Fecal occult blood (FOB) Rapid Test（Fluorescence immunoassay)

User manual

【Product name】

Fecal occult blood (FOB) Rapid Test（Fluorescence immunoassay)

【Package specification】

25 Tests/kit

【Intended use】

This kit is used for quantitative determination of CEA in human whole blood, plasma and serum.

Carcinoembryonic antigen (CEA) is a tumor associated antigen, first described in 1965 by Gold and Freedman1. It is a cell-surface glycoprotein with a molecular weight of 180-200kD, that occurs in high levels in colon epithelial cells during embryonic development. Levels of CEA are significantly lower in colon tissue of adults, but can become elevated when inflammation or tumours arise in any endodermal tissue, including the gastrointestinal tract, respiratory tract, pancreas and breast.

An over expression of CEA protein has been detected in a variety of adenocarcinomas, including gastric, pancreatic, small intestine, colon, rectal, ovarian, breast, cervical and non-small-cell lung cancers. CEA is also expressed by epithelial cells in several non-malignant disorders, including diverticulitis, pancreatitis, inflammatory bowel disease, cirrhosis, hepatitis, bronchitis and renal failure and also in heavy smokers.

Therefore CEA should not be regarded as a tumour-specific marker for the screening of a general population for undetected cancers. However, the determination of CEA levels provides important information about patient prognosis, recurrence of tumours after surgical removal and effectiveness of therapy.

【Inspection principle】

The CEA Rapid Test is a one-step chromatographic sandwich immunoassay designed for the quantitative measurement of CEA. The CEA antigen in the sample was first bound with the conjugated compound of fluorescent labeled CEA monoclonal antibody, then moved and combined with another CEA monoclonal antibody fixed on the nitrocellulose membrane, and the double antibody sandwich complex was formed at the detection line of the cellulose nitrate membrane. The quantitative detection results were obtained by NIR-1000 dry fluoroimmunoassay analyser.

【Components】

Name	Quantity	Component
Test cards	25	It is composed of fluorescent pad (coated with fluorescent labeled CEA monoclonal mouse antibody), nitrocellulose membrane (coated with CEA monoclonal mouse antibody and Goat anti mouse IgG antibody), absorbent paper and backing
Sample diluent	25（300μL/tube）	Phosphate buffer
ID card	1	With specific stand curve file

The components in different batches of kits cannot be used interchangeably.

【Storage conditions and validity】

The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20% ~ 90% relative humidity.

The production date, batch number and expiration date are shown in the outer package of the product.

【Applicable instruments】

Nir-1000 dry fluorescent immunoassay analyzer produced by WWHS Biotech. Inc.

【Sample requirements】

1. Plasma, serum and whole blood can be used as samples. The whole blood should be collected in a tube containing heparin, citrate or EDTA as the anticoagulant. If the serum procedure is used, collect blood in a tube without anticoagulant and allow clotting. Hemolyzed samples should not be used.
2. Venous blood was collected according to routine laboratory methods to avoid hemolysis.
3. It is highly recommended to use fresh samples instead of keeping the samples at room temperature for a long time. After samples were collected, the detection should be completed within 4 hours at room temperature (15℃~30℃). The whole blood sample can be stored at 2℃ ~8℃ for 24 hours. Plasma and serum samples can be stored at 2℃~ 8℃ for 7 days, -20℃for 30 days.
4. Before testing, the sample should return to room temperature (15℃~30℃). The frozen samples should be completely thawed, rewarming and mixed evenly before use. Repeated freeze-thaw cycles should be avoided.

【Procedure】

1. Before the test, please read the instructions completely. If the test card and sample are stored in cold storage, they should be balanced at room temperature (15-30)℃ for not less than 30min before use.
2. Start NIR-1000 dry fluoroimmunoassay analyser according to the instruction manual of the instrument, and carry out quality control verification according to the instruction manual of the instrument （ Note: the reagent has been calibrated in advance, and the calibration curve parameters of each batch of reagent have been stored in the information card. The information card is inserted before use, so it is not necessary to calibrate again, and the test can be carried out only after the quality control is passed. Otherwise, the cause should be found out before testing.)
3. Remove the test card from the aluminum foil bag and use it within 15 minutes.
4. Place the test card on a clean horizontal table and mark it horizontally.
5. Mix 100 μL of patient sample with 300μL of sample diluent. Apply 100 μL of diluted samples to the well of the test card.
6. Insert the test card into NIR-1000 dry fluoroimmunoassay analyser, read and record the results at 15 minutes after addition of samples, then dispose of used test appropriately.

