

Contract No:Co2403079

Date:09/03/2024

Letter of Authorization

Manufacturer: Atlas Medical GmbH
Ludwig-Erhard-Ring 3,
15827Blankenfelde-Mahlow, Germany
Tel: +49 33 70 83 55 030
Email: amug@atlas-medical.com

Regulatory Office: William James House, Cowley Road, Cambridge, CB4 0WX, UK
Tel: +44 1223 858 910
Fax: +44 1223 858 524
Email: info@atlas-site.co.uk

Middle East 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

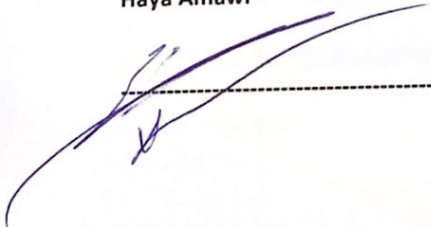
Agent: San Medico
Republic of Moldova, city Chisina
+37368228890

Atlas Medical, hereby appoint the above mentioned agent to import, register and distribute Atlas Medical Products in Moldova

Appointment Conditions:

1. This appointment is valid for 3 year from the above mentioned date.
2. Either Party can cancel this appointment by giving the other party a 60 day notice.

On behalf of the Manufacturer
General Manager
Haya Amawi



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, 2023 (included)

Valable jusqu'au / Expiry date : October 8th, 2026 (included)

Etabli le / Issued on : October 9th, 2023

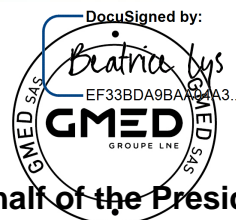


**CERTIFICATION
DE SYSTEMES
DE MANAGEMENT**
Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 36655-2

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

Renouvelle le certificat 36655-1



On behalf of the President
Béatrice LYS
Technical Director

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

2 sites / 2 sites

DocuSigned by:
Beatrice Lys
FF33BDA98AA04A3...


**On behalf of the President
Béatrice LYS
Technical Director**


CE Declaration of Conformity

We,
Atlas Medical GmbH
 Head office: Ludwig-Erhard-Ring 3
 15827 Blankenfelde-Mahlow Germany
 Tel: +49(0)33708355030
 Email: info@atlas-medical.com

Middle East Site: Sahab Industrial Zone Area, King Abdullah II Industrial City
 Amman 11512, Jordan
 Tel.: +962 6 4026468
 Fax: +962 6 4022588
 Email: info@atlas-medical.com

Declare our responsibility that the following product:

Product Code	Product Name	Class	GMDN code
8.00.18.0.0005	RPR Carbon Antigen Reagent, 5 ml/vial	General-IVD	32450
8.00.18.2.1000	RPR Carbon Antigen 1000ml/bottle	General-IVD	32450
8.00.18.0.0050	RPR Carbon Antigen Kit, 50 Tests	General-IVD	32450
8.00.18.1.0050	RPR Carbon Antigen Kit, 50 Tests, White Glass Slide.	General-IVD	32450
8.00.18.2.0500	RPR Carbon Antigen Kit, 500 Tests (2ml latex, 2x0.5 ml control) Without card.	General-IVD	32450
8.00.18.3.0500	RPR Carbon Antigen Kit, 500 Tests (10ml latex, 2x0.5 ml control) Without card, stirring sticks.	General-IVD	32450
8.00.18.0.0100	RPR Carbon Antigen Kit, 100 Tests (2ml latex, 2x0.5 ml control)	General-IVD	32450
8.00.18.2.0100	RPR Carbon Antigen Kit, 100 Tests (2ml latex, 2x0.5 ml control +White Glass slide stirring sticks)	General-IVD	32450
8.00.18.0.0025	RPR Carbon Antigen Kit, 25 Tests (0.5ml latex, 2x0.5 ml control)	General-IVD	32450
8.00.18.0.0150	RPR Carbon Antigen Kit, 150 Tests	General-IVD	32450
8.00.18.0.0200	RPR Carbon Antigen Kit, 200 Tests	General-IVD	32450
8.00.18.0.0250	RPR Carbon Antigen Kit, 250 Tests	General-IVD	32450

Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	September.2021	06.09.2021		

Amin Al-Habashat
 RA Manager

Declaration Ref No: DC21-0193

8.00.18.0.0500	RPR Carbon Antigen Kit,500 Tests	General-IVD	32450
8.00.18.0.1000	RPR Carbon Antigen Kit, 1000 Tests	General-IVD	32450
8.00.18.4.0500	RPR Carbon Antigen Kit,500 Tests (3x3.4ml reagent,2x1 controls)	General-IVD	32450
8.00.18.5.0500	RPR Carbon Antigen Kit, 500 Tests, (3x3.4ml reagent,2x1 controls)	General-IVD	32450
8.00.18.8.0500	RPR Carbon Antigen 500 Test (10ml reagent) without Control's.	General-IVD	32450
8.00.18.9.0050	RPR Carbon Antigen Kit, (5x10ml Reagent,2x2ml Control) , white glass Slide, Stirring Stick.	General-IVD	32450
8.33.04.0.0001	RPR Positive control	General-IVD	32450
8.33.04.1.0001	RPR Positive control ,Bulk	General-IVD	32450
8.33.04.0.0100	RPR Positive control(100ml/vial)	General-IVD	32450
8.33.04.0.0500	RPR Positive control(500ml/bottle)	General-IVD	32450
8.33.08.0.0001	RPR Negative control	General-IVD	32450

Is produced under Atlas quality system (ISO13485: 2016) supported by GMED certificate:

Certificate N^o.: 36655 rev 1

Expiry Date: October 8th.2023

and complies with the essential requirements of
In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
And

EN ISO 18113-1, -2 :2011, EN ISO 15223:2016

**EN ISO 14971:2019, EN ISO 23640 :2015 , ISO 2859 :2017,
EN 13612:2002, EN 13641:2002 , EN 13975:2003, ISO 13485:2016**

And

Intended for In-Vitro Professional use only.

This Declaration includes the batches produced beyond this day according to the product Lot Log.

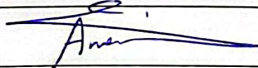
Manufacturer

Atlas Medical GmbH

Ludwig-Erhard-Ring 3

15827 Blankenefelde-Mahlow Germany.



Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	September.2021	06.09.2021		

Anwar Al-Hadad
RA Manager

RPR Carbon Antigen

IVD For In-Vitro diagnostic and professional use only

2°C 8°C
Store at 2 to 8 °C

*INTENDED USE

A manual rapid plasma reagin carbon test for the qualitative and semi-quantitative detection of non-treponemal antibodies against Syphilis in human serum and plasma to provide serological evidence of past/current Syphilis infections when preceded by a positive treponemal test. Not to be used as a screening tool for blood or tissue donations.

INTRODUCTION

Syphilis is a disease caused by infection with the spirochete *Treponema pallidum*. The infection is systemic and the disease is characterized by periods of latency. These features, together with the fact that *T. pallidum* cannot be isolated in culture, mean that serologic techniques play a major role in the diagnosis and follow-up of treatment for syphilis.

Syphilis is categorized by an early primary infection in which patients may have non-specific symptoms, and potentially, genital lesions. Patients tested by serology during the primary phase may be negative for antibodies, especially if testing is performed during the first 1 to 2 weeks after symptom onset. As the disease progresses into the secondary phase, antibodies to *T. pallidum* reach peak titers, and may persist indefinitely regardless of the disease state or prior therapy. Therefore, detection of antibodies to nontreponemal antigens, such as cardiolipin (a lipoidal antigen released by host cells damaged by *T. pallidum*) may help to differentiate between active and past syphilis infection. Nontreponemal antibodies are detected by the rapid plasma reagin (RPR) assay, which is typically positive during current infection and negative following treatment or during late/latent forms of syphilis.

