For the qualitative detection of human occult blood in feces.

INTENDED USE
The FOB Fecal Occult Blood Reagent Strips (Feces) is a dry chemistry assay for the qualitative detection of human occult blood in feces.

SUMMARY
Many diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. The traditional guaiac-based method lacks sensitivity and specificity, and has diet-restrictions prior to testing. The FOB Fecal Occult Blood Reagent Strips (Feces) can qualitatively detect low amounts of fecal occult blood in human feces. The test can detect hemoglobin levels as low as 0.5 mg/dL. The accuracy of the test is affected by the diet of the patients.

PRINCIPLE
The FOB Fecal Occult Blood Reagent Strips (Feces) is a qualitative, chemical assay for the detection of human occult blood in feces. This test is based on the peroxidase-like activity of hemoglobin. Hemoglobin catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The color of the test pad will change from yellow to green or dark blue.

REAGENTS
The test pad contains 3,3',5,5'-tetramethylbenzidine (TMB), diisopropylbenzene dihydroperoxide, and other non-reactive ingredients.

PRECAUTIONS
- For in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The strip should remain in the closed canister until use.
- Do not touch the reagent area of the strip.
- Discard any discolored strips that may have deteriorated.

SPECIMEN COLLECTION AND PREPARATION
- Best results will be obtained if the assay is performed within 6 hours after collection. Specimens collected may be stored for 3 days at 2-8°C if not tested within 1 hour.
- Specimen prepared in the specimen extraction tube may be stored for 3 months at -20°C if not tested within 1 hour after preparation.
- From 3 days before starting the test until the test period begins. Avoid eating raw meat and sausage to prevent false-positive results.
- False-negative results may be caused by consuming Vitamin C.
- Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.
- Patients should eat as much high fiber roughage as possible starting 3 days before test until the test period begins. Avoid eating raw meat and sausage to prevent false-positive results.
- The test is not intended for use with urine, gastric specimens or other body fluids.

EXPECTED VALUES
The expected test results are negative. Any positive result may be a symptom of colorectal cancer, polyps, colitis, diverticulitis, fissures, or other gastrointestinal issues and should be confirmed by a physician.

PERFORMANCE CHARACTERISTICS
Sensitivity
The FOB Fecal Occult Blood Reagent Strips (Feces) can detect levels of human occult blood as low as 0.5 mg/dL hemoglobin. Positive rates vary with immunochemical fecal occult blood tests. They vary in each patient population depending on the age, ethnicity, test used, and predisposition to colorectal disease or factors associated with gastrointestinal bleeding.

Clinical Evaluation
The FOB Fecal Occult Blood Reagent Strips have been compared with another leading commercial chemical rapid test. The correlation between the two systems is 98%.

BIBLIOGRAPHY

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