Procedo
INTERNATIONAL CERTIFICATION

SNAS
Reg. No. 672/Q-084

Quality management system

CERTIFICATE

This is to certify that the Quality management system for medical devices of the company

CiTEST DIAGNOSTICS INC.
170-422, RICHARDS ST, VANCOUVER, BC V6B 2Z4, CANADA

has been found in compliance with requirements of the standard

ISO 13485: 2016 /
EN ISO 13485: 2016 + A11: 2021

for the following scope:

Design and Development, Production and Distribution of In Vitro Diagnostic Reagents,Control Material and Instruments for Clinical Chemistry, Immunochemistry (Immunology),Haemostasis, Infectious Diseases and Immunohaematology, including Professional Laboratory Use, Near Patient and Self Testing

Certificate no.: QMS-13-001-2022/A
Initial certificate issue: 12/04/2022

Date of issue: 07/04/2025
Valid from: 12/04/2025

On condition that the organisation will maintain an effective quality management system for medical devices, this certificate remains valid until ***11/04/2028.***

Digitally signed by Dolgopol Iulian
Date: 2026.01.16 12:15:10 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Procedo
INTERNATIONAL CERTIFICATION
Certification Body

Ľubica Škrovanová
Head of Certification Body

EC Declaration of Conformity

Manufacturer:
Name：CITEST DIAGNOSTICS INC.
Address：170-422 Richards Street, Vancouver BC V6B 2Z4 Canada

European Representative:
Name: CMC MEDICAL DEVICES & DRUGS, S.L.
Address: C/ HoracioLengo No 18, CP 29006, Málaga-Spain

Product Name: FOB (Fecal Occult Blood) Rapid Test (Feces)
Model: Cassette/Dipstick
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III (excluding point 6)
EDMA Code: 12 70 03 21 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 ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016

CITEST DIAGNOSTICS INC

Place, Date of Issue: in Vancouver on 06/03/2020

Signature: Fu yan ping

29/11/2021

Name: Fu Yanping (Position: General Manager) Date:

FOB Rapid Test Cassette (Feces)

English

IVD
CITEST DIAGNOSTICS INC.
170-422 Richards Street
Vancouver BC, V6B 2Z4, Canada
CE
EC REP
CMC MEDICAL DEVICES & DRUGS, S.L.
C/ Horacio Lengo Nº 18, CP 29006, Málaga-Spain

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 25ng/ml or higher, or 3.0μg/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℃). 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

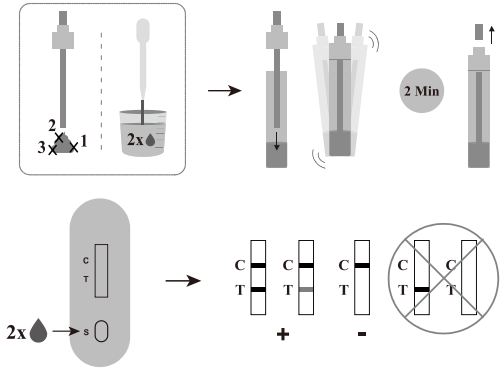
Materials Required But Not Provided

- Specimen collection containers
- Timer
- Droppers

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30℃) 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℃ if not tested within 6 hours. For long term storage, specimens should be kept below -20℃.
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 μL) 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 μL) 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 μL 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.

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	120	4	124
	Negative	3	596	599
Total Result		123	600	723

Relative sensitivity: 97.6% (95%CI*: 93.0%~99.5%);
Relative specificity: 99.3% (95%CI*: 98.3%~99.8%);
Accuracy: 99.0% (95%CI*: 98.0%~99.6%).
*Confidence Intervals

Sensitivity

The FOB Rapid Test Cassette (Feces) can detect levels of Fecal Occult Blood as low as 25ng/ml or 3.0μg/g feces.

Precision

Intra-Assay

Within-run precision has been determined by using 3 replicates of three specimens: 25ng/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 3 independent assays on the same three specimens: 25ng/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

IVD	*In vitro* diagnostic medical device
2°C 30°C	Temperature limit
	Do not use if package is damaged and consult instructions for use
REF	Catalogue number
Σ	Contains sufficient for <n> tests
	Use-by date
LOT	Batch code
	Manufacturer
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Caution
EC REP	Authorized representative in the European Community

REF: TFO-602
Number: 146123001
Date: 2023-08-24