

# INDICAID™

## iFOB IMMUNOCHEMICAL FECAL OCCULT BLOOD RAPID TEST RX

Catalogue No. See Box label

### INTENDED USE

INDICAID™ iFOB Immunochemical Fecal Occult Blood Rapid Test Rx is a rapid test for the qualitative detection of human occult blood in feces. It is used as an aid in the diagnosis of gastrointestinal (GI) bleeding. The device is suitable for use in laboratories and physician's offices.

For *in vitro* diagnostic use only. It is intended for prescription use only.

### SUMMARY

FOB (Fecal Occult Blood) is the trace amount of blood in feces. It cannot be seen with eyes. It could be the early clinical symptom of the common malignant tumor, gastric cancer, colonic cancer, or enteron ulcer. 95% of enteron cancer patients are positive in OBT (Occult Blood Test). About 50-80% of enteron ulcer patients could be positive in OBT. An early detection of FOB is vital in life saving for it can be check up out in the early stage of the diseases.

### PRINCIPLE

The INDICAID™ iFOB Immunochemical Fecal Occult Blood Rapid Test Rx is a double antibody sandwich immunoassay. It is used for the detection of hemoglobin (Hb) in fecal samples. The result is very specific and easier to read than guaiac tests. It is able to detect 50 ng/ml Hb in feces.

When the sample is dropped into the test cassette, capillary action carries the sample along the membrane. When Hb in the sample reaches the Test Zone of the membrane, it will form a colored line. Absence of this colored line suggests a negative result.

To serve as a procedure control, a colored line will appear in the Control Zone, if the test has been performed properly.

### WARNINGS AND PRECAUTIONS

1. This kit is for external only. Do not swallow.
2. Do not interchange materials from different product lots.
3. All specimens should be treated as potentially infectious materials. Protective gloves should be worn when handling the specimen.
4. Do not use test kit beyond the expiration date.
5. Do not use the kit if the pouch is punctured or not well sealed.
6. Discard after first use. The test device cannot be used more than once.
7. Keep out of the reach of children.
8. Do not eat, drink or smoke in the area where the specimens and kits are handled.
9. DISPOSAL OF THE DIAGNOSTIC: The used device, container and collection tube have infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory rule.

### CONTENT OF THE KIT

#### Material Provided

1. Test devices, one test in one pouch. One pouch contains a test cassette and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Collection tubes with 1.5 mL extraction buffer solution.
3. Flushable collection papers
4. Instructions for use
5. Procedure card

#### Material Not Provided

1. External quality control materials
2. Timer (watch or clock)

### STORAGE AND STABILITY

1. Store at 39°F-86°F (4°C-30°C) in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. DO NOT FREEZE.
4. The Test Device should be used within 1 hour once opened.

### SPECIMEN COLLECTION AND PREPARATION

#### Subject preparation

1. Do not collect stool samples during the menstrual period of the patient (wait until three days after the bleeding has stopped), or while the patient has bleeding hemorrhoids or blood in urine. Hands and test area should be kept clean and free from blood to avoid false positive results.
2. Avoid the following drugs for the 7 days before the test—they can make it look like he/she has hidden blood when he/she don't: Aspirin or other non-steroidal anti-inflammatory medications (Ibuprofen, Naproxen, Indomethacin and Phenylbutazone).

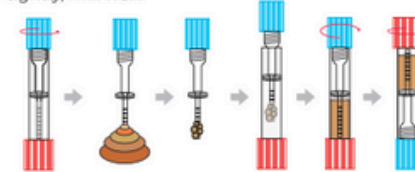
#### Specimen collection

**Note:** Contamination from toilet water and urine should be avoided.

1. Prior to excreting, urinate first if possible. Flush the toilet bowl twice. If necessary, clean the toilet bowl.
2. Take out the collection paper. Peel off tape cover of the collection paper.
3. Place the collection paper across the toilet bowl. Allow the paper to sag just above water. Press the tape down on each side of the toilet bowl.
4. Make bowel movement on the collection paper. If need to urinate, then shift body forward on the toilet seat so as to avoid urinating on the paper.



5. Collect stool sample by using the sample collection tube. Unscrew the smaller cap of the collection tube. Take out the sampling stick.
6. Poke the sampling stick into stool sample in 6 different places. Use only enough fecal material to cover the ridged end of the sampling stick.
7. Put the sampling stick back into the sample collection tube and screw tightly, mix well.

