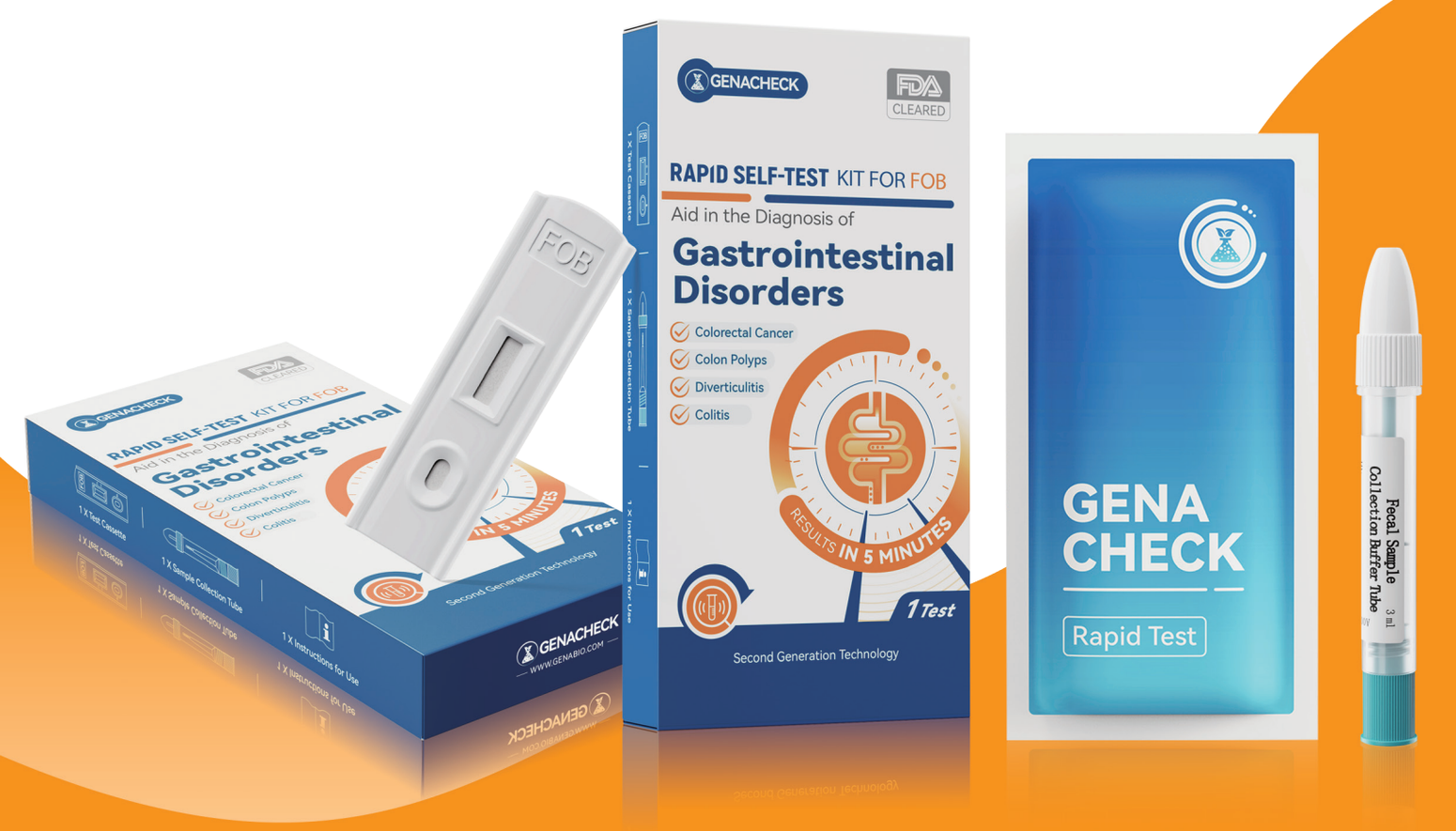
GENACHECK

JLB Sourcing

RAPID SELF-TEST KIT FOR **FOB**

Easy & Fast Testing at Home

- Colon Disease Screening
- FDA Cleared for At-Home Use
- Test Result in Minutes
- Easy-to-Read Results



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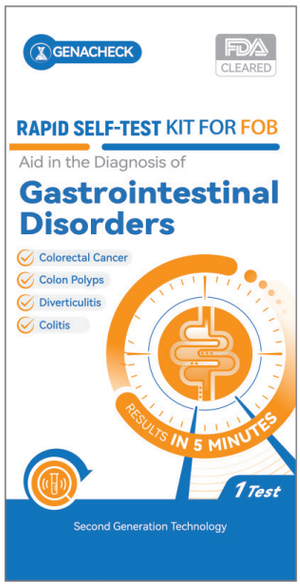

