CPAL
Central **P**ennsylvania **A**lliance **L**aboratory

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FIT Occult Blood
- New Test Introduction –

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Ordering Information:

Mnemonics:	**Fit Chek**
Test Name:	Fit Chek
Test Number:	1757110
Specimen:	Stool in dedicated collection tube Store at room temperature up to 15 days

Effective Date: Testing is available as of November 6, 2015.

Performed: Monday, Wednesday, Friday

Reference Range: Negative

Background:
The presence of fecal occult blood in the stool is associated with gastrointestinal disorders such as diverticulitis, polyps, and Crohn's disease, that may lead to colorectal cancer if not treated. Early diagnosis by fecal occult blood screening and treatment of these problems has been shown to significantly reduce mortality from colorectal cancer.

Conventional test methods used for the detection of fecal occult blood do not provide a high degree of accuracy. To avoid false positive test results, patients are instructed to avoid certain foods prior to testing. Immunological tests developed to detect human hemoglobin are more accurate and do not require special dietary restrictions for patients. The reduction in false positive results correlates to a reduction in follow-up testing, such as colonoscopy.

The OC-Auto Micro 80 iFOB Test is recommended for use in:

1. Routine physical examinations
2. Monitoring for bleeding in patients
3. Screening for colorectal cancer or gastrointestinal bleeding

This test replaces the current test, InSure FIT, which is performed at Quest Diagnostics. Studies have shown increased patient compliance with the iFOB test, which may be due to the collection procedure and requirement of only one specimen. The specimen is collected by scraping a small amount of stool and placing the scraper into a

tube, which is sealed shut for transport. This eliminates the messiness of using the card system and the inconvenience of holding specimens for multi-day collections by the patient.

Principle of Test:
The OC-Auto Micro 80 iFOB Test is an immunoassay utilizing rabbit polyclonal anti-human HbA0 antibodies to specifically detect the presence of Hb in stool. The immunologic test is designed to be used together with an automated analyzer as an immunoassay test system. The system is intended for the qualitative detection of fecal occult blood in stool by professional laboratories.

Results Interpretation:
The ranges are as follows:

Negative	<100 ng Hb/mL
Positive	>/= 100 ng Hb/mL

Limitations:
1. The OC-Auto Micro 80 iFOB Test is intended only for the detection of hemoglobin in stool.
2 Patients with the following conditions should not be considered for testing, as these conditions may interfere with test results: bleeding hemorrhoids, menstrual bleeding, constipation bleeding, urinary bleeding, however they may be tested after such bleeding ceases.
3. Certain medications such as aspirin and non-steroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding in some patients and cause positive results.
4. As with any occult blood test, results obtained with the OC-Auto Micro 80 iFOB Test should not be considered conclusive evidence of the presence or absence of GI bleeding or pathology. OC-Auto Micro 80 iFOB Test is designed for preliminary screening. It is not intended to replace other diagnostic procedures such as colonoscopy or sigmoidoscopy in combination with double contrast barium x-ray. It is not intended for use in patients with upper GI bleeds.
5. Because gastrointestinal lesions may bleed intermittently and blood in stool is not distributed uniformly, a negative test result does not assure absence of lesion.
6. A positive result should be followed up with further studies to establish the source of bleeding.
7. Urine and excessive dilution of samples with water from the toilet bowl may cause erroneous test results. For best result, use the collection paper in the collection kit.
8. OC-Auto Micro 80 iFOB Test is not for use in testing urine, gastric specimens or other body fluids.
9. FOB testing is recommended annually by the American Cancer Society (2008) for average-risk women and men, 50 years of age and older, However, patients with significant risk factors such as family history of colorectal cancer should be screened earlier and more often.
10. The test has not been validated for testing of patients with hemoglobinopathies.

Validation Data:
Precision and Accuracy
Precision and accuracy were assessed using the Accuracy Precision Panel provided by Polymedco. Five samples which contained varying hemoglobin concentrations were run four times each in random order. The five samples produced the expected result each time they were run regardless of the order in which they were run.

Within Run Reproducibility
The positive and negative controls were run within the same run a total of ten times. Both samples produced the same results when processed ten times within the same run.

Between Run Reproducibility
The positive and negative controls were run ten times each on two different days. The two controls produced the same result when run on two different days.

Carryover
A sample with a positive result and a sample with a negative result were run in alternating fashion for a total of ten times. No carry over was detected.

Method Comparison
A total of 50 specimens (25 known positive and 25 known negative) were tested at CPAL utilizing the OC-Auto Micro 80. The same 50 samples were tested at Polymedco's lab using their OC-Auto Micro 80 instrument. There was 100% agreement between CPAL's results and Polymedco's results.

Eight samples were run on the OC-Auto Micro 80 using the iFOB test. The same eight samples were inoculated on the InSure FIT cards for Fecal Globin by Immunochemistry and sent Quest. There was 100% agreement between the InSure FIT and iFOB results.

References:

1. OC-Auto Micro 80 iFOB Test package insert; January 2, 2104.