PRINCIPLE

RPR utilises carbon particles coated with cardiolipin antigen to detect reagin antibodies present in serum or plasma of syphilitic persons.

Specimens that contain reagin cause aggregation of the carbon particles which appear as dark clumps against a white background. The aggregation can be read macroscopically. Non-reactive samples typically appear as a smooth non-aggregated pattern which may form buttons in the centre of the test area.

MATERIALS

MATERIALS PROVIDED

- **RPR carbon antigen reagent:** A particulate carbon suspension coated with lipid complexes, with 0.95 g/L sodium azide.
- **Positive Control:** Human syphilitic serum reactive with the test reagent, with 0.95 g/L Sodium azide. **(Optional).**
- **Negative control:** non-reactive phosphate buffer containing 5% BSA pH7.4, with 0.1% of Sodium azide. **(Optional).**
- **RPR test cards or white glass slide (Optional).**
- **Plastic sticks (Optional).**
- **Package insert.**

NOTE: This package insert is also used for individually packed reagent.

MATERIALS NEEDED BUT NOT PROVIDED

- Rotator (100rpm).
- Timer.
- Calibrated micropipettes and tips.

PACKAGING CONTENT

REF 8.00.18.0.0100 (2mL Reagent, 1x0.5mL Positive Control, 1x0.5mL Negative Control)

REF 8.00.18.0.0500 (10mL Reagent, 1x1mL Positive Control, 1x1mL Negative Control)

REF 8.00.18.3.1000 (2x10mL Reagent, 1x2mL Positive Control, 1x2mL Negative Control)

STORAGE AND STABILITY

- All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C.
- *Do Not Freeze.
- *Signs of deterioration:
 - RPR Carbon: Visible agglutination.
 - Controls: Presence of particles and turbidity.

PRECAUTIONS AND WARNINGS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- *The test is not for near-patient or self-testing.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all negative and positive in the manner as patient specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Components of different human origin have been tested and found to be negative for the presence of antibodies anti- HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.
- *Do not touch, drink, or ingest the reagent.

- *Do not use black glass slides during testing.
- *Perform the test in a well-lit area with good visibility.
- *Failure in following the instructions may give incorrect results or face safety hazards.
- *Wash the area of contact with water immediately if contact occurs.
- *Wash of the hands and the test table top with water and soap.
- *Do not use the reagent if displaying any signs of deterioration.
- *Always use a fresh pipette tip and stirring sticks for each test.
- *Handle the used disinfectant with care.
- *Glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- *Do not use the reagents if the label is missing, damaged, or unclear.
- *Do not use leaked vials and making proper disposal of them.
- *Use forceps, scoops, or other mechanical devices for removing broken glass from the working area. A dustpan and brush should be used to clean up shards/small pieces of broken glass. Broken glass must be disposed of in a sharps container.
- *The reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- *Any serious incident that occur in relation to the device shall be reported to the manufacturer and the competent authority. (Feedback@atlas-medical.com)

COLLECTION, HANDLING AND PREPARATION OF SPECIMEN

- Fresh serum or plasma. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- *Samples may be stored at 2-8° C for up to 7 days. For long term storage sera should be stored at -20° C up to 30 days.

REAGENT PREPARATION

RPR reagent is ready to use. No preparation is required.

PROCEDURES

QUALITATIVE PROCEDURE

- **Mix well the RPR reagent before use.**
- 1. Bring the reagents and samples to room temperature.
- 2. Dispense **50 µL of each sample** into a separate circle on the card. Use a separate tip for each sample.
- 3. Dispense **1 drop of each of positive and negative controls** into two additional circles.
- 4. Gently shake the dispensing vial and slightly press to remove air bubbles from the needle and the drop obtained is correct.

