ACRO BIOTECH, INC

EC Declaration of Conformity

Manufacturer:
Name: Acro Biotech, Inc.
Address: 9500, 7th str., Unit M, Rancho Cucamonga, CA 91730, USA

European Representative:
Name: MedNet GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: FOB Rapid Test
Model: Cassette/Dipstick
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III
EDMA Code: 12 70 03 90 00

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO13485:2012/AC:2012, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 15193:2009, EN ISO 15194:2009, EN 13640:2002, EN 13641:2002, EN 1041:2008,ISO 15223-1:2012

Place, Date of Issue: in Rancho Cucamonga on 14/06/2016

Signature: ____________ ACRO BIOTECH, INC
Name: Joseph Fan
Position: President

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Date: 2021.08.09 09:18:39 EEST
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA mun. CHIŞINĂU SOCIETATEA CU RĂSPUNDERE LIMITATĂ «POSEIDONGRUP» S.R.L.

ACRO BIOTECH, INC

FOB Rapid Test Cassette (Feces)

Package Insert

A rapid, one step test for the qualitative detection of Human Occult Blood in feces.
For professional in vitro diagnostic use only.

INTENDED USE

The FOB Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Human Occult Blood in feces.

SUMMARY

Many diseases can cause hidden blood in the feces. This is also known as Fecal Occult Blood (FOB), Human Occult Blood, or Human Hemoglobin. 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 methods lack sensitivity and specificity, and also have diet restrictions prior to testing.[1,2]

The FOB Rapid Test Cassette (Feces) is a rapid test to qualitatively detect low levels of Fecal Occult Blood. The test uses a double antibody sandwich assay to selectively detect Fecal Occult Blood at 50ng/ml or higher, or 6μg/g feces. In addition, unlike guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

The FOB Rapid Test Cassette (Feces) is a qualitative, lateral flow immunoassay for the detection of Human Occult Blood in feces. The membrane is precoated with anti-hemoglobin antibody on the test line region of the test. 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 line 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 the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains anti-hemoglobin antibody particles and anti-hemoglobin antibody coated on the membrane.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- 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 all procedures 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 assayed.
- The used test should be discarded according to local regulations.
- 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 cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- Specimens should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids 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.
- No dietary restrictions are necessary before using the FOB Rapid Test Cassette.

MATERIALS

Materials Provided

• Test cassettes • Specimen collection tubes with extraction buffer • Package insert

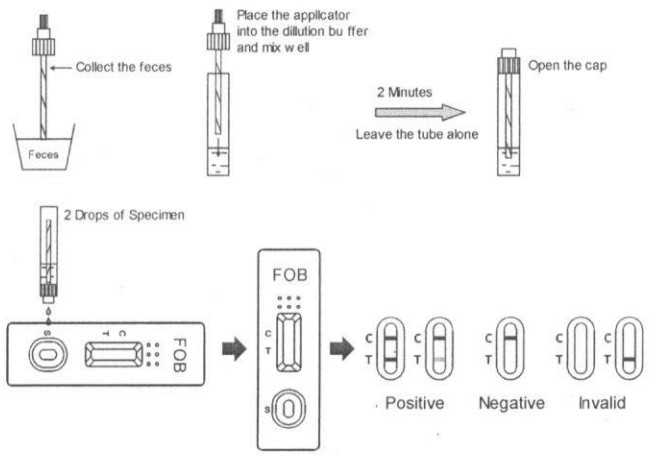
Materials Required But Not Provided

• Specimen collection containers • Timer • Droppers

DIRECTIONS FOR USE

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

1. To collect fecal specimens:
   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.
2. 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 μ L) into the specimen collection tube containing the extraction buffer.
3. Tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the tube alone for 2 minutes.
4. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
5. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 80 μ L) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
6. Read results at 5 minutes after dispensing the specimen. Do not read results after 10 minutes.
7. **Note:** If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 80 μ L of supernatant, dispense into the specimen well (S) of a new test cassette and start afresh following the instructions mentioned above.



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).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Fecal Occult Blood present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

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. 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid 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.

LIMITATIONS

1. The FOB Rapid Test Cassette (Feces) is for in vitro diagnostic use only.
2. The FOB Rapid Test Cassette (Feces) will only indicate the presence of Fecal Occult Blood, the presence of blood in feces does not necessarily indicate colorectal bleeding.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. Other clinically available tests are required if questionable results are obtained.

EXPECTED VALUES

The FOB Rapid Test Cassette (Feces) has been compared with another leading commercial rapid test. The correlation between this two system is 98.6%

PERFORMANCE CHARACTERISTICS

Accuracy

The FOB Rapid Test Cassette (Feces) has been compared with another leading commercial rapid test using clinical specimens.

Method		Other Rapid Test		Total Result
FOB Rapid Test Cassette (Feces)	Results	Positive	Negative	
	Positive	189	4	193
	Negative	10	802	812
Total Result		199	806	1005

Relative sensitivity: 189/199=95% (95%CI*: 91%~97.6%);
Relative specificity: 802/806=99.5% (95%CI*: 98.7%~99.9%);
Accuracy: (189+802)/(189+10+4+802) =98.6% (95%CI*: 97.7%~99.2%). *Confidence Intervals

Sensitivity

The FOB Rapid Test Cassette (Feces) can detect levels of Fecal Occult Blood as low as 50 ng/mL or 6 μg/g feces.

