α-Fetoprotein Assay Kit(AFP)

Method:Latex Immunoturbidimetric Method

Cat.NO.	Package Size
GB8020G	R1:2×15 ml R2:1×15 ml
GS8021G	R1:2×15 ml R2:1×15 ml
GT8021G	R1:2×15 ml R2:1×15 ml

This assay kits apply to biochemistry analyzers: Hitachi7180/7080/7060/7020,AU400/5800,TBA40FR,D XC800,Bayer1800, Dimension RXL Max, etc.

INTENDED USE

For the quantitative in vitro of AFP in human serum or plasma. Fetoprotein is the most important diagnostic indicators of primary liver cancer, mainly used for patients with primary liver cancer has been diagnosed with dynamic monitoring to determine disease progression or treatment of secondary effects.

CLINICAL SIGNIFICANCE

Alpha-fetoprotein (AFP) is a fetuin, which contains 3% sugar and molecular weight is about 70,000. AFP is abound in the fetal period , decreased rapidly after birth, the serum level is minimal in normal person. Fetoprotein is the most important diagnostic indicators of primary liver cancer, for it sharply rises in patients with primary liver cancer. Diagnosis of hepatocellular carcinoma (HCC) by Fetoprotein, not only to observe its absolute value, but also to observe the dynamic changes, the dynamic changes of AFP are:

sustained high concentration type : diagnostic specificity is high, the majority of them are middle or advanced liver cancer;

saddle -shaped, which is rare,but easily missed. The liver cancer often have significant performance when AFP elevated in the peak of the saddle;

3)a sharp rise type : which is more common in the higher degree of malignancy tumors, spread rapidly, but accidentally AFP rise sharply, accompany decreased rapidly with ALT elevated acute hepatic necrosis;

a steady increase type , regular inspection, steadily increase, is with most diagnostic value;

repeated wave type , which is common in acute and chronic benign liver disease. And AFP concentration elevating and going down in human serum is with great value in disease development, efficiency of liver cancer recurrence and observation.

ASSAY PRINCIPLE

AFP reacts with Hypersensitive AFP antibody latex particles reagent, agglutination reaction occurs, detecting the absorbance at a wavelength of 700 nm, the degree of variation in the sample is with direct proportion of AFP.

REAGENTCOMPOSITON

Contents
Reagent R1：Amino Acetic Acid Buffer
Reagent R2：0.12%w/v hypersensitive AFP antibody Latex particles reagent

SAMPLE COLLECTION AND PREPARATION

Fresh Serum.

STABILITY AND PREPARATION OF REAGENTS

1. Fasting serum taken after centrifugation. After centrifugation, to extract the serum for detection.
2. The reagents should be stored at 2-8°C. Do not freeze. The reagents should be stable when stored as instructed until the expiration date on the label.Please prevent cross-contamination if opened.

ASSAY PROCEDURE

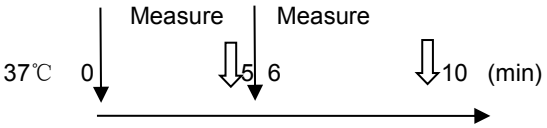
Test Procedure for Analyzers (Hitachi 7180)

Assay Mode: 2 Point End 19-34

Wave length (sub/main): 700nm

Sample 15 µl

R1: 150µl R2: 75 µl



CALIBRATION

We recommend that this assay should be calibrated using Gcell calibrator GC-AFP.

CALCULATION OF RESULTS

$$\text{Concentration} = \frac{\Delta A_{sample}/\text{min}}{\Delta A_{calibrator}/\text{min}} \times \text{Calibrator value}$$

QUALITY CONTROL

Gcell Control (GQ-mAST) is recommended as daily quality control serum. Please confirm the values should be within a specific range. If not, Please check:

1. The instrument settings and light source;
2. Reaction temperature;
3. Expiration date of kit and contents.

REFERENCE RANGE

Serum: < 20ng/ml

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The linear ity range is up to 800ng/mL.

If exceeds the linear range, please dilute it with 0.9% saline, multiply the result by the dilution Factor.

PRECISION

The coefficient of variation (CV) for both Intra assay precision and Inter assay precision is below 10%.

Intra assay precision		
N=20	Sample 1	Sample 2
Mean(U/L)	31.85	110.88
SD	0.77	0.80
CV(%)	2.43	0.72

Beijing Strong Biotechnologies, Inc.
Add: 5/F, KuangYi Building,No.15, Hua Yuan Dong Lu, Haidian District, Beijing 100191, P.R.China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

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Inter assay precision(Level 1)			
N=3	Batch 1	Batch 2	Batch 3
Mean(ng/ml)	23.47	23.9	22
$\overline{X}$	23.12		
(Xmax-Xmin)/ $\overline{X}$	8.22%		

Inter assay precision(Level 2)			
N=3	Batch 1	Batch 2	Batch 3
Mean(ng/ml)	99.5	98.33	99.1
$\overline{X}$	98.98		
(Xmax-Xmin)/ $\overline{X}$	1.18%		

SENSITIVITY
The sensitivity of assay kit is 2.5 ng / ml.

INTERFERENCE
The following analytes were tested up to levels indicated ang found not to interfere:
Bilirubin: up to 60mg/dl
Heparion: up to 40mg/dl
Hemoglobin: up to 1000mg/dl
EDTA: up to 200mg/dl
Sodium citrate: up to 1000mg/dl

CORRELATION
When this method to check the sample with CLIA method simultaneously, the relevant equation is as follows: N = 78, r = 0.993, Y = 0.9239X +4.8628 (Y: The experiment, X: CLIA).

SAFETY PRECAUTIONS AND WARNINGS
1.For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2.Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3.Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4.Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5.Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES
1.Rong Luo,Zhuocheng Li,Jianxiong Chen, Xiongying. Dynamic changes and clinical significance of serum mAST / AST ratio in patients with liver.Journal of Tropical Medicine, 2008, 6(8) :567-569.
2.Lindstrom,F.,Diehl,.h.,Anal.Chem.1960 32:1123
3.Gindler,E.M.,Heth D.A.,ClinChem 1987.17:662

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Beijing Strong Biotechnologies, Inc.
Add: 5/F, KuangYi Building,No.15, Hua Yuan Dong Lu, Haidian District, Beijing 100191, P.R.China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812
Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

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