ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 060578 0021 Rev. 01

Holder of Certificate: **InTec PRODUCTS, INC.**
332 Xinguang Road
Xinyang Industrial Area, Haicang
361022 Xiamen, Fujian
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development,
Production and Distribution of
In Vitro Diagnostic Kits for Immunochemistry,
Infectious Diseases, Clinical Chemistry,
Haemostasis (Coagulation) and Related Instruments**

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 060578 0021 Rev. 01

Report No.: SH2129601

Valid from: 2021-07-31
Valid until: 2024-07-30

Date, 2021-07-28

Christoph Dicks
Head of Certification/Notified Body

«MEDEFERENT GRUP» S.R.L.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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No. Q5 060578 0021 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):

InTec PRODUCTS, INC.
332 Xinguang Road, Xinyang Industrial Area, Haicang, 361022
Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA

Design and Development,
Production and Distribution of
In Vitro Diagnostic Kits for Immunochemistry,
Infectious Diseases, Clinical Chemistry,
Haemostasis (Coagulation) and Related Instruments

InTec PRODUCTS, INC.
308-8 Wengjiao Road, Xinyang Industrial Area, Haicang,
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Design and Development,
Production of
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and Infectious Diseases

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TÜV®

InTec PRODUCTS, INC.

Doc No.: 2019080603

EU Declaration of Conformity

According to Annex III of 98/79/EC

We, **InTec PRODUCTS, INC.,** with registered address at 332, Xinguang Road, Xinyang Industrial Area, Haicang 361022 Xiamen, Fujian, China, herewith declare that the below listed products meet the applicable provisions of the European Directive 98/79/EC for *in vitro* Diagnostic Medical Devices.

EDMA	Product Code	Product Name
15.70.05.01	ITP11002-TC25, ITP11002 TC40	ONE STEP Malaria(p.f) Test
15.70.05.01	ITP11003-TC25, ITP11003 TC40	ONE STEP Malaria(p.f/p.v) Tri-line Test
15.70.05.01	ITP11005-TC25, ITP11005-TC40	Rapid Malaria Test (P.f/Pan)
15.70.01.02	ITP10002-DS50, ITP10002-TC40	Rapid Anti-H.Pylori Test
15.70.01.02	ITP10003-DS50, ITP10003-TC20	ONE STEP H. pylori Ag Test
11.70.03.01	ITP13001-DS50, ITP13001-TC20	Rapid FOB Test
15.70.90.07	ITP71002-DS50, ITP71002-TC40	ONE STEP Anti-Dengue (IgM & IgG) Tri-line Test
15.70.01.05	ITP03004-TC40, ITP03004-DS50	ONE STEP Anti-TP (Treponema Pallidum /Syphilis) TEST
12.70.13.01	ITP08004-TC40	ONE STEP CK-MB Test
12.70.13.02	ITP08003-TC40	ONE STEP Myoglobin Test
12.70.13.03	ITP08001-TC40	ONE STEP Troponin I Test
12.70.13.70	ITP08101-TC20	ONE STEP Myoglobin/CK-MB/cTnI Combo TEST
12.70.09.05	ITP06003-DS50, ITP06003-TC40	ONE STEP Cannabinoids (THC) Test
12.70.09.08	ITP06002-DS50, ITP06002-TC40	ONE STEP Opiate (OPI/Morphine) Test

Technical documentation demonstrating compliance is kept at our registered address and can be made available by the authorized representative in Europe: QARAD b.v.b.a., Cipalstraat 3, B 2440 Geel, Belgium

Nicole Zhang

Date: Aug 06, 2019

Nicole Zhang (Authorized Signatory)

Quality Director

InTec PRODUCTS, INC. Place: Xiamen, China

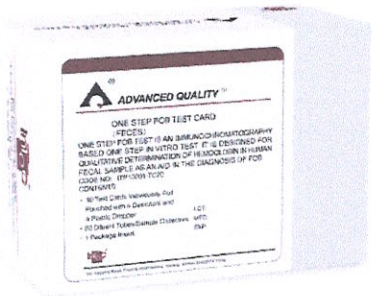
Add: 332 Xinguang Road, Xinyang Industry Area, Haicang Xiamen P. R. China

