# EZ DETECT™

## Fecal Occult Blood Test

**Professional Dispenser Pack containing 48 complete test kits**

REF **1001**

# PHYSICIAN'S INSTRUCTION PAMPHLET

**May 2015**

**INSTRUCT PATIENT TO READ TEST INSTRUCTIONS THOROUGHLY PRIOR TO USE**

**FOR *IN VITRO* DIAGNOSTIC USE**

## I. INTENDED USE

The EZ DETECT™ Test is for *in vitro* qualitative detection of occult blood in the stool -- an early indicator of various gastrointestinal bleeding disorders. The test is dispensed by the physician to the patient for home use.

## II. BACKGROUND AND CLINICAL SIGNIFICANCE

Occult blood in the stool has been measured since 1904 by the guaiac- peroxide reagent system. For the past 14 years, the guaiac slide test has replaced the old classical liquid procedure. The slide test utilizes the same chemical reaction to measure the blood, but differs from the old method in that the stool specimen is smeared on a paper-slide and sent to the laboratory for testing and interpretation of the results. The EZ DETECT™ Test, uses a tissue impregnated **tetramethylbenzidine-peroxide** (TMB) system which eliminates the need for stool sample collection and laboratory testing.

The American Cancer Society recommends that men and women over 50 should use an occult blood test yearly or as often as their physician recommends. Normally, a person may lose up to 2.5 milliliters of blood per day in the stool. Blood loss greater than 3 ml may be indicative of an abnormal condition. Patients with a family history of intestinal disorders or colorectal cancer, as well as those with personal histories of inflammatory bowel diseases such as polyps, colitis, and diverticulitis, should be monitored more frequently for occult blood in the stool. Digital examination, proctosigmoidoscopy, or colonoscopy are also recommended. Polyps, the precursors of colorectal cancer, can be treated successfully if detected early.

The EZ DETECT™ Test is designed to screen for potential problems of the lower intestinal tract. The test detects stool blood that can be caused by a number of conditions such as **ulcers, hemorrhoids, polyps, colitis, diverticulitis, cancer and fissures**. Since these disease conditions may not produce visible symptoms in their early stages, the test may act as an early warning signal. Patients testing positive with EZ DETECT™ must be examined thoroughly with other medical procedures. The EZ DETECT™ Test does not replace regular rectal examinations.

## III. PRINCIPLE AND METHODOLOGY

The EZ DETECT™ Test consists of a biodegradable tissue-paper-film coated with a chromogenic dye (TMB) and peroxide. The film is in the shape of a cross on the **Test Tissue**. As soon as the **Test Tissue** touches the toilet water surface after a bowel movement, hemoglobin from the blood (if present) in the stool liberates oxygen from the peroxide, which in turn oxidizes the colorless dye (tetramethylbenzidine) to a blue-green color.

$$\text{Peroxide} + \text{Hemoglobin} \rightarrow \text{water} + \text{oxygen}$$

$$\text{Oxygen} + \underset{\text{(unoxidized TMB)}}{\text{Tetramethylbenzidine (colorless)}} \rightarrow \underset{\text{(oxidized TMB)}}{\text{blue-green color}}$$

**Methodology**
After a bowel movement, one **Test Tissue** is dropped onto the surface of the water in the toilet bowl. If a fecal specimen contains an abnormal level of blood, a **blue-green cross** will appear. A negative result is indicated by the **absence** of color.

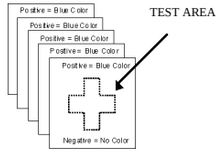
## IV. MATERIALS PROVIDED

Forty-eight (48) test kits are supplied in a professional dispenser package. Each test kit is for one patient's use. The kit contains:

- A Foil Pouch containing Five Test Tissues
- One Positive Control Package
- One Patient Instruction Sheet
- One Test Result Post Card for mailing results to you

**CONTENTS OF ONE TEST KIT**


**Instructions**




**5 Test Tissues**
**(IN FOIL POUCH)**


**Positive Control**


**Result Card**

**Storage and Stability**
Store the EZ DETECT™ carton at room temperature (59° - 86°F / 15° - 30°C).

## V. PRECAUTIONS

- At your convenience, review Sections V through IX herein with the patient.
- The kit contents are for <u>in</u> <u>vitro</u> **diagnostic use only**. The materials are not to be ingested and must be kept out of the reach of children.
- The positive control is an oxidizing agent (Sodium Dichloroisocyanurate). Avoid contact with the eyes, the skin, clothing, heat or open flame. In case of an accidental spill or a direct contact, wash the affected area with large amounts of water. If ingested, administer large amounts of water. Do not induce vomiting. Call the poison control center.
- Ask the patient to hold the **Test Tissues** by the corners. The middle of the **Test Tissue** may be sensitive to the touch. Unused **Test Tissues** must be kept in their original foil pouch, away from light and moisture. Advise the patient to examine the **Test Tissue** before use. Any coloration (blue-green) in the **test area** of the **Test Tissue** indicates deterioration.
- The test should not be performed if the patient is bleeding from hemorrhoids, suffering from constipation, or experiencing menstrual bleeding.

