

RAPYDTEST®

FOR THE DETECTION OF HUMAN HAEMOGLOBIN IN FAECES

APACOR

Faecal Occult Blood (FOB) RAPYDTEST®

Intended Use

The Apacor FOB Rapydtest® is an immunochemical device intended for the qualitative detection of faecal occult blood to be used in laboratories or physicians offices. It is a useful aid to detect bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer. Faecal occult blood tests are recommended for use in:

1. routine physical examinations
2. routine hospital testing
3. screening for colorectal cancer or gastrointestinal bleeding from any source.



Clinical Performance

A total of 251 samples were collected from two hospitals and tested by the FOB Rapydtest® and by a leading commercial FOB rapid test. A comparison of the results for all specimens is shown in the table opposite.

Relative Sensitivity: 100.0%
Relative Specificity: 99.4%
Overall Agreement: 99.6%

	FOB Rapydtest®		
REFERENCE TEST	POSITIVE	NEGATIVE	TOTAL
POSITIVE	76	0	76
NEGATIVE	1	174	175
TOTAL	77	174	251

Performance Characteristics

Sensitivity

The analytical sensitivity of the test is 50 ng hHb/ml buffer or 50 µg hHB/g faeces.

Reproducibility

Known positive samples were tested in multiple assays and identically positive results were observed. Similarly, known negative samples produced negative results when tested in multiple assays.

Specificity

The FOB Rapydtest® is specific to human haemoglobin.

Hook Effect or Prozone Effect

FOB Rapydtest® cassettes do not show any hook effect or prozone effect up to the concentration of 0.5mg hHb/ml buffer.



MICROBIOLOGY
SINGLE USE IN VITRO DIAGNOSTIC DEVICE



Reagents and Materials Provided

1. Individually sealed foil pouches containing:
 - a. One cassette test device.
 - b. One desiccant.
2. Sample extraction tubes, each containing 2ml of extraction buffer.
3. One package insert (instruction for use).

Specimen Collection and Handling

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

1. Collect a random sample of faeces in a clean, dry receptacle.
2. Unscrew the top of the sample extraction tube and remove the applicator stick.
3. Randomly pierce the faecal specimen in at least five (5) different sites. Do not scoop faecal specimen as this will lead to an invalid test result.
4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside grooves. Specimen on the grooves is sufficient for testing. Excess amount of faecal specimen can lead to an invalid test result.
5. Replace the stick in the tube and tighten the cap securely.
6. Shake the extraction tube vigorously.

The specimen is now ready for testing, transportation, or storage.

Note: Specimens extracted may be stored at 2°C-8°C for up to 3 days.

If longer storage is required, freezing at ≤-20°C is recommended.

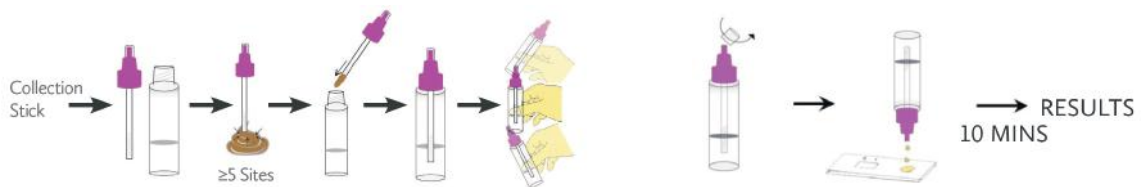
Patient Preparation

1. A specimen should not be collected from a patient with the following conditions that may interfere with the test results:
 - Menstrual bleeding
 - Bleeding haemorrhoids
 - Constipating bleeding
 - Urinary bleeding
2. Dietary restrictions are not necessary.
3. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, corticosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, thus gives positive reactions. On the advice of the physician, these medicines might be temporarily discontinued for 7 days prior to and during the test period.

Test Procedure

- Step 1 Bring the specimen and test components to room temperature if refrigerated or frozen.
- Step 2 When ready to test, open the pouch at the notch and remove the test device. Place the test device on a clean, flat surface.
- Step 3 Shake the sample extraction tube vigorously to ensure an effective liquid suspension.
- Step 4 Hold the tube upright and twist off the tip. Dispense 2 drops of the solution into the sample well(s) of the test device.
Do not overload sample.
- Step 5 Set up the timer.
- Step 6 Results can be read 10 minutes after adding the specimen. Positive results can be visible in a time period as short as 1 minute.

Do not read results after 10 minutes. To avoid confusion, discard the test device after interpreting the result.



References

1. Allison JB, Takawa IS, Ransom LJ, Adrian AL. A comparison of fecal occult blood tests for colorectal–cancer screening. N. Eng. J. Med. 1996; 334:155-159.
2. Saito H. Screening for colorectal cancer by immunochemical fecal occult blood testing (Review). Jpn J. Cancer Res 1996; 87:1011-1024.

PRODUCT	PACK SIZE	CODE
FOB Rapydtest®	25	1642

Products can be ordered direct from Apacor or from an appointed distributor
Visit our website for all the latest information www.apacor.com or email on: orders@apacor.com

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