DIALAB Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
A – 2351 Wiener Neudorf, Austria, IZ-NÖ Süd, Hondastrasse, Objekt M55
Phone: ++43 (0) 2236 660910-0, Fax: ++43 (0) 2236 660910-30, e-mail: office@dialab.at

"DIAQUICK" FOB Cassette
(Fecal Occult Blood)

for the determination of human hemoglobin in human feces

REF	Content
Z01101CE	- 25 tests individually packed (25 x Ref. No: Z01101B) - 25 collection tubes incl. buffer - 1 package insert
Z01102CE	- 5 tests individually packed (5 x Ref. No: Z01101B) - 5 collection tubes incl. buffer - 1 package insert
Z01101B	- 1 test individually packed - 1 collection tube incl. buffer - 1 package insert

For in vitro diagnostic use only

GENERAL INFORMATION

Method	Sandwich type immunochromatographic assay
Shelf life	24 months from date of production
Storage	2 – 30 °C
Sample	human fecal samples
Results	after 5 min., do not read after 10 min.
Sensitivity	40 ng/mL Hb

INTENDED USE

The „DIAQUICK" FOB Cassette is a rapid, visual immunochromatographic test for the qualitative detection of human blood hemoglobin in fecal samples. This test is intended as an aid in the diagnosis of lower gastrointestinal (g.i.) disorders. The test is for in vitro diagnostic use only.

CLINICAL SIGNIFICANCE

The principal use of the „DIAQUICK" FOB Cassette is to screen for lower g.i. pathologies, such as colorectal cancers and large adenomas that bleed. Colorectal cancer is one of the most commonly diagnosed cancers and a leading cause of cancer death in the United States (Liebermann, 1994; MMWP, 1995). Screening for colorectal cancer probably increases the cancer detection at an early stage, therefore reduces the mortality (Dam et.al. 1995; Miller, 1995 and Lang, 1996). Earlier commercially available FOB tests utilized the guaiac test, which requires special dietary restriction to minimize false positive and false negative results. The „DIAQUICK" FOB Cassette is specially designed to detect human hemoglobin in fecal samples by thin layer chromatography, which improved specificity for the detection of lower g.i. disorders, including colorectal cancers and adenomas (Frommer et. al., 1988; St.John et. al., 1993).

TEST PRINCIPLE

The „DIAQUICK" FOB Cassette (Feces) is a qualitative, lateral flow immunoassay for the detection of human occult blood in feces. The membrane is pre-coated with anti-hemoglobin antibody on the test line region of the device. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibody on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

WARNINGS AND PRECAUTIONS

- For professional 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.

STORAGE

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

MATERIALS PROVIDED

- "DIAQUICK" FOB Cassette
- specimen collection tube with extraction buffer
- package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- specimen collection container
- timer

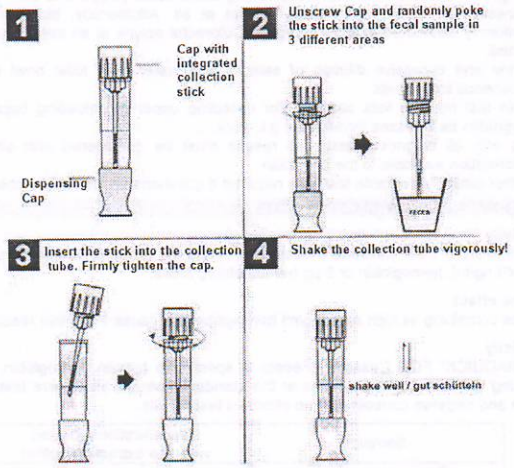
SAMPLE COLLECTION AND PREPARATION

- Specimen should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
- 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.
- Dietary restrictions are not necessary.

DIRECTIONS FOR USE

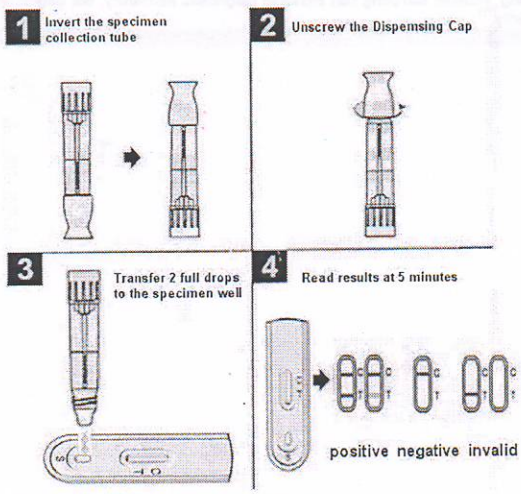
Allow test device, specimen collection tube, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. To collect fecal specimen:
   - Collect feces in a clean, dry specimen collection container. Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours.
   - For a better detection of sporadic bleedings it is recommended to collect fecal samples on 3 days in a row and from 3 consecutive defecations respectively.
2. To process fecal specimen:
   - Unscrew the cap of the specimen collection tube, then randomly poke the specimen collection stick into the fecal specimen on at least 3 different sites. Do not scoop the fecal specimen.
   - Screw on and tighten the cap to the specimen collection tube.
   - Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimen prepared in the specimen collection tube may be stored for 3 days at room temperature (15-30°C) if not tested within 1 hour after preparation.