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: 50ng/ml, 100ng/ml and 10μg/ml positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same three specimens: 50ng/ml, 100ng/ml and 10μg/ml positive specimens. Three different lots of the FOB Rapid Test Cassette (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The FOB Rapid Test Cassette (Feces) is specific to human hemoglobin. Specimens containing the following substances were diluted in the extraction buffer to a concentration of 1.0 mg/ml, and tested on both positive and negative controls with no effect on test results: Bovine hemoglobin, Chicken hemoglobin, Pork hemoglobin, Goat hemoglobin, Horse hemoglobin, Rabbit hemoglobin and Turkey hemoglobin.

BIBLIOGRAPHY

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

Index of Symbols

⚠	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only	⌛	Use by	2	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

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CE EC REP MedNet GmbH Borkstrasse 10 48163 Muenster Germany

DN: 217001
Rev. Date: 2016-04-28

FOB Rapid Test Cassette (Feces)

Contents: Test Cassettes - 25 Package Insert - 1
Specimen collection tubes with extraction buffer - 25

REF TFO-602

LOT FOBYYMMXXXX YYYY-MM

CE Σ 25 IVD 2°C 30°C

BC10021-02

☐ US ■ OUS ☐ DOMESTIC ☐ OTHER

Description 描述	TFO-602 CE box label(25T)	Part Number PN号码		Size 尺寸	75x45mm
Printing Contents 印刷内容	/	L Number L号码	BC10021-02	Size 尺寸	/
Designer 设计者	Nora	Design Date/Version 设计日期/版本	Jun 06 2016/A	Mold Num. 模具号	/
Artwork Checked By 设计审核		Material Checked By 材质/审核			
Approved By Customer/Date 客户确认/日期		Approved By Marketing/Date 市场部确认/日期			
Approved By QA/RA/Date QA / RA确认/日期		Approved By P.M.T /Date 产品管理确认/日期			
Approved By QA/Date 确认/日期		Effective Date 生效日期			

REPUBLICA MOLDOVA, mun. CHIŞINĂU
S.R.L. «POSEIDONGRUP»
IDNO 1014600011116
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

SYNTESYS S.a.s.
di Rinaldo Ruggero e C.

Via G. Galilei, 10/3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a

Quality Management System

for the following scope:

Trading of products for laboratory analysis.
Manufacturing of products for laboratory analysis and sanitary products.

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on:	**2019-06-05**
First issued on:	**2013-06-05**
Expires on:	**2022-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: IT-83562

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
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IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
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IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

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Quality Management System

for the following scope:

Trading of products for laboratory analysis.
Manufacturing of products for laboratory analysis and sanitary products.

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on:	**2019-06-05**
First issued on:	**2014-06-21**
Expires on:	**2022-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

REPUBLICA MOLDOVA mun. CHISINAU S.R.L. «POSEIDONGRUP» IDNO 1014600011116 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Registration Number: IT-93779

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
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CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
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SYNTESYS

ISO9001:2008
Cert. N 6574/0

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DICHIARAZIONE DI CONFORMITA'
Conformity declaration

CE

Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/*manufacturer*

SYNTESYS S.a.s. di Rinaldo Ruggero & C.

indirizzo/*address*

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

O rappresentante il mandatario autorizzato entro la Unione Europea or representing the authorized mandatary within the European Community

Mandatario autorizzato/*authorized mandatary*

indirizzo/*address*

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsability that the product:*

Denominazione degli articoli prodotti/*Description of Manufacturer*	**Contenitori per urina, contenitori per feci, contenitori universali, Pipette Pasteur, Piastre di Petri, Anse Sterili per batteriologia, Aste a "L", Puntali Eppendorf gialli e blue, cuvette per spettrofotometro, tazzine per campionamento siero, bacchette per distacco ed estrazione del coagulo, pinzette in polistirolo monouso, provette monouso in plastica, tappi alettati per provette diam. 12 mm e 16mm, provette con granuli ed acceleratore, provette sottovuoto per prelievo, Sistema SEDIPLAST, Microprovette, Portavetrini, Vetrini precolorati, Portaprovette, supporti per microprovette, bottiglie per raccolta urine.** ***Urine container, faeces container, universal container, Pasteur pipette, Petri dishes, Sterile loops, Sterile loops open "L", Eppendorf tips yellow and blue, cuvettes for spectrophotometer, samples cups, Rod to detach clot, disposable forceps, Disposable plastic tubes, winged stoppers for tubes diam. 12mm & 16mm, Test tube with granules and clot activator, vacuum test tube, SEDIPLAST system, micro test tubes, Slides Mailer,"TESTSIMPLETS" slides rack for test tubes, rack for micro test tubes, Bottles for urine collection.***

REPUBLICA MOLDOVA MUN. CHISINAU S.R.L. "POSEIDONGRUP" IDNO 1014600011116 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SYNTESYS

ISO9001:2008
Cert. N 6574/0

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Materiale/*Material*	**Polipropilene, Polistirolo, Polietilene e Polimetilmetacrilato** ***Polypropylene, Polystyrene, Polyethylene and Polymetilmetacrylate***

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepito in Italia con D.L. del 08/09/2000 n° 332 allegato 1 (requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della sopra citata direttiva / *It meets the CE Directive 98/79 CE about in vitro diagnotic device specifications established by the Italian law n. 332, dated 8th September 2000. The device is made according to the specifications of the III attached of the above-mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/*declares that all technical documents attached to this conformity statment are filed in our company and can be consulted by any authorized body on demand.*

Data 07/01/2016
Issued on January 7th 2016

SYNTESYS S.a.s.
Il legale rappresentante
Rinaldo Ruggero

REPUBLICA MOLDOVA, mun. CHIŞINĂU
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