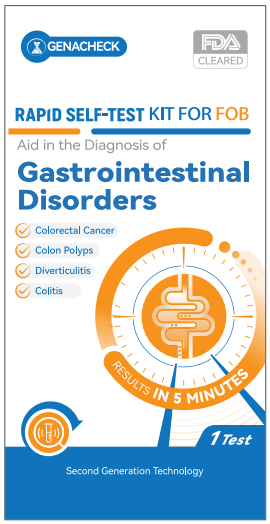
GENACHECK

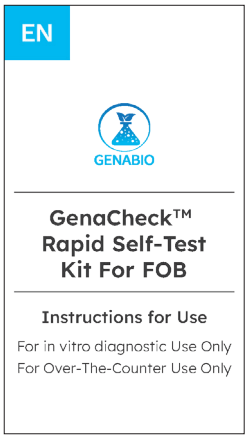
RAPID SELF-TEST KIT FOR **FOB**

Easy & Fast Testing at Home

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

Website: www.genabio.com | Email: info@genabio.com | Phone: 1-800-614-3365





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)

CLINICAL STUDY INFORMATION

A total of 532 clinical fecal specimens were collected from hospital patients.

These specimens underwent testing using three different lots of the GenaCheck™ Rapid Test Kit for Fecal Occult Blood (FOB) while strictly following the provided Instructions for Use. To establish a comprehensive comparison, the same clinical samples were also subjected to testing using a commercial FOB rapid test.

The results of the comparison between the two kits are detailed in the table below. Notably, all three lots of the GenaCheck™ Rapid Test Kit exhibited consistently reliable results, with a relative sensitivity of 99.2% and a relative specificity of 98.9%, respectively. These findings underscore the kit's accuracy and effectiveness in detecting fecal occult blood, affirming its robust performance in clinical settings.

Test Method		Commercial FOB rapid test		Total
		Positive	Negative	
GenaCheck™ Rapid Self-Test Kit for FOB	Positive	245	3	248
	Negative	2	282	284
	Total results	247	285	532
Relative Sensitivity		99.2%		
Relative Specificity		98.9%		

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

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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).

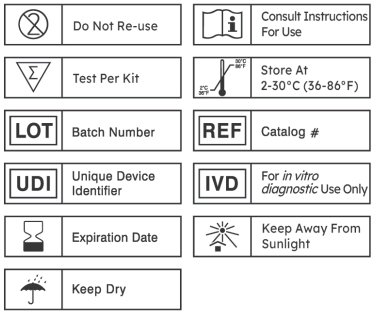
Q: What conditions should the FOB test be stored under?
A: The test device should be stored as packaged in the sealed pouch either at room temperature or refrigerated 2-30°C(36 - 86°F). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch 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



Manufactured For Genabio Diagnostics Inc.

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Rev.01
Effective Date: February 9, 2024

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Additional Information For Laboratory And Physicians Office

Read All The Instructions Before Performing The Test.

Principle Of The Test

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 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 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.

Collection Of Stool From A Toilet Bowl

If Using A Receptacle,

1. 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).

2. Do not contaminate specimen with urine. So please urinate first, if necessary.

3. Have a bowel movement and remove the receptacle with stool out of the toilet bowl.

If Not Using A Receptacle,

1. Do not contaminate specimen with urine. Please urinate first, if necessary.

2. Flush the toilet bowl twice before excreting. If necessary, clean the toilet bowl.

3. Have a bowel movement. Stool that contacts with water or not can be used for following procedures.

Quality Control

A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls should be tested at regular intervals as part of the laboratory quality control process. Users should follow the appropriate local guidelines concerning the running of external quality controls.

It is recommended that a positive Hb control (containing 50 ng/mL) and a negative Hb control (containing “0” ng/mL) be evaluated to perform quality control testing with each new lot, each new shipment, or every 3 months (whichever comes first).

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 report 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 (Hours: 9 AM to 5 PM EST; Mon. - Fri.)

