Instruction for Alpha Fetoprotein (AFP) Test Kit (Immunofluorescence)

1. PRODUCT NAME

Generic name: Alpha Fetoprotein (AFP) Test Kit (Immunofluorescence)

Trade name: AFP.

2. PACKAGE

Specification 1: 25T/kit REF: 52026122

Specification 2: 50T/kit REF: 52027117

Quality Control (optional):

Level 1: 0.5mL × 1 REF: 52105102

Level 2: 0.5mL × 1 REF: 52105103

Level 3: 0.5mL × 1 REF: 52105104

3. INTENDED USE & INDICATION

For in vitro quantitative determination of AFP level in human serum, plasma or whole blood. Clinically, it is mainly used for auxiliary diagnosis, efficacy observation and prognosis of primary liver cancer.

For professional use only.

4. TEST PRINCIPLE

This kit adopts the antibody sandwich method. After the samples containing AFP are fully mixed with the sample diluent, an appropriate amount of the solution is taken and added into the sample well. The AFP in the sample binds to the AFP monoclonal antibody coupled to the fluorescent particles to form a fluorescent particle-antibody-antigen complex. This immune complex is then chromatographed along the nitrocellulose membrane to the determination area (T), combined with the pre-coated AFP monoclonal antibody and continues to chromatograph to the quality control area (C). The fluorescent particle-labeled goat anti-rabbit IgG binds to the precoated rabbit IgG and presents the quality control line. The fluorescence intensity of the assay area is directly proportional to the level of AFP in the sample.

5. MAIN COMPONENTS & ADDITIONAL REQUIRED EQUIPMENT

The test kit consists of test card, magcard, sample diluent, quality control (optional) and the instruction.

(1) The test card consists of card shell and test strip. The test strip contains sample pad/marking pad, nitrocellulose membrane, absorbent paper and PVC plate.

(2) Magcard: load calibration curve information for this batch of reagents.

(3) Sample diluent: the main ingredient is phosphate buffer (PBS). It is portioned into 1.0 mL per tube for each test.

(4) Quality control (optional): Self-prepared lyophilized powders, mainly consist of AFP recombinant antigen and PBS. All are free of human-derived substances and have batch specificity. Please find target values in the target value list.

(5) Equipment: applicable to FA50 and FA120 Quantitative Immunoassay Analyzer manufactured by Genrui Biotech Inc.

Note: Components of kits from different batches should not be used interchangeably.

6. ACCESSORIES REQUIRED BUT NOT PROVIDED

(1) Pipettes and pipette tips: 100 μL

(2) Timer

7. SPECIAL STORAGE & TRANSPORT CONDITIONS

(1) The test kit should be stored at 2-30℃, and the shelf life of test cards and sample diluent is 18 months when sealed. After the test card and sample diluent are opened, the shelf life is 1 hour at 18-30℃ and 40%-65% humidity. When the humidity is > 65%, it should be used right after opened.

(2) The unopened QC is stable for 18 months (see the label for specific date) at -25℃ to 8℃, the reconstituted QC is stable for 6 days at -20℃ or 1 day at 2-8℃ in the shade, and can be freeze-thawed once.

(3) Transport: The test kit is at 2-30℃, the QC is at -25℃-8℃.

8. SAMPLE REQUIREMENTS

(1) The optimal sample is fresh non-hemolyzed serum, plasma or whole blood. It is recommended to use sample from venous blood, as results of other body fluids and samples may not be accurate.

(2) Serum/plasma: After sample collection, serum should be separated as soon as possible to avoid hemolysis. Serum and plasma should complete the test within 6 hours at room temperature. The samples that cannot complete the test should be refrigerated at 2-8℃ for no more than 7 days; serum and plasma should be frozen below -18℃ for no more than 1 month.

(3) Whole blood: It should be used immediately after collection. If it cannot be tested within 4 hours, it should be refrigerated at 2-8℃ for no more than 3 days. Samples should not be frozen.

(4) The samples should be brought to room temperature before determination. The frozen samples should be completely thawed, rewarmed and mixed well before use. Do not freeze and thaw repeatedly.

(5) Human serum is preferred for determination, and sodium citrate or EDTA-K_2 is recommended as an anticoagulant for plasma and whole blood testing.

9. TEST METHOD

Carefully read the instruction before using the test kit and strictly follow the instruction to ensure reliable results. Bring all reagents to room temperature (18-30℃) before use.

(1) Startup: Click “STD Mode” in the main menu to enter the measurement interface, click “Item” to select the test item and click “Type” to select the sample type.

(2) Click “Lot No.” to enter the card reading interface, place magcard of the corresponding item to the magnetic card reader area, when the magcard is read successfully, check whether the magcard and the test card are of the same batch. (Note: reagents are precalibrated and specific calibration curve parameters for each batch of reagents have been stored in the magcard.)

(3) Quality control procedure: It is recommended to refer to the instrument manual and use the Genrui quality control to verify whether the target value of the test quality control is under control during the measurement procedure after calibration. The quality controls should be used as follows.

a）Bring the quality control to room temperature (18-30°C) before use.

b）Carefully open the bottle cap to avoid spraying of the contents.

c）Add 0.5 mL of purified water.

d）Put on the bottle cap and leave it at room temperature for 15 minutes, gently shake the bottle to fully dissolve the dry powder.

e）After the dry powder is fully dissolved, repeat the operation for the sampling.

If the measured values of quality controls are within the given range of target values, the determination of clinical samples and data analysis can be continued; otherwise, the causes should be identified before test.

(4) Sampling:

Add 0.1mL of serum, plasma or whole blood into the container with sample diluent, mix thoroughly. Take 0.1mL of diluted sample, and drop it vertically to the sample well on the test card directly and start timing.