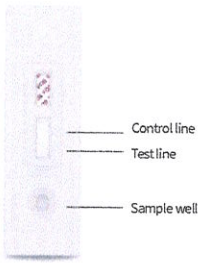
Tel: +86 592 6807188

Fax: +86 592 6519161

http://www.asintec.com

Rapid Fecal Occult Blood (FOB) Test





Intended use

The Advanced Quality Rapid FOB Test is a rapid, serological, immunochromatographic assay for the detection of hemoglobin (hb) in human feces. The test is used to obtain a visual, qualitative result and is intended for healthcare professional use.

Product parameters

- Specimen: feces
- Storage temperature and shelf life: 2~30°C, 24 months
- Detection limit: 0.2μg/ml

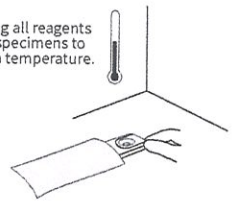
Reference		InTec FOB test		Total results
Method	Result	Positive	Negative	
A leading commercial FOB test	Positive	100	2	102
	Negative	3	202	205
Total results		103	204	307

In a comparison of the InTec FOB test versus a leading commercial FOB rapid test, results gave sensitivity of 98% (100/102), a specificity of 98.5%(202/205),and a total coincidence rate of 98.3%(302/307).

Test procedures

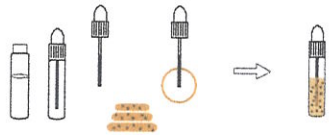
1.Prepare Test

*Bring all reagents and specimens to room temperature.



*Remove the test card from the foil pouch and place on a clean dry surface.

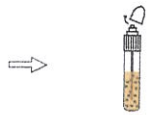
2.Sample preparation



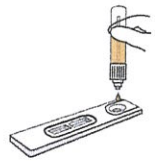
*Collect feces

*Shake and mix well

3. Add sample

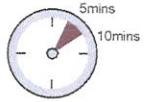


*Turn the lid in clockwise direction



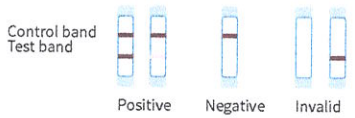
*Dispense 2 drops (100ul) of the specimen into the sample well.

4. Read result



Interpret test results at 5~10mins. Do not read after 10 mins.

Result interpretation



Ordering information

Product	Cat. No.	Type	Pack size	Specimen	Certification
FOB	ITP13001-TC20	Cassette	20T	Feces	CE

ADVANCED QUALITY™

CAT. NO. ITP13001-TC20/DS50

01.05.14.001-150402

RAPID FOB TEST

Fecal Occult Blood Test (Colloidal Gold)
(Feces)

FOR IN VITRO DIAGNOSTIC USE ONLY

This package insert must be read carefully prior to use. Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

INTENDED USE

The Advanced Quality™ Rapid FOB Test is a rapid, serological, immunochromatographic assay for the detection of hemoglobin (hb) in human feces. The test is used to obtain a visual, qualitative result. This test is a rapid test as an aid in the diagnosis of relative infection and relative symptom; it only provides preliminary analysis results but not critical diagnosis criteria, the obtained results should be analyzed in connection with other clinical information, e.g. clinical symptoms, and alternate test to make final decision. The test is intended for healthcare professional use.

SUMMARY AND BIOLOGICAL PRINCIPLE OF THE ASSAY

The detection of fecal occult blood is important for the diagnosis of disease that results in gastrointestinal bleeding and to screen for colorectal cancers and large adenomas that bleed. Screening for colorectal cancer probably increases the cancer detection at an early stage, therefore reduces the mortality.

