Rapid Response™

FIT – Fecal Immunochemical Test
(Feces)
REF FOB-9V30 Product Insert

Intended Use

The Rapid Response™ FIT – Fecal Immunochemical Test 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 physicians' offices as well as for Over-The-Counter use.

Summary and Explanation

Gastrointestinal diseases may cause occult (hidden) blood in stool. 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 method lacks sensitivity and specificity to test for fecal occult blood and has diet-restriction prior to the testing.
The Rapid Response™ FIT – Fecal Immunochemical Test is a rapid test to qualitatively detect low levels of fecal occult blood in feces. The test uses double antibody sandwich assay to selectively detect as low as 50 ng/mL of hemoglobin or 6 µG hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

Principle of the Test

The Rapid Response™ FIT – Fecal Immunochemical Test 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 be added and membrane wicking has occurred.

Warnings and Precautions

1. This test is designed for *in vitro diagnostic* use.
2. Read instructions carefully before using this test.
3. 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.
4. Do not use it if the tube/pouch is damaged or broken.
5. Test is for single use only. Do not re-use under any circumstances.
6. Do not use the test device or collection tube beyond the expiration date.
7. Do not use the kit if the pouch is punctured or is not well sealed.
8. Keep out of the reach of children.
9. Fecal specimens may be infectious; ensure proper handling and discard all used devices according to the local regulations.

Storage and Handling

- Store at 36˚F to 86˚F (2-30˚C) in the sealed pouch up to the expiration date.
- If stored at 36˚F to 46˚F (2-8˚C), 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 to temperatures over 86˚F (30˚C).

Materials Supplied

Materials provided

- Individual pouches
- Specimen collection tubes with extraction buffer
- Instruction for Use

Materials required but not provided

- Timer
- Collection Container

Collection of Stool From a Toilet Bowl

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. 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 has or has not come in contact with water can be used for the following procedure.

Collection and Storage of Specimens

1. Unscrew the green cap 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 green cap securely.
4. Shake the tube with the 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 or pen.

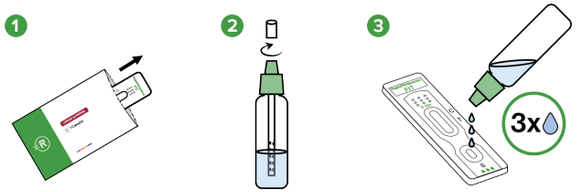
Fig. 1: Specimen collection Steps 1 and 2

Fig. 2: Specimen collection Steps 3 and 4

6. 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.
7. Specimen may be collected from a toilet bowl with or without contact to flushing water, or from a receptacle that has not come in contact with water.
8. 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.
9. Dietary restrictions are not necessary.
10. The sample can be stored at room temperature 46˚F to 86˚F (8-30˚C) up to 24 hours or in a refrigerator 36˚F to 46˚F (2-8˚C) for up to 72 hours.

Test Procedure

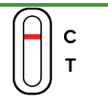
Bring all materials and specimens to room temperature 46˚F to 86˚F (8-30˚C).



1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible. (See illustration 1).
2. Holding the sample collection device upright, carefully unscrew the small white cap of collection device. (See illustration 2).
3. Squeeze 3 drops (~75 uL) of the sample solution in the sample well of the cassette, as in the illustration. (See illustration 3).
4. 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.

Interpretation of the Results

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



NEGATIVE: One red line appears in the control line region I. No line appears in the test line region (T).

INVALID: Control line fails to appear.

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

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 appears, 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 1-888-339-9964.

Limitations

1. 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.
2. This test is limited to the detection of fecal occult blood in human stool sample only.
3. 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 disease is present.

Expected Results

Negative results are expected in healthy women and healthy men. The Rapid Response™ FIT- Fecal Immunochemical Test has a sensitivity of 50 ng hHb/mL of buffer solution.

Performance Characteristics

Detection Limit

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 hHb/ml) of human hemoglobin. The test shows a cut-off of 50 ng hHb/mL, and no pro-zone effect was seen up to 2000 ng hHb/ml. Result are summarized below:

hHb concentration (ng/mL)	Total	Positive	Negative
0	20	0	20
37.5	20	0	20
50.0	20	20	0
62.5	20	20	0
2000	20	20	0

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:

Analyte	Concentration	Rapid Response™ FIT Test Result	
		0ng/mL	50ng/mL
Acetoaminophen	25 mg/dL	-	+
Acetoaceto Acid	2000 mg/dL	-	+
Ascorbic Acid	20 mg/dL	-	+
B-hydroxybutyrate	2000 mg/dL	-	+
Caffeine	20 mg/dL	-	+
Ephedrine	20 mg/dL	-	+

