusive result are: insufficient addition of sample, wrong procedural techniques or deterioration of the reagents. Review the procedure and repeat the tests with a new test. If the problem persists, discontinue using the test kit and contact to your local distributor.

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PPI1017A01
Rev A (13.07.2015)

REF	**Product Reference No.**	IVD	**For in-vitro diagnostic use.**
	**Caution.**		**Store at**
	**Read product insert before use.**		**Number of tests in the pack.**
LOT	**Lot (batch) number.**		**Manufacturer.**
	**Expiry date.**		**Manufacturer telephone number.**
	**Manufacturer fax number.**		