【Reference interval】

Normal persons who do not smoke: 95% had values less than 5 ng/ml. The normal reference value is 5ng/ml in this assay. It is recommended that each laboratory should establish its own normal range based on a representative sampling of the local population.

【Interpretation of results】

1. This reagent is only used for auxiliary detection. If the test results are abnormal, it should be reviewed in time and judged in combination with clinical symptoms.
2. For samples with CEA concentration lower than 1ng/ml and higher than 200ng/ml, the detection results are reported as "< 1ng/ml" and "> 200ng /ml", respectively.

【Limitations of methods】

1. This kit is only used to detect human plasma/whole blood samples
2. Due to the limitations of immunoassay methods of antigen and antibody reaction, the results cannot be used as the only basis for clinical diagnosis, but should be evaluated with all the existing clinical and experimental data.
3. The content of triglyceride in the sample shall not exceed 15mg/ml, the content of hemoglobin shall not exceed 5mg/ml, and the content of bilirubin shall not exceed 0.5mg/ml, and the relative deviation of the test results shall not exceed ±15%。
4. When the concentration of CEA in the sample is less than 20000ng/ml, there is no hook effect.
5. HAMA effect was not produced when the concentration of human anti rat in the sample was less than 50ng/ml.
6. When RF concentration in the sample is less than 2000IU/ml, the relative deviation of the test results is within ±15%.

【Performance】

1. Limits of detection

No more than 1ng /ml.

2. Accuracy

The relative deviation from the target value is within ±15%.

3. Precision

The within and between assay coefficient of variations are within 15%.

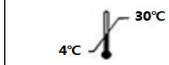
4. Linear range

Within the linear range (1 ~ 200ng/ml), the linear correlation coefficient R≥0.990.

【Note】

1. This kit is only used for in vitro diagnosis.
2. The test card and sample diluent are disposable and cannot be reused.
3. Please check the integrity and validity of the kit package before use, and then open the package. When it is stored at low temperature, it should be restored to room temperature (15℃ ~ 30℃) before opening the package for use. The reagents with damaged inner package and beyond the validity period cannot be used.
4. The requirements of specimen collection and storage should be strictly observed. If the specimen is turbid, it should be centrifuged and discarded before use.
5. The used kits should be treated as potential infectious substances, and all samples, reagents and potential pollutants should be disinfected and treated according to the relevant local regulations.

【Interpretation of signs】

	Storage temperature		Non reusable
	Avoid light	IVD	In vitro diagnostic reagents
	moisture-proof		See instruction manual

【Reference】

[1] Gold, P. and Freedman, S.O., Demonstration of Tumor-specific antigens in human colonic carcinomata by immunological
tolerance and absorbtion. J. Exp. Med. 121:439, 1965.

[2] Khoo SK and MacKay FR. Carcinoembryonic antigen in serum in diseases of the liver and pancreas. J. Clin. Path. 1973; 26: 470-475.

[3] Laurence DJR, Stevens U, and Bellelheim R et al. Evaluation of the role of carcinoembryonic antigen in the diagnosis of gastro-intestinal, mammary and bronchial carcinoma. Br Med J 1972; 3: 605-609.

[4] Moore TL, Kupchik HZ, Marcon N, and Zamchek N. Carcinoembryonic antigen assay in cancer of the colon and pancreas and other digestive tract disorders. Am. J. Dig Dis 1971; 16: 1-7.

[5] Vincent RG, Chu TM, Fergen TB, and Ostrander M. Carcinoembryonic antigen in 228 patients with carcinoma of the lung. Cancer 1975; 36: 2069-2076.

【Essential information】

Registered/manufacturer name: WWHS Biotech. Inc

Address: 505, building 1, Shenzhen Biomedical Innovation Industrial Park, 14 Jinhui Road, Kengzi street, Pingshan New District, Shenzhen

Contact: 0755-84235529

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