THE ADVANCED QUALITY™ Rapid FOB Test is a chromatographic immunoassay for the qualitative determination of Hemoglobin (Hb) in human feces. When feces is added to sample pad, it moves through the conjugate pad and mobilizes gold anti-Hb conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-Hb that is coated on the test region. If Hb is present, the result is the formation of a colored band in the test region. If there is no Hb in the sample the area will remain colorless. The sample continues to move to the control area and forms a pink color, indicating the test is working and the result is valid.

MATERIALS PROVIDED

FOR TEST CARDS:

- Test cards, individually foil pouched with a desiccant.....20
- Diluent Tubes/Sample Collectors.....20
- Package insert.....1

FOR TEST STRIPS:

- Test strips, individually foil pouched with a desiccant.....50
- Sample cups.....50
- Applicator sticks.....50
- Package insert.....1

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer/clock
2. Pipette
3. Controls
4. Disposable gloves

STORAGE AND STABILITY

The kit has a 24 month shelf-life from the date of manufacture. Store the unused kits at 2℃-30℃. If stored refrigerated, ensure that the sealed pouch is brought to room temperature (10℃-30℃) before opening for testing.

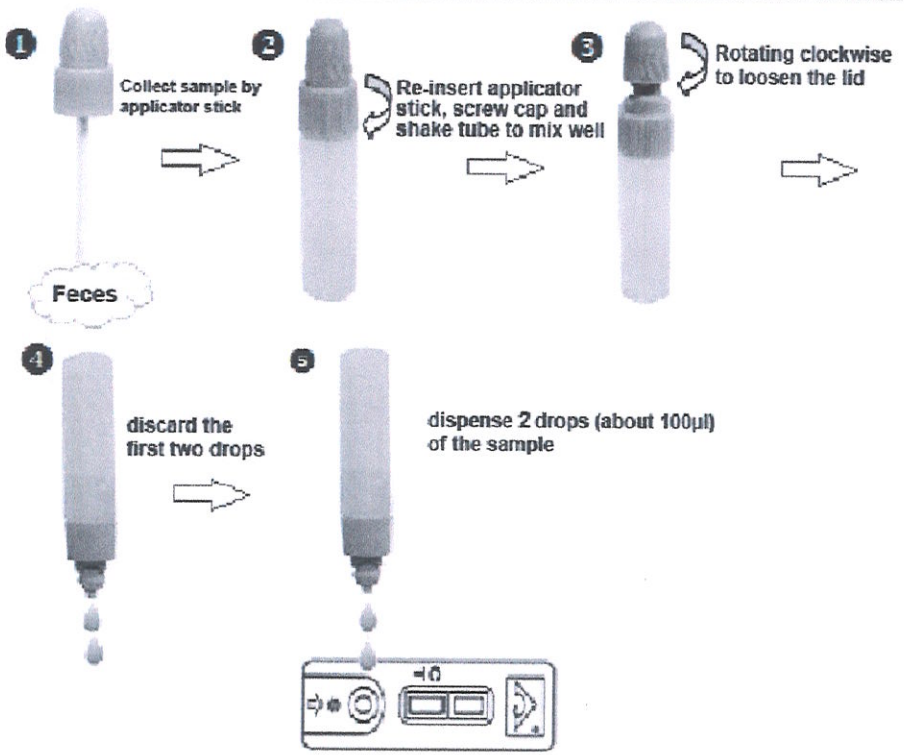
WARNINGS AND PRECAUTIONS

1. For professional and in-vitro diagnostic use only.
2. ALL positive results must be confirmed by an alternate method.
3. The test device should remain in the sealed pouch until use.
4. Do not use kit materials beyond their expiration dates.
5. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
6. The test device should be discarded in a proper biohazard container after testing.
7. Avoid cross-contamination of feces by changing a new specimen pipette for each sample.