5. Dispense **1 drop (17.5 µl)** of **RPR antigen** to each circle next to the sample to be tested.
6. *Close the reagent vial tightly.
7. *Spread the specimen evenly over the test circle.
8. Place the card on a mechanical rotator and rotate at 100 r.p.m. for 8 minutes.
9. Observe macroscopically for agglutination within a minute after removing the card from the rotator.

SEMI-QUANTITATIVE PROCEDURE

- **Mix well the RPR reagent before use.**
1. Make doubling dilutions from Undiluted to 1:16 normal saline.
 2. Place 50 µl of each dilution in to a separate circle on the test card.
 3. Spread each dilution evenly over the test circle.
 4. Continue as from Qualitative procedure .
- The titer of the sample is expressed as the final dilution which shows aggregation of the carbon particles.

INTERPRETATION OF TEST RESULTS

1. **Strong Reactive:** Large clumps of carbon particles with a clear background.



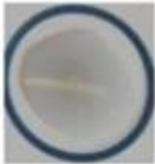
2. **Reactive:** Large clumps of carbon particles somewhat more disperse than Strong Reactive pattern.



3. **Weak Reactive:** Small clumps of carbon particles with light grey background.



4. **Trace Reactive:** Slight clumping of carbon particles typically seen as a button of aggregates in the centre of the test circle or dispersed around the edge of the test circle.



5. **Non-Reactive:** Typically a smooth grey pattern or a button of non-aggregated carbon particles in the centre of the test circle.



***LIMITATION OF THE TEST**

- Pregnancy may give a false positive reaction.
- Hepatitis and Brucellosis may give a false positive reaction.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

PERFORMANCE CHARACTERISTICS



















Sensitivity: 100%.
Specificity: 100%.
Precision: 100%
Hook effect: no prozone effect up to the titer level studied: 1/16.
Interferences: There is no effect from Hemoglobin/Bilirubin and Rheumatoid factor on the results of RPR carbon antigen at the studied concentrations:
 Bilirubin: ≤15 mg/dL.
 Hemoglobin: ≤10 g/L.
 Rheumatoid factor: ≤300 IU/ml.

REFERENCES

- Falcone V.H., Stout G.W. and Moore M.B. Jr., PHR 79: 491-495, 1964.

 **ATLAS Medical GmbH**
 Ludwig-Erhard Ring 3
 15827 Blankenfelde-Mahlow
 Germany
 Tel: +49 - 33708 – 3550 30
 Email: Info@atlas-medical.com
 Website: www.atlas-medical.com

PPI2280A01
Rev C (27.03.2024)

	Catalogue Number		Temperature limit
	<i>In Vitro</i> diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
	Positive control		Negative control

***: Indication of the introduced modifications.**



浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co.,LTD

STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as non-exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC.

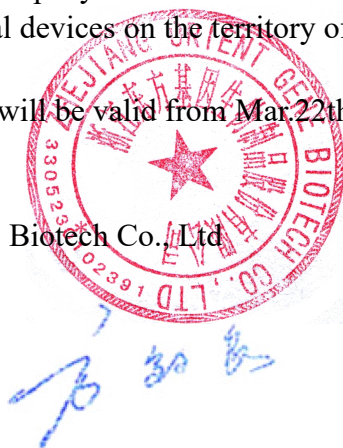
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement letter will be valid from Mar.22th,2024 to Mar.21th, 2025.

