

## Rapid Response™

### Fecal Immunochemical Test

#### Instructions for Use

Familiarize yourself with this test and read the Instructions For Use carefully before testing.

#### Intended Use

The Rapid Response™ 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 Over-The-Counter use.

#### Precautions

- This test is designed for *in vitro* diagnostic use.
- Read the Instructions for use carefully before using this test.
- Warning: the reagents in this kit contain sodium azides 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 if the tube or pouch is damaged or broken.
- The 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.
- If the pouch is punctured or not sealed properly, do not use the kit.
- Keep out of reach of children.
- Fecal specimens may be infectious; ensure proper handling and discard all used devices according to the local regulations.

#### Storage and Stability

- Store at 35-86°F (2-30°C) in the sealed pouch up to the expiration date.
- If stored at refrigerated temperatures 35-46°F (2°-8°C), ensure that the test device is brought to room temperature 77°F (25°C), before opening.
- Keep away from sunlight, moisture, and heat.
- DO NOT FREEZE** [32°F (0°C)]. the kit or expose the kit to temperatures over 86°F (30°C).

#### Collection of Stools from a Toilet Bowl

If using a receptacle,

- Prepare a dry and clean receptacle that can be conveniently placed into and removed from the toilet bowl (above the water surface). Do not use toilet paper (toilet paper may contain substances which are inhibitory for some fecal specimens).
- Do not contaminate the stool with urine. Urinate first if necessary.
- Have a bowel movement and remove the receptacle with the stool from the toilet bowl.

If not using a receptacle,

- Do not contaminate the stool with urine. 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.

#### Limitations

- 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 cancer, 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 Answers

##### 1. What sample can be used with the test?

The Rapid Response 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 medication 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.

##### 2. How do I know that the FOB test has been run correctly?

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 EST Mon. - Fri.).

##### 3. What condition should the FOB test be stored under?

The test device should be stored as packaged in the sealed pouch either at room temperature or refrigerated 35°- 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. How sensitive is the test?

The FOB Test detects hemoglobin in feces at a concentration of 50ng hHb/mL or greater. The addition of other animal hemoglobins showed no cross-reactivity.

##### 5. What is the recommended collection procedure for the fecal specimens?

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. How accurate is this test?

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 rest results may be negative even when disease is present. Please discuss the results of a positive test with your doctor.

#### Discarding The Kit

Once you know your test result, put all the items back into the original box and throw it away with your regular household waste.

#### Glossary of Symbols

|   |   |  |
|---|---|--|
|  Consult instructions for use             |  Test per Kit             |  Catalogue number          |
|  Store between 35-86°F (2-30°C)          |  Expiration Date         |  Do Not Reuse             |
|  For <i>In vitro</i> diagnostic use only |  Lot Number              |  Unique Device Identifier |
|  Keep Dry                                |  Keep Away from Sunlight |  |

#### Assistance

If you have any questions regarding the use of this product, please call Technical Support at 1-888-339-9964 (9:00 a.m. to 5:30 p.m. EST).

