CLIAwaived™ Inc.

CLIAWAIVED,INC. RAPID FECAL OCCULT BLOOD TEST

INTENDED USE

CLIAwaived,Inc. Rapid Fecal Occult Blood (FOB) Card Test is an immunochromatographic assay intended for the determination of human hemoglobin in feces by professional laboratories or physician's offices. It is useful to determine gastrointestinal bleeding founding a number of gastrointestinal disorders such as colorectal carcinoma, colon polyps, diverticulitis and ulcerative colitis.

CLIAwaived,Inc. Rapid Fecal Occult Blood (FOB) Card Test is recommended for use in 1) routine physical examination, 2) hospital monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

SUMMARY AND EXPLANATION

The presence of hemoglobin in feces can be indicative of gastrointestinal tract conditions associated with bleeding such as colorectal carcinoma, colon polyps, Crohn's disease, and ulcerative colitis.

The CLIAwaived,Inc. Rapid Fecal Occult Blood Test is designed to detect lower levels of fecal occult blood than standard guaiac tests. The basis of the test is an immunochromatographic sandwich capture method, which yields results more specific to human hemoglobin and are easier to interpret than those of guaiac-based devices.

PRINCIPLE OF THE TEST

The CLIAwaived,Inc. Rapid Fecal Occult Blood Test is a method that employs a unique combination of polyclonal and monoclonal antibodies to selectively identify hemoglobin in test samples with a high degree of sensitivity. In less than five minutes, elevated levels of human hemoglobin as low as 50ng Hb/ml can be detected and positive results for higher levels of hemoglobin can be seen in the test as early as two or three minutes.

A fecal sample is collected and prepared for testing using the fecal collection tube; the resulting sample fluid is added directly to the test device. The sample fluid mixes with anti-hemoglobin dye-conjugate in the test membrane forming an antigen-dye complex, which migrates through the test device. The complex is captured in the test (T) zone by immobilized anti-hemoglobin antibodies. The captured dye-complex becomes visible as a rose-pink band within the test zone, which indicates the test has detected human hemoglobin, a positive result. In the absence of hemoglobin, no line will form in the test zone.

A built-in procedural control indicates proper kit performance. The control result is viewable as a rose-pink band in the control (C) zone within the five-minute testing period. The control band is formed by a non-specific sandwich dye conjugate reaction and should appear regardless of the test result.

A rose-pink band in the test zone and in the control zone at or before five minutes is considered a positive result by the criteria of the test. A band only in the control zone at five minutes is a negative result.

REAGENTS AND MATERIALS PROVIDED

1. 10 Test Devices
2. 10 Sample Collection Tubes with Buffer
3. 1 Product Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer
2. An absorbent cloth or tissue (preferably disposable) or a clean disposable cup.

STORAGE

Store test device at room temperature (15-30°C). Refer to the expiration date printed on the foil pouch for stability. Sample collection tube after collecting sample should be stored refrigerated (2-8°C) if not used immediately.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use product beyond the expiration date.
3. Patient samples may contain infectious agents and should be handled accordingly. Dispose of all used test components in a biohazard container.

PATIENT LIMITATIONS

1. Specimen should not be collected from a patient with the following conditions that may interfere with test results:
    - Menstrual bleeding
    - Bleeding hemorrhoids
    - Constipation bleeding
    - Urinary bleeding
2. Alcohol and certain medications such as aspirin, indomethacin, reserpine, phenylbutazone, corticosteroidal and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding in some patients.

SAMPLE COLLECTION AND PREPARATION

1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Insert the stick into the fecal specimen at several different sites.
4. Collect a thin smear of specimen on the probe tip section only. Remove excess sample from the stick by gently wiping with an absorbent tissue.
5. Replace the stick in the tube and tighten securely.

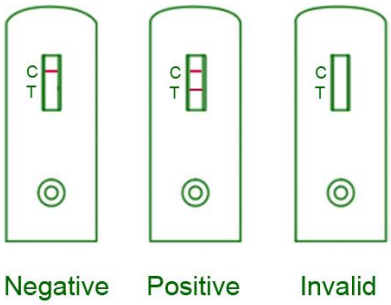
TEST PROCEDURE

1. Shake the tube vigorously to ensure a good liquid suspension.

2. Holding the tube upright, snap off the tip.
3. Dispense 2 - 3 drops of solution into the sample (S) well.
4. Wait five minutes and read the result.

***IMPORTANT**: The result must be interpreted between 5 and 10 minutes. Waiting more than ten minutes may cause the reading to be inaccurate.*

INTERPRETATION OF RESULTS



Negative: At five minutes, one rose-pink color band appears in the control (C) zone indicating a negative result and that the specimen does not contain a detectable level of human hemoglobin.

Positive: At five minutes, two rose-pink color bands appear: one in the test (T) zone and one in the control (C) zone. A positive result indicates that the specimen contains human hemoglobin. A positive result may be read sooner than 5 minutes.

Invalid: At five minutes, no bands appear, or a test band appears without a control band, disregard the result, indicating the test is invalid. It is recommended that the specimen be re-tested.

Note: There is no meaning attributed to line color intensity or width. A positive result may be read sooner than 5 minutes; however, a negative result must be read after 5 minutes.

QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.

The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

LIMITATIONS

1. As with any diagnostic test, CLIAwaived,Inc. Rapid Fecal Occult Blood may not be considered as a conclusive diagnosis for gastrointestinal bleeding or pathology. It is not intended to replace other diagnostic procedures such as G.I. fibro scope, endoscopy, colonoscopy or other x-ray analysis.
2. Although the test is very accurate in detecting human hemoglobin, there is a possibility false result may occur. In addition, because many bowel lesions, including some colorectal cancers and polyps, may bleed intermittently or not at all, occult blood may not be uniformly distributed throughout the fecal sample. Thus test results may be negative even when disease is present.
3. CLIAwaived,Inc. Rapid Fecal Occult Blood Test has not been tested for toilet water interference and that samples that have touched the toilet water should not be used for testing.
4. CLIAwaived,Inc. Rapid Fecal Occult Blood Test has not been tested on abnormal blood from Thalassemia and Sickle Cell patients.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity:** The analytical sensitivity of the test is 50ng hHb/ml buffer or 5 ug hHb/g feces.
2. **Accuracy:** There were 120 human hemoglobin free feces extraction specimens collecting over 10 days from in house and grouped these samples into 6 in an evenly distributed number 20. The 6 groups of extraction samples were spiked with human hemoglobin for six different concentrations, respectively, 0ng/ml; 20ng/ml; 40ng/ml; 50ng.ml; 100ng/ml; 2000ng/ml. The results obtained agreement 98% with the predicate device.
3. **Specificity:** The CLIAwaived,Inc. Rapid Fecal Occult Blood Test is specific to human hemoglobin. Specimens containing the following substances have no effect on test result:

Substance	Concentration
Chicken Hemoglobin	500 ug/ml
Pork Hemoglobin	500 ug/ml
Beef Hemoglobin	500 ug/ml
Goat Hemoglobin	500 ug/ml
Horse Hemoglobin	500 ug/ml
Rabbit Hemoglobin	500 ug/ml
Horseradish Peroxidase	2000 ug/ml

REFERENCES

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MANUFACTURED FOR:
CLIAwaived™ Inc.

SAN DIEGO, CA 92130
MADE IN USA

TC-F735-10G
TC-F735-20G

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