PRODUCT FEATURES

Detection for: Human Fecal Occult Blood

Test Time: 5 minutes

Sensitivity: 50ng/ml hHb

Relative Sensitivity: 99.2%

Relative Specificity: 98.9%

ORDER INFORMATION

Name	Item No.	Package
GenaCheck™ Rapid Test Kit for FOB	RA9-E01701	1 Test per Box

	Dimension	Pack Size	Gross Weight	Quantity
Carton	L: 37cm w: 25cm H: 33cm	102 (boxes per carton)	4kg	102 (tests per carton)
Pallet	L: 112cm w: 100cm H: 111cm	36 (cartons per pallet)	184kg	3672 (tests per pallet)

20820 Century Corner Drive, Ashburn, Virginia 20147, United States

Establishment Registration & Device Listing

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Proprietary Name:	GenaCheck Rapid Self-Test Kit for FOB
Classification Name:	REAGENT, OCCULT BLOOD
Product Code:	KHE
Device Class:	2
Regulation Number:	864.6550
Medical Specialty:	Hematology
Registered Establishment Name:	GENABIO DIAGNOSTICS INC
Registered Establishment Number:	3016609999
Premarket Submission Number:	K110309
Owner/Operator:	Genabio Diagnostics Inc.
Owner/Operator Number:	10063095
Establishment Operations:	Repackager/Relabeler; Complaint File Establishment

EN

GENABIO

GenaCheck™ Rapid Self-Test Kit For FOB

Instructions For Use

For in vitro diagnostic Use Only
For Over-The-Counter Use Only

Step By Step Instructions

1 Preparation

COLLECTION OF STOOL FROM A TOILET BOW

If using a receptacle

• Prepare a dry and clean receptacle that can be placed into and taken out from a toilet bowl conveniently (above the water surface). Do not use toilet paper (toilet paper may contain substances which are inhibitory for some fecal specimens).
• Do not contaminate specimen with urine. So please urinate first, if necessary.
• Have a bowel movement and remove the receptacle with stool out of the toilet bowl.

If not using a receptacle

• Do not contaminate specimen with urine. Please urinate first, if necessary.
• Flush the toilet bowl twice before excreting. If necessary, clean the toilet bowl.
• Have a bowel movement. Stool that contacts with water or not can be used for following procedures.

2 Specimen Collection

1. Unscrew the bottom cap (blue end) of the collection tube and remove the applicator stick.
2. Insert the stick into the fecal specimen at 6 different sites.
3. Insert the sampled applicator back into the tube and tighten the bottom (blue end) securely. The narrow hole only allows the stick to go through and will prevent the excess sample from getting into the tube.

4. Shake the tube with bottom cap vigorously for about 5 seconds to release and disperse the stool sample into the collection buffer.
5. If necessary, it is recommended to write identifying information on collection tube with a marker pen.

Note:

• Specimen should not be collected during or within three days of menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
• The specimen may be collected from stool in a toilet bowl with or without contact to water, or stool from a receptacle before going into the toilet bowl.
• 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.
• The stool sample can be stored at room temperature 15-30°C (59-86°F) up to 24 hours or in a refrigerator 2-8°C (36-46°F) for up to 72 hours.

3 Test Procedure

1. Bring all materials and specimens to room temperature 15-30°C (59-86°F).
2. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
3. Holding the sample collection device upright, carefully break off the tip of collection device.
4. Squeeze 3 drops (~75uL) of the fecal sample solution in the sample well of the cassette, as in the illustration.
5. Read the test results between 5-10 minutes. Test results read earlier than 5 minutes and later than 10 minutes are not valid. Before reading results, please put device on a clear and single-colored background to avoid visual disturbances.

6. After your result is known put all contents back in the original box and dispose with your daily household waste products.

4 Result Interpretation

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

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

Invalid: The result is invalid if no Control line appears in the control region (C), even if a line appears in the test region (T). You should repeat the test with a new cassette.

Note: If the test line is weak, it is recommended that the test be repeated in 48 hours.

Intended Use

The GenaCheck™ Rapid Self-Test Kit for FOB is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in human fecal specimens. The device is suitable for use in laboratories and physician's offices as well as for Over-The-Counter use.

Test Principle

The GenaCheck™ Rapid Self-Test Kit for FOB is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique. The membrane is pre- coated with anti-hemoglobin antibody on the test line region of the device. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. The mixture moves upward on the membrane 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

• 1 × Test cassette
• 1 × Specimen collection tube with extraction buffer
• 1 × Instructions for Use
• 1 × Additional information for Laboratory and Physicians Office

Materials Required But Not Provided

You will need a clock or timer, and or specimen collection containers.

