SPECTRUM

The Creative Approach to Bioscience

Reagents for STAT LAB T Analyzer & Auto Chemistry Analyzer

AFP kit

REF:	400 001	50 Tests
R1:		1 x 7.6 ml
R2:		1 x 3.8 ml
REF:	400 002	250 Tests
R1:		1 x 38 ml
R2:		1 x 19 ml

GENERAL

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

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.

This kit is for the quantitative in vitro of AFP in human serum or plasma. 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.

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.

Specimen concentrations of AFP are determined by interpolation from a 6 points calibration curve prepared from calibrators of known concentrations.

REAGENTS

R1: Amino Acetic Acid Buffer solution (< 100 mM), 0.1% sodium azide.

R2: 0.12%w/v hypersensitive AFP antibody Latex particles reagent ready to use.

Calibrator

Different 6 levels of Human serum containing specific amounts of AFP and 0.1% sodium-azide.

Assigned Value: Stated on Calibrator Label.

Storage and Stability

Store all reagents refrigerated at 2-8°C. Unopened reagents are stable up to the expiration date printed on the labels. Opened vials are stable for one month.

Additional Reagents

Control set available upon request

SAMPLES

Fresh Serum

PRECAUTIONS

1. The reagent is for in vitro diagnostic use only.
2. Reagents are liquid stable, ready-to-use reagents. Mix by inverting at least 10 times before use.
3. Do not mix reagents of different lots.
4. **DO NOT FREEZE**.
5. All human specimens should be regarded as potentially Bio hazardous. Therefore, universal precautions should be used in specimen handling (gloves, lab garments, avoid Aerosol production, etc.

PROCEDURE

Wavelength	700 nm
Method	fixed rate
Temperature	37 °C

	Calibrator	Sample
R1 (µL)	150	150
Calibrator(µL)	15	-
Sample (µL)	-	15
Mix and incubate for 5 minutes exactly, then add R2		
R2(µL)	75	75
Read the absorbance (A1) Immediately after 5 minutes Read absorbance (A2)		

CALCULATION

Generate a reference calibration curve using AFP calibrators, Determine (Δ A) Sample and each calibrator:
(Δ A) Sample= A2-A1 sample
(ΔA) Calibrator = A2-A1 for each calibrator
Plot the calibration curve and obtain the results
*Note: for semi-auto chemistry analyzers please adjust the test by double the volumes

Reference Range

Serum: < 20 ng/ml

Calibration example:

Calibrator ng/ml	Absorbance
0	**-0.008**
22.4	**0.017**
97.0	**0.053**
190.0	**0.117**
374.4	**0.173**
684.4	**0.245**

Note:
Each laboratory should establish its own calibration Curve
The given values can only be an average indication.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity** 2.5 ng / ml.
2. **Linearity:** up to 800ng/ml.
   If exceeds the linear range, please dilute it with 0.9% saline, multiply the result by the dilution Factor.

3. **Correlation:** A study using 40 human specimens between this procedure and reference method CLIA yielded a correlation coefficient of 0.9874 and a linear regression equation of y = 1.021 x + 0.014

4. 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	Lot 1	Lot 2	Lot 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%		

INTERFERENCES

Substance	**Tolerance**	**Unit**
bilirubin	60	mg/dL
Hemoglobin	600	mg/dL
EDTA	200	mg/dL
Sod.citrate	1000	mg/dL

REFERENCES

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