## VI. SPECIMEN COLLECTION AND HANDLING

The specimen for the test is the feces. **No specimen collection or handling of the feces is required to perform the test.**

To increase the probability of detection, the test is performed on **three consecutive bowel movements.** If the sequence is broken, the test should be continued until three bowel movements have been tested. Some gastrointestinal bleeding occurs intermittently. Checking three consecutive bowel movements will offer a better chance of finding lower intestinal bleeding.

## VII. MEDICATIONS

Some of the known drugs that cause or affect intestinal bleeding are: aspirin and other analgesic drugs, indomethacin, phenylbutazone, corticosteriods and other anti-inflammatory drugs, reserpine, butazolidine, premorin, and persantine. These drugs may produce gastrointestinal bleeding that may cause positive results. The use of rectal ointments should also be avoided during the testing period.

If the patient is taking any prescribed drugs, make a careful evaluation of the drug monograph and advise the patient accordingly. High doses of iron supplements may interfere with test results.

## VIII. DIET

**While this test has no diet restrictions (rare meat and vitamin C do not interfere) it is advisable to tell the patient to eat a normal diet** including vegetables, fruits and cereals (such as bran and whole grain). This diet will give a better test result by adding roughage which can help uncover such things as silent lesions which bleed intermittently.

## IX. PRE-TEST INSTRUCTIONS FOR THE PATIENT

For two days before and during the test period, the patient should avoid medication that, in your opinion, may cause intestinal bleeding. Make sure that the patient can discern color change. If color-blind, advise the patient to get help to read the results.

All toilet cleaners, disinfectants, or deodorizers (such as Tidy Bowl™, Vanish™, etc.) should be removed from the toilet bowl and the tank. The toilet should be flushed repeatedly until the water is clear.

## X. TEST PROCEDURE

### A. TOILET WATER QUALITY CHECK

The following check is performed to make certain the toilet water is satisfactory for the test. Even though EZ DETECT ™ has been shown to be unaffected by toilet water in the last several years of use in various U.S. regions, we recommend the following water quality check:

1. Open the foil pouch and take out one **Test Tissue**, and carefully drop it on the surface of the water in the toilet bowl.
2. If any trace of blue-green color appears on the **Test Tissue** after two minutes, the toilet water is unsuitable for the test. If no color appears in the cross area, the patient should be instructed to flush the toilet and continue with the bowel movement tests.
3. The patient should record the results by marking an "X" in the proper column on the Test Result Card.

### B. PROCEDURE FOR TESTING FOR BLOOD IN THE STOOL

**The patient should be advised to:**

1. Urinate first and then flush the toilet;
2 Have a bowel movement;
3. Carefully drop a **Test Tissue** into the toilet bowl;
4. Any trace of blue-green color appearing in the **Test Tissue** within two minutes means excessive blood is present in the stool. The patient should be advised to record his results by making an "X" in the proper column on the Test Result Card. Flush the toilet.
5. Steps 1 thru 4 should be repeated for the next two consecutive bowel movements.
6. **The patient should be instructed to stop testing and contact you if any of the tests from the three bowel movements show a blue- green color in the test area of the Test Tissue**. Any unused **Test Tissue** may be discarded in a trash can.

### C. TEST PERFORMANCE CHECK

The patient should perform this test **only** if he or she did not see any color in the bowel movement tests above.

Flush toilet. Carefully tear open and empty the contents of the Positive Control Package in the toilet bowl. **After one minute**, drop the last **Test Tissue** onto the top of the water. Color should appear on the **test area** of the **Test Tissue** within two minutes. In most cases the color will be blue-green, but in some cases the tissue over-reacts and a rust color may appear. Any color change indicates that the test tissues are performing properly. If there is **no** color change during the test performance check the patient will need to re-do the test using a new test kit.

## XI. INTERPRETATION OF RESULTS

If no trace of blue-green color is seen in the **test area**, the result is negative. The appearance of any trace of blue-green indicates a positive result. The color may vary in shade and intensity depending upon the amount of blood present in the stool. A negative or positive result does not prove conclusively the absence or presence of an abnormal condition (see section XII, "Limitations").

The patient should be instructed to record all results on the provided Test Result Post Card and mail or bring it to you, even if the results are negative.