Performance Characteristics

Detection Limit

hHb concentration (ng/mL)	Total	Positive	Negative
0	20	0	20
37.5	20	0	20
50.	20	20	0
62.5	20	20	0
2000	20	20	0

The sensitivity of the device was tested by spiking 100 hemoglobin-free stool samples with varying concentrations (0, 37.5, 50, 62.5 and 2000 ng/mL hHb) of human hemoglobin. The test shows a cut-off of 50 ng/mL hHb and no pro-zone effect was seen up to 2000 ng/mL hHb

Potential Interferences

An interference study was carried out by adding known amounts of potential interfering substances to aqueous fecal samples that contain “0” and 50 ng /mL of human hemoglobin. Substances tested included horseradish peroxidase (20 mg/mL), aqueous extracts of red radish, raw turnip, cauliflower and broccoli, dietary supplements of chloride, fluoride, Vitamin C (ascorbic acid) and iron, and toilet water with and without cleaner and deodorizer.

Potential Cross Reactors

A cross-reactivity study of animal hemoglobin was carried out by spiking negative (0 ng/mL hHb) and positive (50 ng/mL hHb) fecal samples with beef hemoglobin, chicken hemoglobin, fish hemoglobin, horse hemoglobin, goat hemoglobin, pig hemoglobin, rabbit hemoglobin and sheep hemoglobin, respectively, at the concentration of 200 ng/mL.

Reproducibility

Inter-Site

To evaluate reproducibility of the test, 75 hemoglobin-free fecal samples spiked with varying levels (0, 37.5, 50, 62.5, and 2000 ng/mL hHb) of human hemoglobin were tested at 3 medical laboratories with 3 lots of tests and run 5 times for each lot at each site. The results are summarized below:

3 Sites	Total Results	Lot 1	Lot 2	Lot 3
Hb concentrations		P/N	P/N	P/N
0 ng/mL	45	0/15	0/15	0/15
37.5 ng/mL	45	0/15	0/15	0/15
50 ng/mL	45	15/0	15/0	15/0
62.5 ng/mL	45	15/0	15/0	15/0
2, 000 ng/mL	45	15/0	15/0	15/0

Intra-Run

Intra-Run reproducibility was determined by testing 3 lots of test cassettes by spiking 50 hemoglobin-free fecal samples with varying levels (0, 37.5, 50, 62.5, and 2000 ng/mL hHb) of human hemoglobin and run 10 times each. The results are summarized below:

	Total Results	Lot 1	Lot 2	Lot 3
Hb concentrations		P/N	P/N	P/N
0 ng/mL	30	0/10	0/10	0/10
37.5 ng/mL	30	0/10	0/10	0/10
50 ng/mL	30	10/0	10/0	10/0
62.5 ng/mL	30	10/0	10/0	10/0
2, 000 ng/mL	30	10/0	10/0	10/0

Inter-Day

Day to day reproducibility study was carried out by testing cassettes from the same lot with 50 fecal samples spiked with varying levels (0, 37.5, 50, 62.5, and 2000 ng/mL hHb) of human hemoglobin on 3 consecutive days with 10 replicates each day. The results are summarized below:

3 days	Total Results	Lot 1	Lot 2	Lot 3
Hb concentrations		P/N	P/N	P/N
0 ng/mL	30	0/10	0/10	0/10
37.5 ng/mL	30	0/10	0/10	0/10
50 ng/mL	30	10/0	10/0	10/0
62.5 ng/mL	30	10/0	10/0	10/0
2, 000 ng/mL	30	10/0	10/0	10/0

Accuracy

A study was conducted to evaluate the GenaCheck™ Rapid Self-Test Kit for FOB and compare results with a commercially available Fecal Occult Blood Rapid Test at three physician office laboratories by technical personnel, and one medical laboratory by non-technical personnel with diverse educational backgrounds and ages.

Consumer results using the GenaCheck™ Rapid Self-Test Kit for FOB compared to both the professional and predicate test results were evaluated.

Study Of Technical Personnel

In each POL site, 100 human stool extraction samples were spiked with human hemoglobin at the following concentrations: 0, 37.5, 50, 62.5, and 500 ng/mL (20 replicates at each concentration). Results obtained from 3 sites agreed 99.0% with the expected results and 98.0% with results of predicated device.

Study Of Non-Technical Personnel

150 human stool extraction samples were spiked with hHb at the following concentrations: 0, 37.5, 50, 62.5, and 500ng/mL (30 at each concentration). Thirty (30) participants without technical background were enrolled to conduct the study in a medical laboratory. Each participant tested 5 samples (1 at each concentration) with the two FOB devices. Results obtained from lay users agreed 98.7% with the expected results and 98.0% with results of predicated device.

