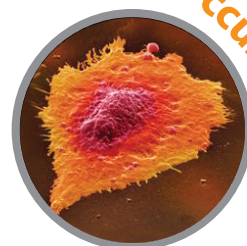


OnSite™

Fecal Occult Blood



Accurate Screening for Colorectal Cancer

OnSite FOB colorectal cancer screening test provides highly sensitive and specific, easy-to-read results with no dietary restrictions

Colorectal cancer is the third most common type of cancer in both men and women. Early detection of this disease through routine screening of patients age 50 and over can reduce the number of related deaths by 30%. The fecal occult blood test is the ideal method to screen for colorectal cancer as well as other gastrointestinal diseases, such as

- cancer
- polyps
- colitis
- diverticulitis

Two types of FOB tests are commercially available: Guaiac FOB tests and immunochemical FOB test (iFOBT).

The Guaiac method uses a dye that undergoes a color change when the heme group of hemoglobin (Hb) is present, but it is often difficult to interpret. In addition, restrictions on diet and medication are required to avoid costly false positive results caused by non human Hb.

In contrast, the **OnSite** FOB Rapid Test is an immunochemical assay designed specifically to detect low levels of human fecal occult blood. It offers many advantages over the Guaiac method:

- highly sensitive and specific
- clear, easy-to-read result
- no dietary restrictions
- only 1 or sometimes 2 specimens required
- **Positivia** external FOB assay control is available

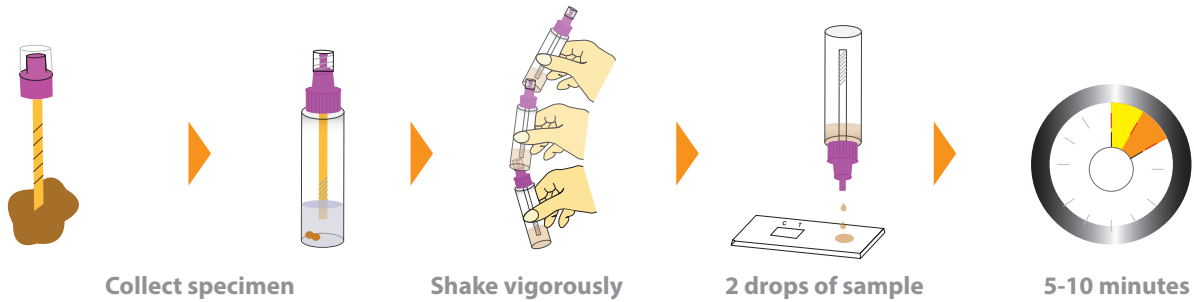
FOB Test Summary & Comparison

	OnSite FOB Rapid Test	Guaiac Test
Test method	Immunochemical assay	Chemical test
Interpretation	Clear, accurate reading	Color change, often difficult to interpret
Specificity	>98%, highly specific for human Hb	Poor, detects nonhuman Hb
Sensitivity	Adjustable, as low as 25 ng/mL	> 90,000 ng/mL
Accuracy	> 95%	< 86%
Dietary & Drug Restrictions	NONE	YES, several days
Specimens required	ONE required, TWO recommended	THREE separate samples

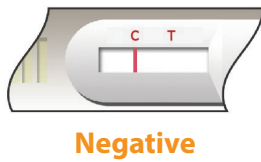


OnSite FOB Rapid Test At a Glance

Simple, rapid procedure



Clear, easy-to-read result



Sensitivity

The **OnSite** FOB Rapid Test has three levels of analytical sensitivity to meet different needs:

- 25 ng hHb/mL buffer
- 50 ng hHb/mL buffer
- 100 ng hHb/mL buffer

Hook Effect

The **OnSite** FOB Rapid Test has a wider detection range than other iFOBT eliminating the risk of false negative results from specimens with a high concentration of hemoglobin.

	OnSite FOB Rapid Test	Other iFOBT
Hb detectable level	Up to 4 mg/mL	Up to 2 mg/mL

Accuracy

A total of 175 specimens were collected and tested by the **OnSite** FOB Rapid Test and by a leading immunochemical FOB test. The results show that both tests have high degree of agreement.

Leading iFOBT	OnSite FOB Rapid Test		Total
	Positive	Negative	
Positive	47	1	48
Negative	1	126	127
Total	48	127	175

Relative Sensitivity: 97.9%, Relative Specificity: 99.2%, Overall Agreement: 98.9%.

Cross Reactivity

Hemoglobin from different species was added to negative specimens and weak positive specimens. The **OnSite** FOB Rapid Test displayed very low risk of cross reactivity compared to other iFOBT. The **OnSite** FOB Rapid Test is specific to human hemoglobin so it will not cross react with sources of hemoglobin consumed by the patient as meat.

Hemoglobin	Hb Concentration without Cross Reaction	
	OnSite FOB Rapid Test	Other iFOBT
Bovine Hemoglobin	2 mg/mL	1 mg/mL
Chicken Hemoglobin	2 mg/mL	1 mg/mL
Fish Hemoglobin	2 mg/mL	1 mg/mL
Goat Hemoglobin	2 mg/mL	1 mg/mL
Horse Hemoglobin	2 mg/mL	1 mg/mL
Pork Hemoglobin	2 mg/mL	1 mg/mL
Sheep Hemoglobin	2 mg/mL	1 mg/mL
Rabbit Hemoglobin	2 mg/mL	1 mg/mL
Turkey Hemoglobin	2 mg/mL	1 mg/mL

Interference

The **OnSite** FOB Rapid Test gives correct results with no interference from common medicine or dietary substances eliminating the need for restricting diet or medication for three days before testing as required for Guaiac method.

Example Substance	Concentration	OnSite FOB Rapid Test	
		Negative	Positive
Control	N/A	Negative	Positive
Ascorbic Acid	20 mg/ dL	Negative	Positive
Bilirubin	100 mg/ dL	Negative	Positive
Caffeine	40 mg/ dL	Negative	Positive
Glucose	2,000 mg/dL	Negative	Positive
Iron (Fe ³⁺ /Fe ²⁺)	5 mg/ mL	Negative	Positive
Horseradish Peroxidase	20 mg/ mL	Negative	Positive

Also noted, toilet bowl cleansers and deodorizers/fresheners have no interference on the results of the **OnSite** FOB Rapid Test.

