

# *i*-CHROMA™ FOB Test

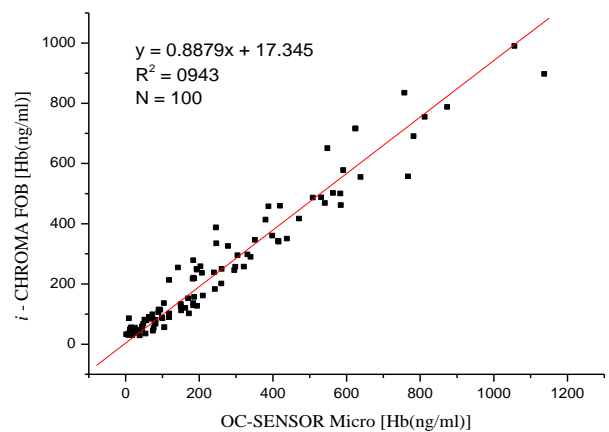
## General Information

Colorectal cancer is the third most common cancer in world, with about 1 million new cases and more than 500,000 deaths per year. Screening method for colorectal cancer include the fecal occult blood (FOB) test, barium enema, sigmoidoscopy and colonoscopy. Large randomized controlled trials have shown that FOB screening can result in decreased colorectal cancer mortality. The standard FOB test uses the chemical, Guaiac, which is sensitive to Hb peroxidase activity. However, the standard Guaiac-FOB test has low sensitivity for clinically significant colorectal neoplasia and has low specificity due to its non-specificity for human Hb. To overcome these potential problems in immunochemical test, *i*-CHROMA™ FOB uses the specific monoclonal antibodies against human Hb as capture and detector reagents

Cancer

## Key Features of *i*-CHROMA™ FOB Test

- Quantitative Test Result
- Sample Type: feces
- Detection Limit: 25 ng/ml
- Working range: 25 ng/ml ~ 1,000 ng/ml
- Cut Off: 50 ng/ml
- Precision: CV% 2-10 in working range.
- Long Shelf Life: 20 months
- Fast Test Result: 10 minutes
- Comparable Test Result with Full Automatic Analyzer
- No Calibration Needed



Comparison Data with OC-SENSOR Micro

## Principle

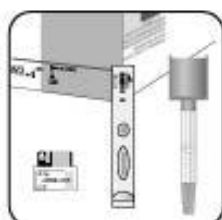
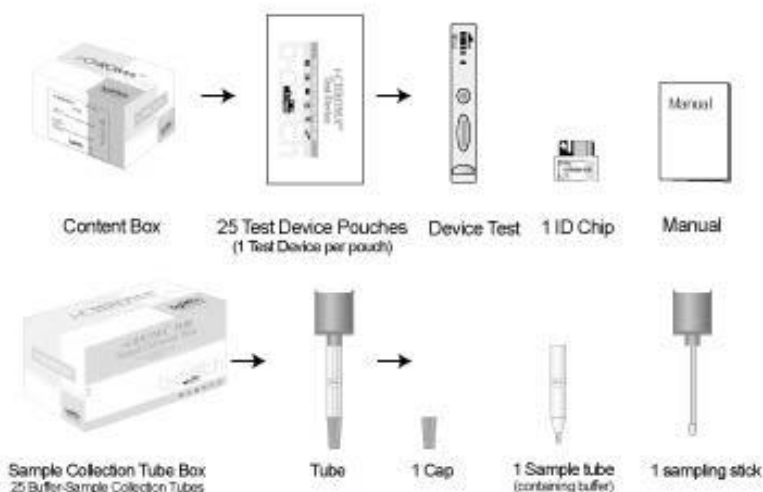
*i*-CHROMA™ FOB is based on fluorescence immunoassay technology. The *i*-CHROMA™ FOB uses a sandwich immuno-detection method, such that by mixing detection buffer with human Hb specimen in sample collection tube, the fluorescence-labeled detector anti-Hb antibody in buffer binds to Hb in fecal specimen. As the sample mixture is loaded onto the sample well of the Test Device and migrates the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and FOB are captured by anti-human Hb sandwich pair antibody that has been immobilized on test strip. Thus the presence of more Hb in fecal specimen would lead to accumulation of more complexes on the test strip. Signal intensity of fluorescence of detector antibody reflects amount of human Hb captured. *i*-CHROMA™ Reader processes and shows Hb concentration in fecal specimen. The result unit of *i*-CHROMA™ FOB is displayed as an ng/ml from *i*-CHROMA™ Reader. The working range of *i*-CHROMA™ FOB test system are 25-1,000 ng/ml.

## Test Procedure

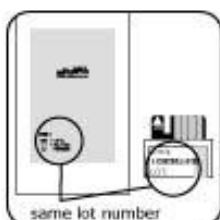
1. Set a Test Device on a dust-free clean surface.
2. Check and insert ID Chip onto the instrument. Make sure that the Test Device lot # matches ID Chip lot #.
3. Take out one Sample Collection Tube from refrigerator and leave it at room temperature for 20 minutes.
4. Remove the upper cap with sampling stick from the Sample Collection Tube.
5. Put the sampling stick into the fecal sample about 5~6 times at different sites and try to avoid obtaining clumps of fecal matter.
6. Return the sampling stick with feces into the Sample Collection Tube. Tighten the upper cap and then shake the tube up and down to make sure that the feces are mixed well with the buffer.
7. Take out the lower cap of Sample Collection Tube. Squeeze the tube gently and discard the first 2 drops of mixed sample into a waste container.
8. Load next 2 drops into the well of Test Device ; full 2 drops are required for an accurate test result.
9. Leave Test Device at room temperature for 10 minutes before inserting the device into the holder of *i*-CHROMA™ Reader.
10. To start scanning, insert Test Device onto the holder of *i*-CHROMA™ Reader and press "SELECT" button. Checking the direction of Test Device, push the device back all the way.
11. The instrument will automatically start to scan the Test Device immediately.
12. Read the results on the display screen of *i*-CHROMA™ Reader.

## i-CHROMA™ FOB

### Contents



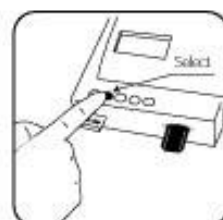
- 1** Check the contents :  
1 ID Chip, 1 Test Device,  
1 sample collection tube



- 2** Check and make sure that  
ID Chip lot number matches  
Test Device lot number.



- 3** Insert the ID chip into the  
instrument.



- 4** Press "Select"



- 5** Turn and remove the  
upper cap with sampling  
stick from the Sample  
Collection Tube.



- 6** Collect the fecal sample  
by putting the sampling stick  
into the fecal sample at  
6 different sites.



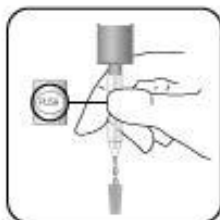
- 7** Return the sampling stick with  
fecal sample into the Sample  
Collection Tube and tighten  
the upper cap.



- 8** Shake the tightened tube  
(from step #7) well.



- 9** Turn to separate the lower  
cap of the Sample  
Tube.



- 10** Squeeze the "PUSH" button  
on the tube gently to discard  
the first 2 drops of the mixed  
sample.



- 11** "PUSH" button is designed for  
accurate measurement of  
2 drops.



- 12** Wait 10 minutes



- 13** Place the Test Device on  
the Test Device holder of  
the instrument.



- 14** Press "Select"



- 15** Read the result of the  
display screen