(5) Insert it into the analyzer’s test card slot (the sample well end towards the inside). Click “Measure”, the instrument will automatically detect and print out the results after 15 minutes (If using “Fast Mode”, after 15 minutes of external incubation, quickly insert card and click “Measure”, then instantly the instrument will detect and print out the results).

Note: For detailed instructions on how to operate the instrument, please refer to the

manual of Quantitative Immunoassay Analyzer.

10. REFERENCE RANGE

Reference range: 0-20 ng/mL

Note: Due to geographical, ethnic, gender and age differences, it is recommended that each laboratory establishes its own reference range.

11. **EXPLANATION FOR TEST RESULTS**

(1) When the control area (C) appears fluorescent strips, the analyzer will automatically detect the fluorescence and analyze the test card, and then provide quantitative results.

(2) When the control area (C) does not appear fluorescent strips, the analyzer cannot detect the fluorescence and alarm will be activated automatically, indicating that the operation is incorrect or the test card is damaged. In this case, carefully read the instructions again and re-test with a new test card, if the problem still exists, immediately stop using products of this batch and contact your supplier.

(3) When the measured value of the sample is higher than 300 ng/mL, the instrument shows > 300 ng/mL, and when the measured value of the sample is less than 5 ng/mL, the instrument shows < 5 ng/mL.

(4) This test kit does not produce Hook Effect within 2000 ng/mL.

12. DETECTION LIMIT

(1) This test kit is for in vitro diagnostic use only.

(2) Diagnosis and treatment can not solely base on this test result, please taking into account the clinical history and other laboratory test results. Each laboratory is recommended to establish its own reference range based on its patient population.

13. INTERFERING SUBSTANCE

(1) Hemoglobin, bilirubin, cholesterol, triglyceride, total protein, HAMA and rheumatoid factor in samples can interfere with the test results, the maximum allowable concentration of hemoglobin is 2.2 g/dL, bilirubin is 65 mg/dL, cholesterol is 1000 mg/dL, triglyceride is 1500 mg/dL, total protein is 500 g/L, HAMA is 1000 ng/mL, rheumatoid factor is 1500 IU/mL.

(2) No cross reaction occurs for the potential cross-reactants below :carcinoembryonic antigen(CEA), prostate specific antigen(PSA), troponin I(TnI), albumin, tissue polypeptide specific antigen(TPS), carbohydrate antigen 125(CA125), carbohydrate antigen 153(CA153), carbohydrate antigen 199(CA199), carbohydrate antigen 242(CA242), carbohydrate antigen 724(CA724), carbohydrate antigen 50(CA50), β-human chorionic gonadotropin(β-HCG), squamous cell carcinoma antigen(SCC)..

14. PRODUCT PERFORMANCE INDICATORS

(1) Limit of detection: 5 ng/mL

(2) Linearity range: 10-300 ng/mL (Linear correlation coefficient: r ≥ 0.9900)

(3) Precision: intra-batch precision: CV ≤ 15%; inter-batch precision of the kit CV ≤ 20%

(4) Accuracy: -15% ≤ Bias% ≤ +15%

(5) QC precision: CV ≤ 15%

(6) Expected results of QC: the test results shall be within the target range

(7) Moisture content: the moisture content of the QC (lyophilized powder) is ≤ 10%

15. PRECAUTIONS

(1) Once opened, use the test cards as soon as possible, which may be exposed to moisture in the air. Do not reuse the test cards.

(2) Components in test kit of different batches cannot be used interchangeably.

(3) For substances containing sources of infection or suspected of containing sources of infection, there should have proper bio-safety assurance procedures. Pay attention to the following notes:

-- Wear gloves when handling sample or disinfecting the reagent.

-- Disinfect spilled sample or reagent with disinfectant.

-- Disinfect or handle potential contamination sources of all samples or reagents in accordance with local regulations.

16. EXPLANATION OF GRAPHIC SYMBOL

	Consult instructions for use		Temperature limit
LOT	Batch code		Use-by date
IVD	*In vitro* diagnostic medical device	CE	CE Marking
	Date of manufacture		Biological risks
	Manufacturer		Volume
Σ	Contains sufficient for < n>tests		Keep away from sunlight
	Do not re-use		Keep dry
EC REP	Authorized representative in the European community	REF	Catalogue number

17. REFERENCE

(1) Wespic, H.C. Alpha-fetoprotein: its quantification and relationship to neoplastic disease, ppp 115-129 In Alpha fetoprotein, Laboratory Procedures and Clinical Applications, Kirkpatirck, A. and Nakamuram R (eds.), Masson Publishing, New York (1981) After Radical Prostatectomy. J. Urol. 142:1082- 90 (1989).

(2) Mcintire, K.R., Waidmann, T.A., Moertel, C.G. and Go, V.L.W. Serum alpha-fetoprotein in patients with neoplasms of the gastrointestinal tract. Cancer Res. 35:991-996 (1975).

(3) Javadpouf, N., Mcintire, K.R. and Waidmann, T.A. Human chorionic gonadotropin (HCG) and alpha-fetoprotein (AFP) in sera and tumor cells of patients with testicular seminoma. Cancer 42:2768-2772. (1978).

18. METROLOGICAL TRACEABILITY

The kit is traceable to the certified reference material WHO 72/225.

19. HELP INFORMATION

If you need help, please contact after sales department.

20. MANUFACTURER

Genrui Biotech Inc.

Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China.

21. INSTRUMENTS & APPLICATIONS

Genrui's Immunofluorescence products are designed to work in automated lab, which are compatible with the FA50/FA120 Quantitative Immunoassay Analyzer. There may or may not be an application developed for your particular instrument, please visit the instrument section of our website.

IVD CE EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd
2595AA, The Hague, Netherlands
Email:peter@lotusnl.com