SPECIMEN COLLECTION AND PREPARATION

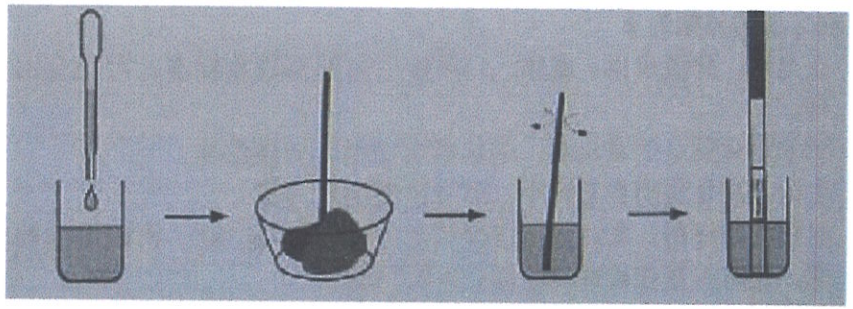
FOR TEST CARDS:

1. Remove the applicator stick from the diluent tubes/sample collectors. Insert and turn the stick into the feces at different sites (fully covering the spiral groove on the applicator stick).
2. Re-insert the applicator stick into the diluent tubes/sample collectors, screw the cap and shake the tube vigorously to mix the sample well.
3. Testing should be performed immediately after the feces have been collected. If the feces cannot be processed immediately, it may be held at 2 ~ 8 °C for up to 48 hours.



FOR TEST STRIPS:

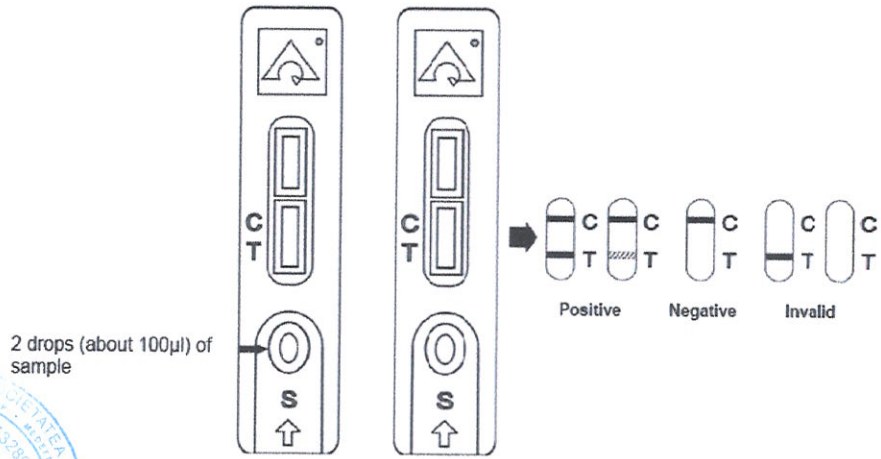
1. Dispense 0.5ml diluent (physiological saline) into the sample cup.
2. Insert and turn the applicator stick into the feces 5-6 times at different site (fill up the ditch with feces and please check the quantity whether too much or not).
3. Insert the applicator stick into the sample cup, mix well to provide a good homogenous extraction and suspention.
4. Testing should be performed immediately after the feces have been collected. If the feces cannot be processed immediately, it may be held at 2 ~ 8 °C for up to 48 hours.



ASSAY PROCEDURES

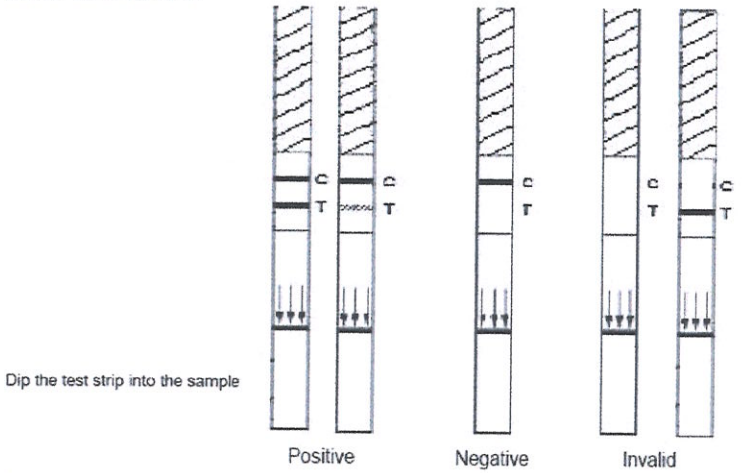
For Test Cards:

1. Read package insert carefully before testing. Bring all reagents and samples to room temperature (10-30°C). Do not open pouches until ready to perform the assay.
2. Remove the test card from the foil pouch and place on a clean dry surface.
3. Identify the test card for each specimen or control.
4. Rotating clockwise to loosen the lid of diluent tubes/sample collectors cap.
5. Invert the diluent tubes/sample collectors and discard the first two drops of diluent, then dispense 2 drops (about 100µl) of sample which has been mixed evenly and without bubble into the circular sample well on the card, start timing.
6. Interpret the test results within 5-10 minutes. **Do not interpret the results after10 minutes.**



For Test Strips:

1. Read package insert carefully before testing. Bring all reagents and samples to room temperature (10-30°C). Do not open pouches until ready to perform the assay.
2. Remove the test strip from the foil pouch and place on a clean dry surface.
3. Identify the test strip for each specimen or control.
4. Dip the test strip into the sample cup with the arrows pointing toward the sample diluent.
5. The sample diluent level must not exceed the maximum line.
6. Interpret the test results at 5-10 minutes. **Do not interpret the results after 10 minutes.**



Caution: Use a clean pipette or tip for every sample to avoid cross-contamination.

NOTE:

1. *In case the tests did not run due to solid particles fallen into the round window, stir the sample added until seeing the liquid running through the reaction zone.*
2. *A positive result may be interpreted early, however read any negative at 5 minutes to ensure sample is negative and not a low concentration of the hemoglobin It is recommended to run a known positive control and negative control in each performance to ensure the assay procedure.* ***Do not interpret the results after10 minutes.***
3. *No test provides absolute assurance that a specimen does not contain low levels of hemoglobin.*

INTERPRETATION OF RESULTS

1. **Positive:** In addition to the control band, a distinct colored band also appears on the test region.
2. **Negative:** Only one purplish red colored band appears on the control region.

3. **Invalid:** There should always be a control line in the control region (C) regardless of test result. If control line is not seen, the test is considered invalid. Repeat the test using a new test device.

PERFORMANCE CHARACTERISTICS

Sensitivity

The Rapid Fecal Occult Blood (FOB) Test can detect Hemoglobin in human feces with concentration of 0.2μg/ml or greater.

Accuracy

Reference		InTec FOB test		Total Results
Method	Result	Positive	Negative	
A leading Commercial FOB test	Positive	100	2	102
	Negative	3	202	205
TOTAL RESULTS		103	204	307

In a comparison of the InTec FOB test versus a leading commercial FOB rapid test, results gave sensitivity of 98% (100/102),a specificity of 98.5%(202/205),and a total agreement of 98.3%(302/307).

Interference testing

No interference was found with any of the substances at the following concentrations:

substance	concentration
Swine hemoglobin	1mg/ml
Chicken hemoglobin	1 mg/ml
Bovine hemoglobin	1 mg/ml
Rabbit hemoglobin	1 mg/ml
Dog hemoglobin	1 mg/ml
Sheep hemoglobin	1 mg/ml
HRP	2 mg/ml

LIMITATIONS

1. The assay should be performed in normal room temperature.
2. Test cards/strips should be used immediately after being taken from the package. Avoid exposing the test strips in the air for too long before use.

3. The test cards/strips may be stored under room temperature and dry condition. If refrigerated, the cards/strips should be brought to room temperature before testing.
4. Although the test is very accurate, a low incidence of false results can occur.
5. If negative or questionable results are obtained, the test should be repeated on a fresh feces using a new device.
6. A negative result does not rule out FOB because the Hemoglobin may be absent at the time the specimen is taken or may not be present in sufficient quality to be detected at early stage.
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

InTec PRODUCTS, INC. (XIAMEN)
332, Xinguang Rd, Xinyang IND Area, Haicang, Xiamen, 361022, P.R. China
Telephone: +86 592 6807188
E-mail: intecproducts@asintec.com
Website: www.intecasi.com