

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 as an aid in the diagnosis of gastrointestinal disorders. 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 harmful chemicals which may react with lead or copper plumbing. When disposing of such reagents, always flush with large volumes of water.
- 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.
- If the test does not show any Control or Test line in the window, or if the line looks messy or incomplete, discard the test. Repeat the test again with a new cassette, following the instructions carefully. If the second test also doesn't show any lines, call Technical Support at 1-(888) 339-9964 between 9:00 a.m. and 5:30 p.m. EST for help.

Storage and Stability

1. Store at 36-86°F (2-30°C) in the sealed pouch up to the expiration date.
2. If stored at refrigerated temperatures 36-46°F (2°-8°C), ensure that the test device is brought to room temperature 77°F (25°C), before opening.
3. Keep away from sunlight, moisture, and heat.
4. **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,

1. 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.
2. Do not contaminate the stool with urine. Urinate first if necessary.
3. Have a bowel movement and remove the receptacle with the stool from the toilet bowl.

If not using a receptacle,

1. Do not contaminate the stool with urine. 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 water may be used.

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. Although the test is accurate, a low rate of false negative results may occur. Many bowel lesions only bleed sometimes or not at all. This means the distribution of blood may not be even in your fecal sample. Therefore, test results may be negative even when the disease is present.
3. Some substances such as aspirin, alcohol, and some medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.
4. This test is limited to the detection of fecal occult blood in human stool sample only.

Questions and Answers

1. How does the Rapid Response™ Fecal Immunochemical Test work?

The test uses antibodies to detect small amounts of hemoglobin (between 50 and 2000ng hHb /mL) in human fecal samples. The antibodies in the test bind with hemoglobin, which provides a result that is visible.

2. What does a positive result mean?

The test detected blood in your fecal sample. Positive results for fecal occult blood suggest that you may have a gastrointestinal disease. You may not experience symptoms during the early stages of gastrointestinal disease, but invisible blood may be found in your fecal sample.

If you have received a positive result, please consult with your physician as soon as possible.

3. What does a negative result mean?

The test did not detect blood in your fecal sample. Rarely, the test may provide a negative result that is incorrect. This could be because the blood is not distributed evenly in your fecal sample even when the disease is present.

4. What does an invalid result mean?

The test was not able to provide a result - even if the test line (T) shows up. You should repeat the "Test Procedure" with a new test device using the same sample. Remember that a red line should always appear in the control line region (C) between 5 to 10 minutes. This confirms that there was enough volume of specimen added, and that you used the correct technique.

If the second test does not show the control line, refer to the Assistance section below for Technical Support.

5. When is the best time to take the test?

The test can be used with samples collected at any time of the day. You do not have to follow strict dietary or medication restrictions. No fasting is needed to take this test.

6. Is this test reliable?

A study was completed where 98.7% of individuals were able to follow the test instructions and get a correct result.












7. Is the collection tube meant to have liquid in it?

Yes, the liquid in the tube is a buffer solution. The solution aids in the analysis of your sample.

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 36-86°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.

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Pickering, ON L1W 4B2 Canada
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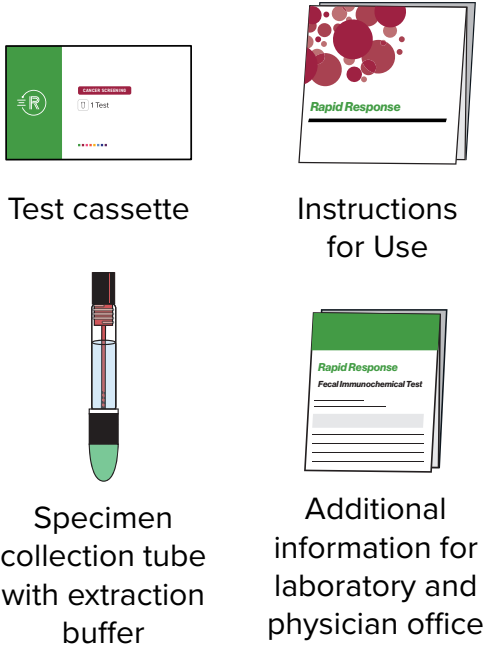


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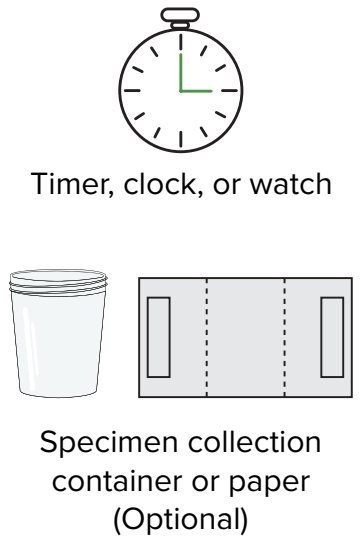
Bring all materials and specimens to room temperature 46°F - 86°F (8 - 30°C).

Materials

Materials Provided

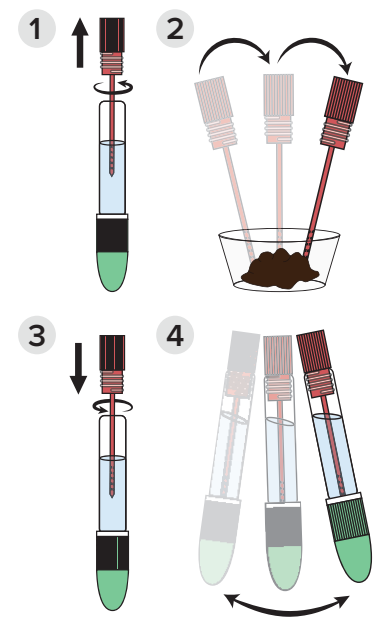


Materials Required but Not Provided



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:

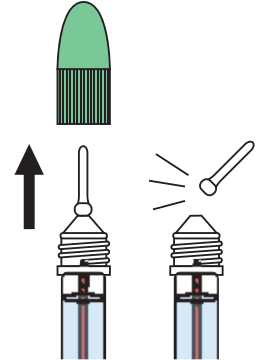
- Specimen should not be collected during or within three days of menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
- The specimen may be collected from a stool in a toilet bowl with or without contact to water, or stool from a receptacle before going into the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

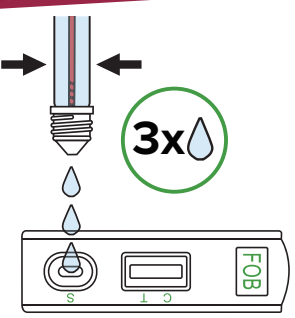
1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.



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



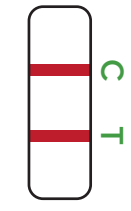
3. Squeeze 3 drops of the stool sample solution into the sample well of the cassette, as in the illustration.



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.



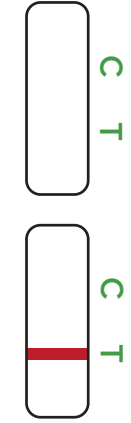
Reading the Results



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.

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