##### Manufactured For:

**BTNX, Inc.**

722 Rosebank Road

Pickering, ON L1W 4B2 Canada

Technical Support: 1-888-339-9964 Fax: +1-905-944-0406

Website: www.btnx.com

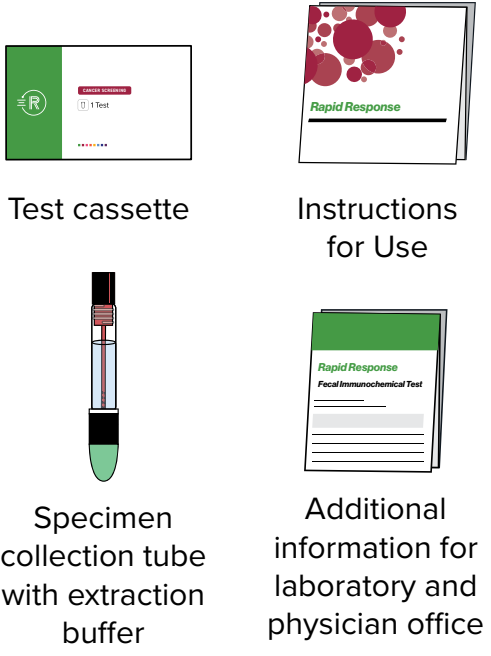


**Fecal Immunochemical Test**

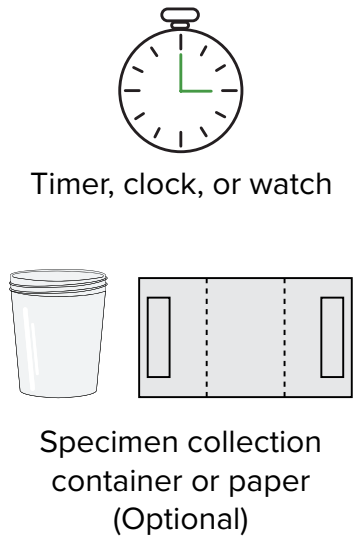
Bring all materials and specimens to room temperature 46°F - 86°F (8 - 30°C).

**Materials**

**Materials Provided**

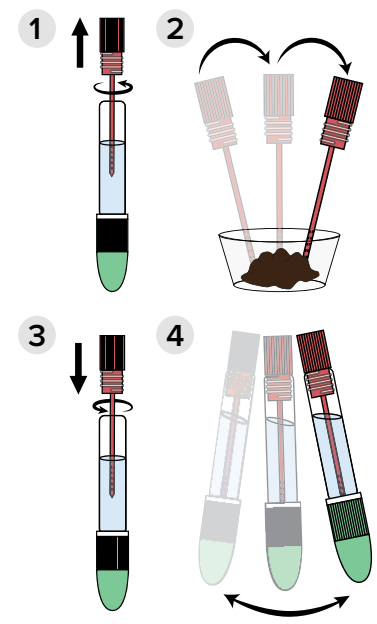


**Materials Required but Not Provided**



**Collection For Testing**

1. Unscrew the bottom cap (red end) of the collection tube and remove the applicator stick.
2. Insert the stick into the stool specimen at 6 different sites.
3. Insert the sampled applicator back into the tube and tighten the bottom (red 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 (red end) vigorously for about 5 seconds to release and disperse the stool sample into the collection buffer.



5. If necessary, write identifying information on the collection tube with a marker pen.

**NOTE:**

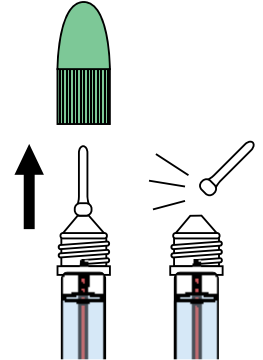
- Specimen should not be collected during or within three days of menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
- The specimen may be collected from a stool in a toilet bowl with or without contact to water, or stool from a receptacle before going into the 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 up to 24 hours or in a refrigerator for up to 72 hours.

**Testing Procedure**

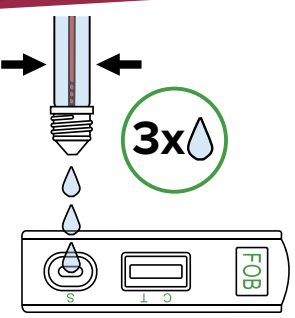
1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.



2. Holding the sample collection device upright, carefully break off the tip of the collection device.



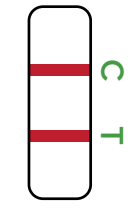
3. Squeeze 3 drops of the stool sample solution into the sample well of the cassette, as in the illustration.



4. Read the test result between 5-10 minutes. A test result read earlier than 5 minutes and later than 10 minutes is not valid. Before reading results, place the device on a clear and single-colored background.



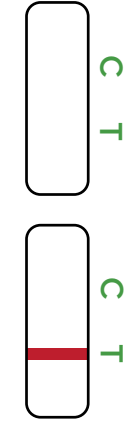
**Reading the Results**



**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).



**NEGATIVE:** One red line appears in the control line region (C). No line appears 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.

**Assistance**

If you have questions, reach out to our Technical Support:

Email: support@btnx.com

Tel: 1-888-339-9964

Hours: Monday-Friday 9:00AM-5:30PM EST.

BTNX Inc.

Email: support@btnx.com

Technical Service: +1-888-339-9964

Fax: +1-905-944-0406

www.btnx.com