Gentisic Acid	20 mg/dL	-	+
Phenylpropanolamine	20 mg/dL	-	+
Salicylic Acid*	20 mg/dL	-	+
Phenothiazine	20 mg/dL	-	+
EDTA	20 mg/DL	-	+
Acetosalicylic Acid	20 mg/dL	-	+
Cannabinol	10 mg/dL	-	+
Codeine	10 mg/dL	-	+
Ethanol	1.0 %	-	+
Methanol	10 %	-	+
Albumin	2000 mg/dL	-	+
Glucose	2000 mg/dL	-	+
Bilirubin	1000 mg/dL	-	+
Hemoglobin	2000 mg/dL	-	+

Interfering substances	Rapid Response™ FIT Test Result	
	0ng/mL	50ng/mL
Horseradish peroxidase (20 mg/mL)	-	+
Extract of red radish	-	+
Extract of raw turnip	-	+
Extract of cauliflower	-	+
Extract of broccoli	-	+
Dietary supplements with chloride, fluoride, and iron	-	+
Dietary supplements with Vitamin C	-	+
Toilet water with cleaner and deodorizer	-	+
Toilet water without cleaner and deodorizer	-	+

Potential Cross Reactors

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

Hemoglobin Type (200 ng/mL)	Rapid Response™ FIT Test Result	
	0ng	50ng
Beef hemoglobin	-	+
Chicken hemoglobin	-	+
Fish hemoglobin	-	+
Horse hemoglobin	-	+
Goat hemoglobin	-	+
Pig hemoglobin	-	+
Rabbit hemoglobin	-	+
Sheep hemoglobin	-	+

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 hHg/mL) 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
2000 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 hHg/mL) 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
2000 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 hHg/mL) 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
2000 ng/mL	30	10 / 0	10 / 0	10 / 0

Accuracy

A study was conducted to evaluate the Rapid Response™ FIT – Fecal Immunochemical Test and compare results with a commercially available Fecal Occult Blood Rapid Test at three physician office laboratories by technical personnel, and on medical laboratory by non-technical personnel with diverse educational backgrounds and ages. Consumer results using the Rapid Response™ FIT – Fecal Immunochemical Test 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 500 ng/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.

Tests (testers)	Total Evaluated Samples	Correct Results	Discrepant Results	Agreement
Rapid Response™ FIT Test Lay user vs. Expected	150	148	2	**98.7%**
Rapid Response™ FIT Test Lay user vs. Predicate Test	150	147	3	**98.0%**
Rapid Response™ FIT Test technicians vs Expected	100	99	1	**99.0%**
Rapid Response™ FIT Test technicians vs Predicate test	100	98	2	**98.0%**

Results generated by 3 trained technicians with the Rapid Response™ FIT – Fecal Immunochemical Test as compared to the predicate test:

		Predicate Test		Total Results
Rapid Response™ FIT	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%)

Part 1: Study with Stool Specimen

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 years old, and their educational and ethnical background were recorded. In this study, all the lay users conducted the test with Rapid Response™ FIT – Fecal Immunochemical Test and the predicate devices, using their own specimens that were collected in the washrooms at the sites by each lay user.

		Predicate Test		Total Results
Rapid Response™ FIT Test		Positive	Negative	
	Positive	5	1	6
	Negative	2	52	54
Total Results		7	53	60

Percent Positive Agreement = 5/7 = 71.4%
(95% C.I. = 38%-94%)
Percent Negative Agreement = 52/53 = 98.1%
(95% C.I. = 91%-100%)
Overall Agreement = 57/60 = 95.0% (95% C.I. = 88%-97%)

Professional Study

After the lay user testing, the specimens were sent to professionals to test with Rapid Response™ Fecal Immunochemical Test – FIT 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:

		Professional Test		Total Results
Rapid Response™ FIT Test		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 = 53/53 = 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 Rapid Response™ FIT – Fecal Immunochemical Test 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 prepared specimens of known concentrations is shown below:

		Predicate Test		Total Results
Rapid Response™ FIT Test		Positive	Negative	
	Positive	33	2	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%)

References

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

Manufacture Information

Company: BTNX Inc.
Address: 722 Rosebank Road, Pickering, ON L1W 4B2, Canada

Tel: +1-905-944-9565
Fax: +1-905-944-0406
Website: www.btnx.com

Technical Support: 1-888-339-9964
(Hours: 9 AM to 5:30 PM Eastern Time; Mon.–Fri.)

