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Newscen One-Step Fecal Occult Blood (FOB) Diagnostic Kit

INTENDED USE

One-Step Fecal Occult Blood (FOB) Diagnostic Kit is a detection of hemoglobin in feces for self-testing. Immune method is a qualitative detection of hemoglobin in feces. Chemical method is semi-quantitative detection of hemoglobin in feces.

PRINCIPLE

Colloidal Immunization Method: One-Step Fecal Occult Blood (FOB) Diagnostic Kit is a immunoassay for the determination of human hemoglobin (Hb) in feces. Antibodies to Hb are precoated onto membrane as a capture reagent on the test zone. During the test, specimen is allowed to react with the colloidal gold particles, which have been labeled with antibodies to Hb. If Hb is present, a red colored line will develop on the membrane in proportion to the amount of Hb present in the specimen. To serve as a procedural control, red colored line in the control zone will always appear regardless of the presence of Hb.

Chemical Method: Hemoglobin has peroxidase activity which can cause peroxide decompose then release oxygen atom. The oxygen atom oxidizes 3, 3', 5, 5'-tetramethyl-benzidine indicator, which have been combined with the kit to change the color. When specimen contains a certain amount of Hb, the color will change from orange to yellow-green or dark green. Very high concentration of Hb, may cause the color development to dark blue.

COMPONENTS

REAGENTS AND MATERIALS PROVIDED

Each kit contains:

1. Each pouch contains one cassette with one desiccant bag
2. Collection tube (with diluent buffer)
3. Instruction for use
4. Color card

MATERIALS REQUIRED BUT NOT PROVIDED

Clock or stopwatch

WARNING AND PRECAUTIONS

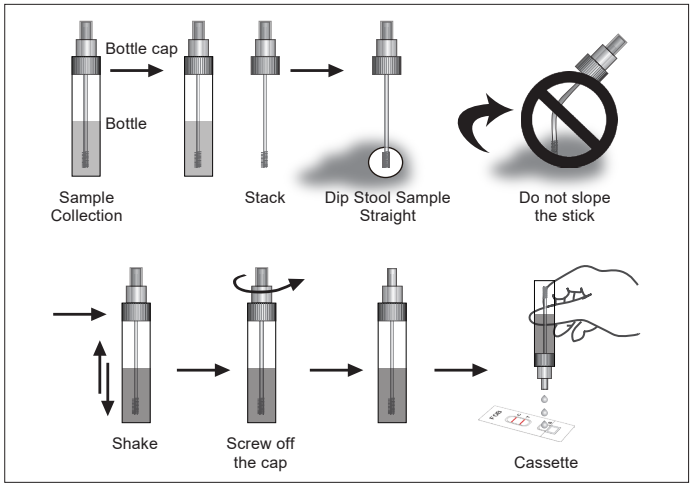
1. For in vitro diagnostic use only.
2. Do not use beyond the labeled expiration date.
3. Do not use the test if the pouch has been perforated.
4. Do not modify the test procedure.
5. Do not reuse the test devices. Discard it in the dustbin after single use.
6. Do not use the test if the pouch has been perforated.
7. Always interpret the results under good light conditions to avoid misreading of the results.
8. If desiccant bag is not present in the pouch, DO NOT USE the test.
9. Always add accurate volume of specimen by following the instruction.
10. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
11. Clean up spills thoroughly using an appropriate disinfectant.
12. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.

STORAGE

One-Step Fecal Occult Blood (FOB) Diagnostic Kit should be stored at room temperature (4-30°C, do not freeze) for 24 months from the date of manufacture. Keep the test cassette in sealed pouch until use. Once you have taken the test cassette out of the pouch, perform the test as early as possible (within 1 hour) to avoid test cassette from becoming moist.

SAMPLE COLLECTION AND TEST PREPARATION

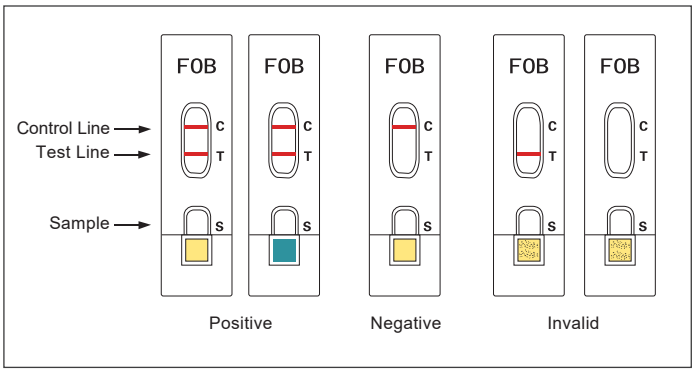
1. Get samples by a clean and dry container or toilet paper.
2. Unscrew the top of the sample collection device and use the sample collection stick to collect fecal sample by dipping the stick into at least 3 different sites of the same fecal sample or take 20-50mg (about soybean size).
3. Put the sample collection stick containing the sample back in the sample collection device and screw it tightly. Shake it very well.
4. If the specimen is not used immediately following collection, but is to be used within 7 days it should be refrigerated, and brought back to room temperature before testing. Specimen also could be stored frozen at -20°C for maximum 3 months. Prior to testing, the frozen specimen must be completely thawed, thoroughly mixed, and brought to room temperature.