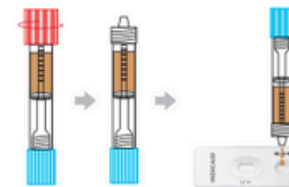


**Note:** It is recommended test should be performed immediately after the specimens have been collected. Specimens may be stored at 36°F-46°F (2°C-8°C) for up to 30 days. For long-term storage, specimens should be kept below -4°F (-20°C). The test sample must be returned or mail to the doctor/laboratory within 48h if being test by POC.

### TEST PROCEDURE

Test must be at room temperature 50°F-86°F (10°C-30°C).

1. Remove the test device from the sealed foil pouch by tearing at the notch and place it on a level surface.
2. Shake sample well to mix. Hold the collection tube upright and make sure the bigger, red cap is facing upwards. Carefully unscrew the bigger, red cap of the collection tube.
3. Squeeze 3 drops of sample solution to the sample well, as in the illustration.
4. Read the test results at 10 minutes. Some positive results may be seen earlier. **Do not read results after 30 minutes.**



### READING THE RESULTS

#### Positive (+)

Rose-pink lines are visible in both the control region and the test region. It indicates a positive result for Hb.

#### Negative (-)

A rose-pink line is visible in the control region. No color line appears in the test region. It indicates that the concentration of the Hb is zero or below the detection limit of the test.

#### Invalid

If a colored line is not visible in a control region, the test is invalid. Another test should be run to re-evaluate the sample. Please contact the distributor with the lot number.



**Note:** Any shade of rose-pink line is acceptable. The intensity and width of the lines do not matter.

#### LIMITATIONS

1. This test is for testing human fecal samples only. The performance of this test using other samples has not been validated.
2. This test has not been validated for testing of samples with heterophil antibody, as well as patients with hemoglobinopathies. Hemoglobinopathies is the medical term for a group of blood disorders and disease that affect red blood cells.
3. A positive result means that the test has detected blood. There are many GI conditions that may cause blood in stool. False positive results may also be caused by diet and medications. Further examinations should be performed by a physician to determine the exact cause and source of the occult blood in the stool.
4. If the test result is negative, the patient could still have bowel condition that you should know about. Another sample should be tested again in a year. This is necessary because if the patient has polyps, they may not bleed all the time. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
5. If a suspicious result is obtained, it is recommended to re-test the specimen with another test.
6. The Immunochemical Fecal Occult Blood Test may be used to check for lower GI bleeding. However, it is never used to diagnose this condition. The test does not replace the patient's regular physical or rectal examination by a doctor.
7. This device has not been validated for testing loose stool sample.

#### ASSISTANCE

If you have any question regarding to the use of this product, please call our Technical Support Number 1-877-934-9344 (8:00 a.m. to 6:00 p.m. PST M-F)

#### QUALITY CONTROL

**Internal Control:** The Procedural Control is found in the procedural control region of the test cassette to assure the operator that the test has been properly performed. This control does not ensure that the capture antibody is accurately detecting the presence or absence of Hb in the sample.

**External controls:** External controls are used to assure the operator that the capture and conjugated antibodies are present and reactive. Controls should be assayed according to manufacturer instructions once per kit lot, following the local and state guidelines. If controls do not perform as expected, the test results should not be used.

FOBT-Check positive and negative controls are recommended. Call the customer service if you have any question: 1-877-934-9344.

#### PERFORMANCE CHARACTERISTICS

**Sensitivity:** The sensitivity of the test device is 50ng hHb/mL of buffer.

**Repeatability:** Repeatability of the test device was evaluated in house by testing 7 levels of spiked stool samples. The overall percent agreement was 99.3%, positive percent agreement was 100% (96.2%-100%), and negative percent agreement was 98.1% (89.9-99.7%).

**Reproducibility:** This study was performed at three POC sites by testing 7 levels of spiked stool samples. The Overall Percent Agreement was 99.1%, Positive Percent Agreement was 99.2% (98.6%-99.6%), Negative Percent Agreement was 99.0% (98.0%-99.5%).

**Accuracy:** The INDICAID™ iFOB Immunochemical Fecal Occult Blood Rapid Test Rx was evaluated in comparison to a commercially available predicate device at three POC sites. The results are given below.