Storage And Stability

• Store at at 2-30°C (36-86°F) in the sealed pouch up to the expiration date.
• If stored refrigerated, ensure that the test device is brought to room temperature before opening.
• Keep away from sunlight, moisture, and heat.
• DO NOT FREEZE the kit or expose the kit over 30°C (86°F).

Warnings And Precautions

• This test is designed for “in vitro diagnostic" use.
• Read instructions carefully before using this test.
• Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
• Do not use it if the tube/pouch is damaged or broken.
• Test is for single use only. DO NOT re-use under any circumstances.
• Do not use the test device or collection tube beyond the expiration date.
• Do not use the kit if the pouch is punctured or is not well sealed.
• Keep out of the reach of children.
• Fecal specimens may be infectious; ensure proper handing and discard all used devices according to the local regulations.
• If the test does not show any Control or Test line in the window or a smudged or partial line, the test should be discarded. Do not use the results. Run the test again with a new cassette and follow the procedure exactly. If the second test does not show lines, please contact Technical Services at 1-800-614-3365.

Limits Of The Test

• As with all diagnostic tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
• This test is limited to the detection of fecal occult blood in human stool sample only.
• Although the test is highly accurate in detecting human hemoglobin, a low incidence of false positive results may occur.
In addition, because many bowl lesions, including some polyps and colorectal cancers, may bleed intermittently or not at all, occult blood may not be uniformly distributed throughout a fecal sample. Thus test results may be negative even when the disease is present.

Questions And Answers

Q: What sample can be used with this test?
A: The test is for use with fecal specimens that 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 or 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 test.

Q: How do I know that the FOB test has been run correctly?
A: A red line should appear in the control line region after five minutes (do not interpret results after 10 minutes). A result should be considered invalid if the control line fails to appear. This could be due to insufficient specimen volume or incorrect procedural techniques. If control line failure is noted, review the technique used and repeat with a new test. If the problem persists, discontinue using the test kit immediately and contact Technical Services (refer to Manufacturer section for more information).

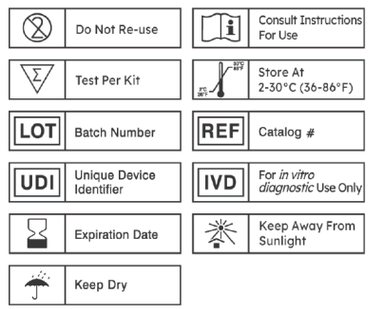
Q: What conditions should the FOB test be stored under?
A: The test device should be stored as packaged in the sealed pouch either at room temperature or refrigerated 2-30°C(36 - 86°F). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze and do not use beyond the expiration date.

Q: How sensitive is the test?
A: The FOB Test detects hemoglobin in feces at a concentration of 50 ng/mL hHb or greater. The addition of other animal hemoglobins showed no cross-reactivity.

Q: What is the recommended collection procedure for the fecal specimens?
A: Specimens should be collected in a clean, dry specimen collection container. Best results will be obtained if the assay is performed within 24 hours after collection. Specimens collected may be stored for 72 hours refrigerated if not tested within 24 hours.

Q: How accurate is this test?
A: The FOB test was shown to be greater than 98% in agreement with another commercially available test. Although the test is highly accurate in detecting human hemoglobin, a low incidence of false positive results may occur, because many bowel lesions, including some polyps and colorectal cancers, may bleed intermittently or not at all, or blood may not be uniformly distributed throughout a fecal sample. The results may be negative even when disease is present. Please discuss the results of a positive test with your doctor.

Index Of Symbols



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COMPANY INTRODUCTION

Genabio is a global leader in the production of over-the-counter self-testing products, with an impressive sales record of over $100 million in the past three years. Our extensive customer base spans across the USA, Canada, the UK, Japan and India.

A significant aspect of our product range is the FDA approval, including the COVID-19 Rapid Self-Test Kit. These sought-after products can be found in thousands of locations, including renowned pharmacy chains like Walgreens, leading hospitals such a NYU Langone Health, accredited laboratories like SV Diagnostics Labs and Molecular Testing Labs, and various government departments.

In 2023, Genabio marked a pivotal moment in initiating our listing and financing efforts in Hong Kong. Simultaneously, we are focused on enhancing our brand identity and emphasizing clinical research within the United States. This commitment to research and development aligns with our expansion plans, which encompass increasing our production capacity in both the United States and China.

Our overarching vision is to be the world's foremost provider of self-testing solutions, offering precise, user-friendly, and cost-effective health diagnostics for individuals worldwide.

Our mission is to enhance global health awareness and accessibility, by delivering quality, FDA-approved self-test kits, by driving innovation, and by expanding our reach to ensure individual scan monitor their health with precision and convenience.