α-Fetoprotein Assay Kit(AFP)

Method:Latex Immunoturbidimetric Method

INTENDED USE

For the quantitative in vitro of AFP in human serum. 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 abounding 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 rise 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, this is rare, but easily missed. The liver cancer often has 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 630 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 dates on the label.Please prevent cross- contamination if opened.

ASSAY PROCEDURE

Method : Fixed time
Wave length : 630 nm
Delay time : 60 sec
Read time : 300 sec
Method of calibration : Multi standard non-linear
Number of calibrator : 6 calibrator

	Calibrators	Sample
R1	**160 µl**	**160 µl**
Cal.	**15 µl**	**---**
Sample	**---**	**15 µl**
Mix & incubate for 5 min		
R2	**80 µl**	**80 µl**
Mix & aspirate , Delay time 60 sec (A1) & read time 300 sec A2 at 630 nm (generate calibration curve using multi standard Kit)		

CALIBRATION

We recommend that this assay should be calibrated using BIOMED calibrator AFP.

QUALITY CONTROL

BIOMED Control 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 linearity range is 5-800ng/mL.

In the range of 5-800ng/mL, the linear correlation r2≥0.990; in the range of 5～40ng/mL, the bias should be ≤±4ng/mL; in the range of 40 ～ 800ng/mL, the bias should be no more than ±10%.

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

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
Intralipid: up to 500mg/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.,ClinChem1987.17:662

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

EGY- CHEM for lab technology
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