EXAMINATION PROCEDURE

Allow the test, specimen and/or controls to reach room temperature prior to testing.

1. Specimen collection. Please see also SPECIMEN COLLECTION.
2. Before opening, allow the test cassette to reach room temperature. Use it immediately after opening.
3. Place the test cassette on a dry, clean, non-absorbent flat surface, and break off the tip of the collection device and squeeze 2-3 drops of the extracted sample into Sample well, and start the timer and wait for the colored line(s) to appear.
4. Read the Chemical Method result within 1 minute and read the Immune Colloidal Method result through the result window in 5 minutes.
5. Get the final result according to the synthetically.



INTERPRETATION OF RESULTS

Interpretation of Immune Colloidal Method:

1. **Negative**: No red lines appear within 5 minutes in the test zone (T), only a red line in the control zone (C).
2. **Positive**: One red line in the control zone (C) and one red line in the test zone (T).
3. **Invalid**: If no red lines appear, the test is invalid. Discard the test and repeat with new specimen and new cassette.

Interpretation of Chemical Method:

1. **Negative**: There is no color change of indicator in 1 minute after adding the specimen.
2. **Positive**: The color of the indicator changes from orange to yellow-green or dark green in 1 minute after adding the specimen.
3. **Invalid**: If the color mixed, the test is invalid. Discard the test and repeat with new specimen and new cassette.

The final interpretation:

1. If both of the Immune Colloidal Method and the Chemical Method show positive, the final result is positive, which indicates there is blood in specimen.
2. If the Immune Colloidal Method shows positive while the Chemical Method shows negative, this indicates occult bleeding. The concentration of Hb in the specimen is much lower. The final result is also positive.
3. If the Immune Colloidal Method shows negative while the Chemical Method shows positive, this probably because the high concentration of Hb causing antigen excess, and have hook effect. It is suggested that the specimen be diluted 100 times and retest, if the Immune Colloidal Method shows positive, this indicates the digestive tract bleed profusely; if the Immune Colloidal Method still shows negative, this indicates some substances interfered, the result should be negative.
4. If both of the Immune Colloidal Method and the Chemical Method show negative, the final result is negative.
5. If any one of the Immune Colloidal Method and the Chemical Method shows invalid, the test result is invalid, please retest with a new one.

Built-In Control

One-Step Fecal Occult Blood (FOB) Diagnostic Kit has a built-in procedural control that demonstrates assay validity. A red line appearing adjacent to the control zone (C) indicates that the test runs correctly.

LIMITATION

1. Specimen collection should not be performed during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine, false-positive test results may be obtained.
2. If the subjects ate meat, pluck or chalybeate food within 3 days, the Chemical Method test result may show positive. Please pay attention to the result and confirm again.
3. Interference substance in the samples or failed operation may cause false result. Please retest with a new one or use other way to confirm.
4. The test can not diagnose pathological changes in gastrointestinal tract bleeding, only for screening test. The test results can not instead of endoscopy, X-ray and other clinical analysis. For the positive result, please confirm the result by other clinical examination.
5. Negative results do not exclude bleeding since it can be intermittent.
6. Colorectal polyps at very early stages may not bleed.
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Analytic Sensitivity: 0.2μg/mL for Immune Colloidal Method; 2μg/mL for Chemical Method

Analytic Specificity: For Immune Colloidal Method, 0.5mg/mL hemoglobin solution of pig, beef, sheep, dog, chicken and rabbit; 2mg/mL horse radish peroxidase sample; water and sample diluent were shown not to interfere with FOB test by Immune Colloidal Method. There is no cross react with water and sample diluent for Chemical Method. The 1.66μmol/L acetaminophen, 206μmol/L amoxicillin, 227μmol/L ascorbic acid, and 26.1μmol/L para-aminosalicylic acid were shown not to interfere with FOB test by Immune Colloidal Method.

Precision

In the enterprise internal control study, 10 replicate assays were performed with precision sample. The time and intensity of the test result was totally the same.

Clinical Study

The study included 116 positive and 126 negative patient fecal sample confirmed with routine diagnostic method were tested against Fecal Occult Blood (FOB) Diagnostic Kit.

Table 1 Results of Performance

Method		One-Step Fecal Occult Blood (FOB) Diagnostic Kit		Total Results
Other FOB Rapid Test	Results	Positive	Negative	
	Positive	111(A)	5(B)	116
	Negative	1(C)	125(D)	126

Sensitivity=A/(A+B)*100%=95.7%
Specificity=D/(C+D)*100%=99.2%

REFERENCE

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INDEX OF SYMBOLS

	Do not re-use
REF	Catalogue number
IVD	For In Vitro Diagnostic medical device
	Use by date
	Date of manufacture
4 C 30 C	Temperature limitation
	Consult instructions for use
EC REP	Authorized Representative in the European Community
LOT	Batch code
Σ n	Contains sufficient for < n > tests
CE 0123	CE Mark
	Manufacturer

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