Tests (tester)	Total Evaluated Samples	Correct Results	Discrepant Results	Agreement
GenaCheck™ FOB Test Layuser vs. Expected	150	148	2	98.7%
GenaCheck™ FOB Test Layuser vs. Predicate test	150	147	3	98.0%
GenaCheck™ FOB technicians vs Expected	100	99	1	99.0%
GenaCheck™ FOB technicians vs Expected	100	98	2	98.0%

Results generated by 3 trained technicians with the GenaCheck™ Rapid Self-Test Kit for FOB as compared to the predicate test:

Tests (tester)	Total Evaluated Samples	Correct Results	Discrepant Results	Total Results
GenaCheck™ Rapid Self-Test Kit for FOB	Results	Positive	Negative	
	Positive	59	1	60
	Negative	1	39	40
Total Results		60	40	100

Percent Positive Agreement = 59/60 = 98.3% (95% C.I. = 91.1% - 100%) Percent Negative Agreement = 39/40 = 97.5% (95% C.I. = 86.8% – 99.9%) Overall Agreement = 98/100= 98.0% (95% C.I. = 93.0% - 99.8%)

Lay User Study

An additional U.S. study was performed with 20 lay users from a general population at each of 3 sites and were asked to participate in the OTC and comparison studies. All the lay users were at ages of 50 plus yrs old, and their educational and ethnic background were recorded. In this study, all the lay users conducted the test with GenaCheck™ Rapid Self-Test Kit for FOB and the predicate devices, using their own specimens that were collected in the wash rooms at the sites by each lay user.

After the lay user testing, the specimens were sent to professionals to test with GenaCheck™ Rapid Self-Test Kit for FOB and predicate devices for comparison. The professionals were blinded by masking the stool sample receptacles before being sent to them. The results of the testing performed by the lay users with their own specimen and the professional testing are shown below.

Part 1: Study With Users' Own Specimen

		Predicate test		Total Results
GenaCheck™ Rapid Self-Test Kit for FOB		Positive	Negative	
	Positive	5	1	6
	Negative	2	52	54
Total Results		7	53	60

Percent Positive Agreement= 2/7= 71.4% (95% C.I. =38 % - 94%) Percent Negative Agreement= 1/53= 98.1 % (95% C.I. = 91 % - 100%) Overall Agreement= 57/60= 95.0% (95% C.I. = 88% - 97%)

		Predicate test		Total Results
GenaCheck™ Rapid Self-Test Kit for FOB		Positive	Negative	
	Positive	6	0	6
	Negative	1	53	54
Total Results		7	53	60

Percent Positive Agreement= 6/7 = 85.7% (95% C.I. =50% - 99%) Percent Negative Agreement =0/53 = 100% (95% C.I. = 94% - 100%) Overall Agreement= 59/60= 98.3% (95% C.I. = 91% -100%)

Part 2: Study With Prepared Specimens

A study was performed to evaluate the ability of a lay user to interpret results at concentrations around the cutoff and obtain interpretation equivalent to the predicate test. A series of, negative human stool samples were spiked with human hemoglobin (hHb) at the following concentrations: 0, 37.5, 50, 62.5, and 500 ng/mL and tested by the lay users with both devices.

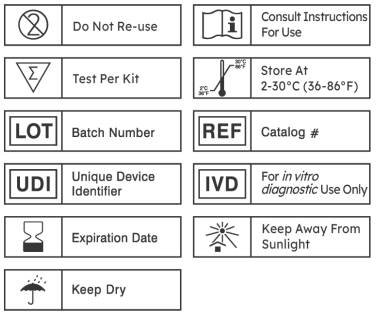
Specimens at each concentration were divided into 12 containers (60 total), and each lay user.picked one randomly and tested it with GenaCheck™ Rapid Self-Test Kit for FOB and the predicate device.

The lay users were blinded by masking the stool sample receptacles before being sent to them for testing. The results of the lay user testing using pre-pared specimens of known concentrations is shown below.

		Predicate test		Total Results
GenaCheck™ Rapid Self-Test Kit for FOB		Positive	Negative	
	Positive	33	0	35
	Negative	2	23	25
Total Results		35	25	60

Percent Positive Agreement= 33/35 = 94.3% (95% C.I. = 82% - 98%) Percent Negative Agreement= 23/25 = 92% (95% C.I. = 80% - 98%) Overall Agreement= 56/60= 93.3% (95% C.I. = 84% - 97%)

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.

CONTACT US

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