**Note: For valid conclusions, the results for Test Tissue #1 (toilet water quality test)** must be negative (no trace of blue-green color on the **Test Tissue**) and the results for **Test Tissue #5** (quality control check for test tissue) must be positive (any trace of blue-green color on the **Test Tissue**).

## XII. LIMITATIONS

1. As with any other in vitro diagnostic test, the results obtained from the EZ DETECT™ Test should be used as a preliminary screen to other medically established procedures and be interpreted in conjunction with other clinical data available to you. The test does not replace other established diagnostic procedures, such as proctosigmoidoscopy, barium enema, X-ray studies, etc. The results obtained with EZ DETECT™ Test should not be considered conclusive for the presence or absence of a pathological condition.
2. Some of the previously mentioned drugs (see section VII), may induce gastrointestinal bleeding, and may cause positive results.
3. The EZ DETECT™ Test is a **qualitative test** for blood in the stool. Even though the amount of color varies according to the concentration of blood, the test itself should not be used for quantitative information.
4. It is important that no urine be present during testing. Large amounts of urine may make the results difficult to see.

## XIII. PERFORMANCE CHARACTERISTICS

**Sensitivity**
The sensitivity of the EZ DETECT™ Test is approximately 2.0 mg hemoglobin/100 ml water.

**Correlation Data (Clinical Evaluation)***
101 patients were tested with the EZ DETECT™ Test and the Hemoccult® slide test. The patients tested were ambulatory, hospitalized, or in a nursing home and had various types of bleeding disorders. 22 patients were found positive, while the other 79 patients gave negative results for blood in the feces. All positive tests showed a 100% correlation with the Hemoccult® slide test.

**Accuracy and Precision**
Multiple testing (n=20) on a sample containing 2.0mg hemoglobin/100ml gave a positive result each time (100%). Multiple testing (n=20) on a sample devoid of hemoglobin gave a negative result each time (100%).

---

* For more clinical data on the EZ DETECT™ Test, you may send for the booklet "Technical Data on EZ DETECT".

Hemoccult® - Trademark of Smith Kline Diagnostics.

## XIV. LITERATURE


1. Winawer, S.J. and Fleisher, M., "Sensitivity and specificity of the fecal occult blood test for colorectal neoplasia." **Gastroenterology** 82, 986-991 (1971).
2. Macrae, F.A., et al, "Optimal dietary conditions for Hemoccult testing." **Gastroenterology** 82, 899-903 (1982).
3. Eddy, D.M., et al, "Screening for colorectal cancer in a high risk population." **Gastroenterology** 92, 682-693 (1987).
4. Hulst, L.A., "Zur Frage der Okkulten Blutung and Ihner Bewetung Fur die Klinik." **Klin. Wochenscher** 13, 912-914 (1934).
5. Ahlquist, D.A., et al, "A new quantitative assay for fecal hemoglobin, HemoQuant: Analysis in health and GI disease." **Gastroenterology** 84, 1089 (1983). Abstract.
6. Schwartz, S., et al, "Fecal recovery of hemoproteins from blood, meat and fish ingested by normal volunteers: The HemoQuant assay." **Gastroenterology** 84, 1302 (1983). Abstract.
7. Schwartz, S., et al, "The HemoQuant test: A specific and quantitative determination of heme (hemoglobin) in feces and other materials." **Clinical Chemistry** 29, No. 12, 2061-2067 (1983).
8. Welch, C.L. and Young, D.S., "Spectrophotometry of occult blood in feces." **Clinical Chemistry** 29, No. 12, 2022-2025 (1983).
9. Barry, M.J., et al, "Effect of workup strategy on the cost effectiveness of fecal occult blood screening for colorectal cancer." **Gastroenterology** 93, 301-310 (1987).
10. Fleisher, M., "Problems and pitfalls in fecal occult blood testing." **Primary Care and Cancer** p. 29-34, Aug. (1988).


## XV. SYMBOLS

| | |
|---|---|
|  | Storage Temperature |
|  | Lot Code |
|  | Expiration |
|  | Manufacturer |
|  | Authorized Representative |
|  | Caution, see instructions |
|  | For in vitro diagnostic use |
|  | Catalog No. |

## XVI. ORDERING INFORMATION

**ORDERING:** Send purchase order to:


Biomerica, Inc.
17571 Von Karman Avenue
Irvine, CA 92614 USA
Tel: 949-645-2111 Fax: 949-553-1231
E-mail: info@biomerica.com
Web Site: www.biomerica.com


according to IVDD 98/79/ EC
MDSS GmbH
Schiffgraben 41
D-30175 Hannover
Germany

61001.doc May 2015