Zhejiang Orient Gene Biotech Co.,Ltd

General Manager:

Date:2024/3/22



地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
Add: 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China
电话 Tel:+86-572-5226111 传真 Fax: +86-572-5226222 邮编 P.C.:313300



Certificate

No. Q5 092305 0001 Rev. 01

Holder of Certificate: **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01

Report No.: SH2198802

Valid from: 2022-04-11

Valid until: 2024-03-16

Date, 2022-04-11

Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 092305 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate



浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD



CE-DOC-OG039
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

H. pylori Ag Rapid Test Strip (Feces)	GCHP-601a
H. pylori Ag Rapid Test Cassette (Feces)	GCHP-602a

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: *Shanghai International Holding Corp. GmbH (Europe)*

EC Representative's Address: *Eiffestrasse 80, 20537 Hamburg, Germany*

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: November 28, 2017

Name of authorized signatory: *Joyce Pang*
Position held in the company: *Vice-President*



浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD



CE-DOC-OG060
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

Fecal Occult Blood Rapid Test Strip (Feces)	GEFOB-601b
Fecal Occult Blood Rapid Test Cassette (Feces)	GEFOB-602b

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

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I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: November 28, 2017

Name of authorized signatory: *Joyce Pang*
Position held in the company: *Vice-President*

Fecal Occult Blood Rapid Test Cassette (Feces)



INTENDED USE

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces by professional laboratories or physician's offices. It is useful to detect bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.

Fecal Occult Blood Rapid Test Cassette (Feces) is recommended for use in 1) routine physical examinations, 2) hospital monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

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.

Fecal Occult Blood Rapid Test Cassette (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 50 ng/mL of hemoglobin or 6 µg hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

Fecal Occult Blood Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The membrane is pre-coated with anti-hemoglobin antibodies on the test line region of the device. During testing, the specimen reacts with the colloidal gold coated with anti-hemoglobin antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibodies 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 PROVIDED

20 Test cassettes
20 Specimen collection tubes with buffer
1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers 2. Clock or timer

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out of the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. **Do not use specimen with visible blood for the testing.**
6. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens.
7. Specimen extraction buffer contains Sodium Azide (0.1%). Avoid contact with skin or eyes. Do not ingest.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air conditioning.

PATIENT PREPARATION

1. A specimen should not be collected from a patient with following conditions that may interfere with the test results:

- Menstrual bleeding
 - Bleeding hemorrhoids
 - Constipating bleeding
 - Urinary bleeding.
2. Dietary restrictions are not necessary.
 3. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, cortocosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, thus gives positive reactions. On the advice of the physician, such substances should be discontinued at least 48 hours prior to testing.

SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

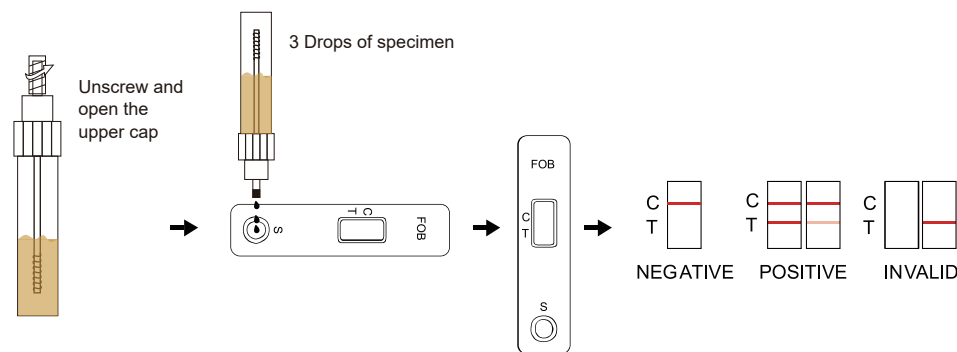
1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Randomly pierce the fecal specimen in at least five (5) different sites.
4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside grooves.
5. Replace the stick in the tube and tighten securely.
6. Shake the specimen collection bottle so that there is proper homogenisation of feces in buffer solution.

Note: Specimens prepared in the specimen collection tube may be stored at room temperature (15-30°C) for 3 days maximum, at 2-8°C for 7 days maximum or at -20°C for 3 months maximum if not tested within 1 hour after preparation.

