

Carbohydrate Antigen 125 (CA125) Rapid Quantitative Test (Fluorescence immunoassay)

User manual

【Product name】

Carbohydrate Antigen 125 (CA125) Rapid Quantitative Test (Fluorescence immunoassay)

【Package specification】

25 Tests/kit、40 Tests/kit

【Intended use】

This kit is used for quantitative determination of CA125 in human whole blood, plasma and serum.

CA125 is a high molecular weight mucin type glycoprotein, originally defined by the CA12-5 monoclonal antibody (MAb) established by Bast et al. CA125 is a protein that is a so-called tumor marker or biomarker, which is a substance that is found in greater concentration in tumor cells than in other cells of the body. In particular, CA125 is present in greater concentration in ovarian cancer cells than in other cells. It was first identified in the early 1980s, and the function of the CA125 protein is not currently understood.

CA 125 is usually measured from a blood sample. It can also be measured in fluid from the chest or abdominal cavity. The tests currently in use are all based upon the use of an antibody that is directed against the CA 125 protein (monoclonal antibody technique).

CA125 has proved especially valuable to oncologists in both detection of ovarian cancer and disease monitoring of ovarian cancer patients.

【Inspection principle】

The CA125 Rapid Test is a one-step chromatographic sandwich immunoassay designed for the quantitative measurement of CA125. The CA125 antigen in the sample was first bound with the conjugated compound of fluorescent labeled CA125 monoclonal antibody, then moved and combined with another CA125 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	25/40	It is composed of fluorescent pad (coated with fluorescent labeled CA125 monoclonal mouse antibody), nitrocellulose membrane (coated with CA125 monoclonal mouse antibody and Goat anti mouse IgG antibody), absorbent paper and backing
Sample diluent	25/40	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°C~30°C, 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°C~30°C and 20% ~ 90% relative humidity.

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

【Applicable instruments】

Mod:NIR-1000 Dry Fluoroimmunoassay Analyser 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°C~30°C). The whole blood sample can be stored at 2°C~8°C for 24 hours. Plasma and serum samples can be stored at 2°C~8°C for 7 days, -20°C for 30 days.
4. Before testing, the sample should return to room temperature (15°C~30°C). 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)°C 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 10 minutes after addition of samples, then dispose of used test appropriately.

【Reference interval】

Normal healthy adult women who did not suffering from ovarian cancer, 95% had CA125 values less than 35U/mL. 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 CA125 concentration lower than 20U/mL and higher than 500U/mL, the detection results are reported as "< 20U/mL" and "> 500U/mL", respectively.

【Limitations of methods】

1. This kit is only used to detect human plasma/ serum and whole blood samples

- 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.
- 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 $\pm 15\%$.
- When the concentration of CA125 in the sample is less than 20000ng/mL, there is no hook effect.
- HAMA effect was not produced when the concentration of human anti rat in the sample was less than 50ng/ml.
- When RF concentration in the sample is less than 2000IU/mL, the relative deviation of the test results is within $\pm 15\%$.

【Performance】

1. Limits of detection

No more than 20U/mL.

2. Accuracy

The relative deviation from the target value is within $\pm 15\%$.

3. Precision

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

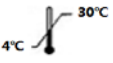




4. Linear range

Within the linear range (20-500U/mL), the linear correlation coefficient $R \geq 0.990$.

【Note】

- This kit is only used for in vitro diagnosis.
- The test card and sample diluent are disposable and cannot be reused.
- 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 ($15^{\circ}\text{C} \sim 30^{\circ}\text{C}$) before opening the package for use. The reagents with damaged inner package and beyond the validity period cannot be used.
- The requirements of specimen collection and storage should be strictly observed. If the specimen is turbid, it should be centrifuged and discarded before use.
- 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】

	Temperature limit		Do not re-use
	Keep away from sunlight	IVD	In vitro diagnostic medical device
	Keep dry		Consult instructions for use

【Reference】

- BAST R C Jr, KLUG T L, ST J E, et al. A radioimmunoassay using a monoclonal antibody to monitor the course of epithelial ovarian cancer[J]. N Engl J Med, 1983, 309(15): 883-887.
- van Dalen A, Favier J, Burges A, et al. Prognostic significance of CA 125 and TPS levels after 3 chemotherapy courses in ovarian cancer patients. Gynecol Oncol 2000; 79: 444-450.
- Bast RC. Jr, Xu F-J, Yu Y-H, et al. CA 125: the past and the future. Int J Biol Markers 1998; 13: 179-187.
- Yin BWT, Lloyd KO. Molecular cloning of the CA 125 ovarian cancer antigen: identification as a new mucin, MUC 16. J Biol Chem 2001; 276: 27371-27375.

【Basic Information】

Registrant/Manufacturer: WWHS Biotech.Inc.

Address: Rm 505, 1st Building, Shenzhen Biomedicine Innovation Industrial Park, No. 14th, Jinhui Road, East Jinxiu Road, Kengzi Street, Pingshan District, Shenzhen, Guangdong, P.R. China

Contact: 0755-84235529

Name of after sales service unit: WWHS Biotech. Inc

Contact information: 0755-84235529

Production address: Rm 505, 1st Building, Shenzhen Biomedicine Innovation Industrial Park, No. 14th, Jinhui Road, East Jinxiu Road, Kengzi Street, Pingshan District, Shenzhen, Guangdong, P.R. China

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