ASSAY PROCEDURE

1. Remove the test device from the sealed pouch and use it as soon as possible.
2. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approx. 100µL) to the specimen well (S) of the test device, then start the timer. Avoid trapping air bubbles in the specimen well.
3. Wait for the red line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

POSITIVE:* Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).
*NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of hemoglobin present in the specimen. Therefore, any shade in the test region indicates positive result.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test and contact your local distributor.

Digitally signed by Turchevici Valeriu
Date: 2019.11.20 18:53:47 EET
Reason: MoldSign Signature
Location: Moldova

QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability. The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

LIMITATIONS

1. This test kit is to be used for the qualitative detection of human hemoglobin in fecal samples. A positive result suggests the presence of human hemoglobin in fecal samples. The presence of blood in stools may be due to several causes, besides colorectal bleeding, such as hemorrhoid, blood in urine or stomach irritations.
2. The „DIAQUICK" FOB Cassette (Feces) is for in vitro diagnostic use only.
3. Not all colorectal bleedings may not be due to precancerous or cancerous polyps. The data obtained by this test should be used in conjunction with other clinical findings and testing methods, such as barium enema, sigmoidoscopy or colonoscopy.
4. The „DIAQUICK" FOB Cassette (Feces) will only indicate the presence of human hemoglobin in the specimen. The presence of blood in feces can also have other reasons than colorectal bleeding.
5. Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
6. Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results.
7. This test may be less sensitive for detecting upper g.i. bleeding because blood degrades as it passes through the g.i. track.
8. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
9. Other clinically available tests are required if questionable results are obtained.

PERFORMANCE CHARACTERISTICS

Sensitivity
The „DIAQUICK" FOB Cassette (Feces) can detect the levels of human occult blood as low as 40 ng/mL hemoglobin or 5 µg hemoglobin/g feces.

Prozone effect
Samples containing as high as 1 mg/ml hemoglobin still cause a positive result.

Specificity
The „DIAQUICK" FOB Cassette (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration were tested on both positive and negative controls with no effect on test results.

Sample	Concentrations (diluted with the extraction buffer)
Bovine hemoglobin	1 mg/mL
Chicken hemoglobin	1 mg/mL
Pork hemoglobin	1 mg/mL
Goat hemoglobin	1 mg/mL
Horse hemoglobin	1 mg/mL
Rabbit hemoglobin	1 mg/mL
Turkey hemoglobin	1 mg/mL

Please note: the Performance Characteristics of the Test were determined for singular sampling. Multiple sampling can increase diagnostic sensitivity, but decrease diagnostic specificity.

EXPECTED VALUES

The „DIAQUICK" FOB Cassette (Feces) has been compared with another leading commercial rapid test. The correlation between these two systems is 98%.

REFERENCES

1. Dam, J.V., et al.; Fecal Blood Screening for Colorectal Cancer; Archive of Internal Medicine; (1995) 155: 2389 – 2402.
2. Frommer, D.J. et. al.; Improved Screening for Colorectal Cancer by Immunological Detection of Ocult Blood; British Medical Journal, (1988) 296: 1092 – 1094.
3. Liebermann, D.; Screening/Early Detection Model for Colorectal Cancer, Why Screen? Cancer Supplement; (1994) 74(7): 2023 – 2027.
4. Miller, A.B.; An Epidemiological Perspective on Cancer Screening; Clinical Biochemistry (1995) 28 (1): 41 – 48.
5. Ransohoff, D.F. and Lang, C.A.; Improving the Fecal Occult-Blood Test; The New England Journal of Medicine; (1996) 334 (3):189-190.
6. Screening for Colorectal Cancer – United States, 1992 – 1993 and New Guidelines; Mobility and Mortaliy Weekly Report; (1995) 45 (5): 107 – 110
7. St. John, D.J.B., et. al.; Evaluation of New Occult Blood Test for Detection of Colorectal Neoplasia; Gastroenterology; (1993) 104:1661 – 1668