Study Site	New Test FOB Test	Predicate Test		
		FOB One Step Rapid Test		
		Positive #	Negative #	Total #
Site DH	Positive #	35	0	35
	Negative #	0	101	101
	Total #	35	101	136
Site DS	Positive #	45	0	45
	Negative #	1	101	102
	Total #	46	101	147
SiteDT	Positive #	52	1	53
	Negative #	0	189	189
	Total #	52	190	242
Combined Sites	Positive #	132	1	133
	Negative #	1	391	392
	Total #	133	392	525

The overall agreement rate between INDICAID™ iFOB Immunochemical Fecal Occult Blood Rapid Test Rx and predicate device was 99.6%, with positive agreement rate of 99.2% (95.9%-99.9%) and negative agreement rate of 99.7% (98.6%-100%).

**Prozone effect:** There is no prozone effect with the test, when the hHb level is no more than 200, 000 ng /mL(0.2 mg/mL).

**Specificity:** The INDICAID™ iFOB Immunochemical Fecal Occult Blood Rapid Test Rx equivalently detected variants of hemoglobin (HbA, HbS and HbC).

The following substances, when spiked in both positive and negative specimens, did not interfere with the test results.



SUBSTANCES	CONCENTRATIONS
Beef Hemoglobin	500 µg/ml
Chicken Hemoglobin	500 µg/ml
Fish hemoglobin	500 µg/ml
Horse hemoglobin	500 µg/ml
Goat hemoglobin	500 µg/ml
Pig hemoglobin	500 µg/ml
Rabbit hemoglobin	500 µg/ml
Sheep hemoglobin	500 µg/ml
Beef	Meat extract
Chicken	Meat extract
Fish	Meat extract
Horse	Meat extract
Goat	Meat extract
Pig	Meat extract
Rabbit	Meat extract
Sheep	Meat extract
Red radish	Aqueous extract
Raw turnip	Aqueous extract
Cauliflower	Aqueous extract
Broccoli	Aqueous extract

Parsnip	Aqueous extract
Cantaloupe	Aqueous extract
Horseradish	Aqueous extract
Vitamin C (ascorbic acid)	250 µg /ml
Horseradish peroxidase	20000 µg/ml
Iron (FeCl3·6H2O)	2.0 mg/ml

#### BIBLIOGRAPHY OF SUGGESTED READING

1. Michael Pignone, Marci Kramish Campell, Christopher Phillips, Meta-analysis of Dietary Restriction during Immunochemical Fecal Occult Blood Testing. Effective Clinical Practice July/August 2001 Volume 4 Number 4
2. Robert H. Fletcher, Diet for Immunochemical Fecal Occult Blood Test Screening: Help or Harm? Effective Clinical Practice July/August 2001 Volume 4 Number 4
3. Shlomo Vinker, Sasson Nakar, Elliot Rosenberg, Eliezer Kitai, The Role of Family Physicians in Increasing Annual Immunochemical Fecal Occult Blood Test Screening Coverage: A Prospective Intervention Study. IMAJ. Vol 4. June 2002
4. Sara H. Mitchell, David C. Schaefer, Srinivasan Dubagunta, A New View of Occult and Obscure Gastrointestinal Bleeding, AMERICAN FAMILY PHYSICIAN, FEBRUARY 15, 2004 / VOLUME 69, NUMBER 4
5. David H. Stockwell, Paula Woo, Brian C. Jacobson, Renee Remily, Sapna Syngal, Jacqueline Wolf, Francis A. Farraye, Determinants of Colorectal Cancer Screening in Women Undergoing Mammography, THE AMERICAN JOURNAL OF GASTROENTEROLOGY Vol. 98, No. 8, 2003
6. Technology Evaluation Center, Immunochemical versus Guaiac Immunochemical Fecal Occult Blood Tests, Assessment Program Volume 19, No. July 2004
7. Mike Corbett, Sharon L. Chambers, Bruce Shadbolt, Lybus C Hillman and Doug Taupin. Colonoscopy screening for colorectal cancer: the outcomes of two recruitment methods. MJA 2004; 181: 423-427
8. VIJU P. DEENADAYALU, DOUGLAS K. REX, Fecal-based DNA assays: A new, noninvasive approach to colorectal cancer screening. CLEVELAND CLINIC JOURNAL OF MEDICINE VOLUME 71 · NUMBER 6 JUNE 2004

#### INDEX OF SYMBOLS

 Keep away from sunlight	 Store between 39°F-86°F (4°C-30°C)	 Keep dry
 Do not re-use	 REF Catalog number	 LOT Batch number
 Expiration date	 IVD In vitro diagnostic medical device	 Consult instructions for use

#### DISTRIBUTED BY

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