Glossary of Symbols

Consult instructions for use
Test per Kit
EC REP Authorized Representative
Store between 36°F to 86°F (2°C to 30°C)
Use by
Do Not Reuse
LOT Lot Number
IVD For *in vitro* diagnostic use only
REF Catalogue #

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

BTNX Inc.
722 Rosebank Road,
Pickering, ON, L1W 4B2
Canada
Technical Support: 1-888-339-9964
Hours: Monday–Friday, 9am–5:30pm (EST)

CLIA WAIVED

Quick Reference Instructions

Rapid Response™ FIT – Fecal Immunochemical Test
(Feces)
REF FOB-9V30

Intended Use

The Rapid Response™ FIT – Fecal Immunochemical Test 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 OTC use.

Principle

The Rapid Response™ FIT – Fecal Immunochemical Test 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.

What's In The Kit

- Individual pouches
- Specimen collection tubes with extraction buffer
- Instruction for Use

What Will You Need

- You will need a clock or timer
- Specimen collection containers

Storage and Stability

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

Precaution

- 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 plumping 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 smudge 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 1-888-339-9964.

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 has or has not come in contact with water can be used for the following procedure.

Collection of Specimen For Testing

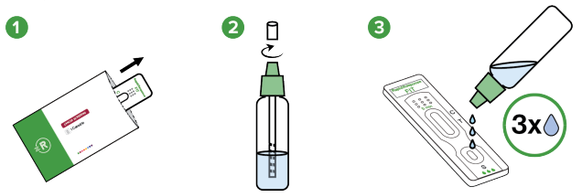
Fig. 1: Specimen collection Steps 1 and 2

Fig. 2: Specimen collection Steps 3 and 4

1. Unscrew the green cap 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 green cap securely.
4. Shake the tube with the 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 or pen.
6. 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.
7. Specimen may be collected from a toilet bowl with or without contact to water, or from a receptacle that has not come in contact with water.
8. 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.
9. Dietary restrictions are not necessary.
10. The stool sample can be stored at room temperature up to 24 hours or in a refrigerator for up to 72 hours.

Test Procedure

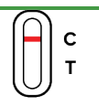
Bring all materials and specimens to room temperature 46°F - 86°F (8-30°C).



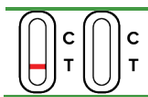
1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible. (See illustration 1).
2. Holding the sample collection device upright, carefully unscrew the small white cap of collection device. (See illustration 2).
3. Squeeze 3 drops (~75 µL) of the fecal sample solution in the sample well of the cassette, as in the illustration. (See illustration 3).
4. 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.

Interpretation of Results

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



NEGATIVE: One red line appears in the control line region I. No line appears in the test line region (T).



INVALID: Control line fails to appear.

NOTE: If the test line is weak, it is recommended that the test be repeated in 48 hours.
If the second test does not show lines, please contact Technical Services at 1-888-339-9964 (hours: 8 AM to 5 PM Eastern Time; Mon. - Fri.).

Limits of the Test

1. 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.
2. This test is limited to the detection of fecal occult blood in human stool sample only.
3. Although the test is highly accurate in detecting human hemoglobin, a low incidence of false positive results may occur. In addition, because many bowel 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 disease is present.

Questions and Answer

1. **Q: What sample can be used with this test?**
   A: The Rapid Response™ FIT – Fecal Immunochemical 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 FIT test.
2. **Q: How do I know that the FIT 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 at 1-888-339-9964 (hours: 9 AM to 5:30 PM Eastern Time; Mon.–Fri.)
3. **Q: What conditions should the FIT test be stored under?**
   A: The test device should be stored as packaged in the sealed pouch either at room temperature or refrigerated 36° - 86°F (2-30°C). 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.
4. **Q: How sensitive is the test?**
   A: The Rapid Response™ FIT – Fecal Immunochemical Test detects hemoglobin in feces at a concentration of 50 ng hHb/mL or greater. The addition of other animal hemoglobins showed no cross-reactivity.
5. **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.
6. **Q: How accurate is this test?**
   A: The Rapid Response™ FIT – Fecal Immunochemical 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 rest results may be negative even when disease is present. Please discuss the results of a positive test with your doctor.

Discarding the Kit

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

Manufacture Information

Company: BTNX Inc.
Address: 722 Rosebank Road, Pickering, ON L1W 4B2, Canada

Tel: +1-905-944-9565
Fax: +1-905-944-0406
Website: www.btnx.com

Technical Support: 1-888-339-9964
(Hours: 9 AM to 5:30 PM Eastern Time; Mon.–Fri.)

Glossary of Symbols

Consult instructions for use	Test per Kit	Authorized Representative
Store between 36°F to 86°F (2°C to 30°C)	Use by	Do Not Reuse
Lot Number	For *in vitro* diagnostic use only	Catalogue #

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

CE

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722 Rosebank Road,
Pickering, ON, L1W 4B2
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