TEST PROCEDURE

Allow the test cassette, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean, flat surface.
3. Shake the specimen collection tube several times.
4. Hold the specimen collection tube upright and then unscrew and open the upper cap.
5. Squeeze 3 drops (~90 µL) of the sample solution in the sample well of the cassette and start the timer.
6. Wait for the colored line(s) to appear. Read results in 5 minutes. Do not interpret the result after 5 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

Negative: One colored line appears in the control line region (C). No line appears in the test line region (T).

Invalid: Control line fails to appear. The test should be repeated using a new cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and

Fecal Occult Blood Rapid Test Cassette (Feces)

cannot determine the concentration of analytes in the specimen.

2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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.

LIMITATIONS

1. This test kit is to be used for the qualitative detection of human hemoglobin in fecal samples. A positive result suggests the presence of human hemoglobin in fecal samples. In addition to intestinal bleeding the presence of blood in stools may have other causes such as hemorrhoids, blood in urine etc.
2. Not all colorectal bleedings are due to precancerous or cancerous polyps. The information obtained by this test should be used in conjunction with other clinical findings and testing methods, such as colonoscopy gathered by the physician.
3. Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
4. Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results. The use of a receptacle is recommended.
5. Feces specimens should not collect during the menstrual period and not three day before or afterwards, at bleeding due to constipation, bleeding haemorrhoids, or at taking rectally administered medication. It could cause false positive results.
6. This test may be less sensitive for detecting upper g.i. Bleeding because blood degrades as it passes through the g.i. Track.
7. The Fecal Occult Blood Rapid Test Cassette (Feces) is to aid diagnosis and is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy, or X-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.

PERFORMANCE CHARACTERISTICS

1. Sensitivity: 99.6%

Fecal Occult Blood Rapid Test Cassette (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or 6 µg hemoglobin/g feces.

2. Prozone Effect:

It is observed that this FOB test can detect 2 mg/mL hemoglobin.

3. Specificity: 99.9%

Fecal Occult Blood Rapid Test Cassette (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration was tested on both positive and negative controls and showed no effects on test results at standards concentration.

Substances	Concentrations (Diluted with the extraction buffer)
Beef hemoglobin	2 mg/mL
Chicken hemoglobin	0.5 mg/mL
Pig hemoglobin	0.5 mg/mL
Goat hemoglobin	0.5 mg/mL
Horse hemoglobin	20 mg/mL
Rabbit hemoglobin	0.06 mg/mL

REFERENCES

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INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog#

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Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

GEFOB-602b

H. pylori Ag Rapid Test Cassette (Feces)



INTENDED USE

H. pylori Ag Rapid Test Cassette (Feces) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of H. Pylori antigen in feces. It is for professional *in vitro* diagnostic use only.

INTRODUCTION

H. Pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis.^{1,2} The prevalence of H. pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. Pylori infection with stomach cancer.³ H. Pylori colonizing in the gastrointestinal system elicits specific antibody responses^{4,5,6} which aids in the diagnosis of H. Pylori infection and in monitoring the prognosis of the treatment of H. Pylori related diseases. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. Pylori infection. Successful eradication of H. pylori is associated with clinical improvement in patients with gastrointestinal diseases providing a further evidence.⁷

PRINCIPLE

H. pylori Ag Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing H. Pylori antibodies conjugated with color particles (H. Pylori conjugates). 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated H. Pylori antibodies.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antigen of H. Pylori if present in the specimen will bind to the H. Pylori antibodies conjugates. The immunocomplex is then captured on the membrane by the pre-coated H. Pylori antibodies, forming a burgundy colored T band, indicating a H. Pylori antigen positive test 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. Otherwise, the test result is invalid and the specimen must be retested with another device.

PRODUCT CONTENTS

H. pylori Ag Rapid Test Cassette (Feces) containing anti- H. pylori antibodies particles and anti-H. pylori antibodies coated on the membrane.

MATERIALS SUPPLIED

20 Sealed pouches each containing a test cassette and a desiccant
20 Specimen collection tubes with extraction buffer, 2.0 mL
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. Specimen collection containers.

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use it if the tube/pouch is damaged or broken.
3. Test is for single use only. Do not re- use under any circumstances.
4. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
6. Humidity and temperature can adversely affect results

SPECIMEN COLLECTION

Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.

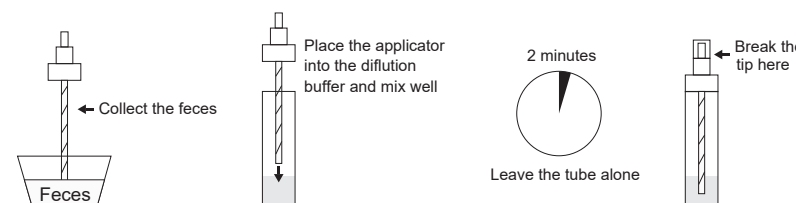
To process fecal specimens:

• For Solid Specimens:

Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.

• For Liquid Specimens:

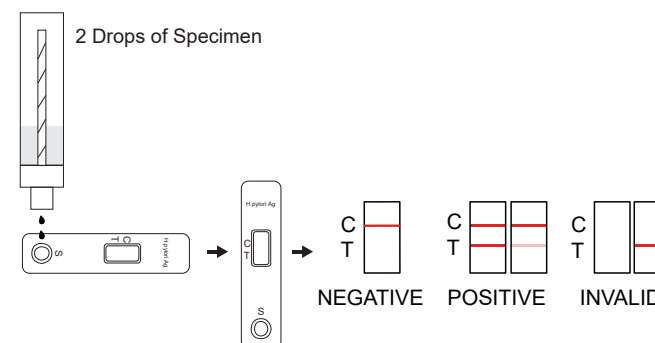
Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the dilution buffer. Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.



TEST PROCEDURE

1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
2. Specimen collection. See also specimen collection.
3. Holding the sample collection device upright, carefully break off the tip of collection device.
4. Squeeze 2 drops (~80 µL) of the sample solution in the sample well of the cassette, as in the illustration.
5. Read the test results in 10 minutes. It is important that the background is clear before the result is read. Do not read results after 10 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS



H. pylori Ag Rapid Test Cassette (Feces)

Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).

Invalid: Control line fails to appear.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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.

LIMITATIONS

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of H. Pylori antigen in feces from individual subjects. Failure to follow the procedure may give inaccurate results.

2. H. pylori Ag Rapid Test Cassette (Feces) is limited to the qualitative detection of H. Pylori antigen in feces. The intensity of the test band does not have linear correlation with the antigen titer in the specimen.

3. A negative result for an individual subject indicates absence of detectable H. Pylori antigen. However, a negative test result does not preclude the possibility of exposure to or infection with H. Pylori.

4. A negative result can occur if the quantity of the H. Pylori antigen present in the specimen is below the detection limits of the assay, or the antigen that are detected are not present during the stage of disease in which a sample is collected.

5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHARACTERISTICS

A study was performed with 165 patient feces samples including both symptomatic gastrointestinal disorders and samples from non-symptomatic patients and 100 normal feces samples.Comparison for all subjects with H. pylori Ag Rapid Test Cassette (Feces) and reference ELISA kit is showed in the following table:

Method		EIA		Total Results
H.P Test Cassette	Results	Positive	Negative	
	Positive	163	0	163
	Negative	2	100	102
Total Results		165	100	265

Relative sensitivity: 98.8%

Relative specificity: 100%

Accuracy:98.9%

REFERENCE

1. Marshall,B.J.et.al. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia.149:439-44, 1985.

2. Marshall,B.J.et.al. Prospective double-blind trial of duodenal ulcer relapse after eradication of Campylobacter pylori. Lancet. Dec.1437-42,1988.

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