Cat. No 7-432

BS-400
Chemistry Analyzer

CE CORMAY

A-400 ALPHA-FETOPROTEIN

DIAGNOSTIC KIT FOR DETERMINATION OF α- FETOPROTEIN CONCENTRATION

INTRODUCTION

α-fetoprotein (AFP) is fetoprotein with a molecular weight of approximately 70 kD containing about 3 % sugar. While it is present in high concentrations during fetal growth, its concentration rapidly decrease after birth and is present at extremely low levels in normal human blood.

AFP shows a notable increase in primary hepatic cancer and is considered to be of great diagnostic importance. It is also thought that fluctuations in blood AFP are useful for evaluating the progress, effects of therapy, and postoperative prognosis of hepatoma.

METHOD PRINCIPLE

When an antigen-antibody reaction occurs between AFP in a sample and anti-AFP antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change, with the magnitude of the change being proportional to the quantity of AFP in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of know concentration.

REAGENTS

Package

1-Reagent	1 x 33 ml
2-Reagent	1 x 17 ml

The reagents when stored at 2-10°C are stable up to expiry date printed on the package. Protect from light and avoid contamination!

Concentrations in the test

suspension of latex particles sensitized with (rabbit) anti-AFP antibodies (pH 7.3)	0.12 w/v%
glycine buffer solution (pH 8.3)	

Warnings and notes

- Product for in vitro diagnostic use only.
- Reagent bottles should be shaken before use by gently inverting several times.
- After measurements are taken, reagent bottles should capped and kept at 2-10°C. Care should be taken not to interchange the caps of reagent bottles.
- Reagents with different lot numbers should not be interchanged or mixed.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Serum.

After blood has clotted thoroughly, the sample is centrifuged and the serum is separated from blood cells and fibrins. Samples can be stored for several weeks at 2-8°C or for 1 year at -20°C. Repeated freezing and thawing should be avoided.

Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in automatic analyser BS-400.

1-Reagent and 2-Reagent are ready to use.

For reagent blank 0.9% NaCl is recommended.

APPLICATION

BASIC

Test information		Reagent volume	
No.	48	R1	150
Test	AFP	R2	75
Full Name	Alpha-fetoprotein	R3	
Std. No.	48	R4	

Sample volume

Standard	18	15	10
Increased	36	15	10
Decreased	9	15	10

Reaction Parameters

Reac. Type	Endpoint	Direction	Increase
Pri. Wave	570	Rgt. Blank	44 45
Sec. Wave	800	Reac. Time	63 64

Result Setup

Decimal	0.01	Slope	1
Unit	ng/ml	Inter	0

Judgment Criteria

Absorbance	0	0	Lin. Range
Incre. Test	0		Lin. Limit
Decre. Test	0		Subs. Limit

□ Prozone ○ Rate ○ Antigen

Q1	0	Q2	0	Q3	0	Q4	0
PC	0			ABS	0		

CALIBRATION

Calibration

Rule	Spline
Replicate	1
K	

Judgment Criteria

Sensitivity	Blank Abs.
Factor Diff.	Error Limit
SD	Corr. Coeff.

REFERENCE VALUES [5]

serum	< 15 ng/ml

It is recommended for each laboratory to establish its own reference ranges for local population. Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL I (Cat. No 4-288) with each batch of samples. For the calibration of automatic analysers systems the CORMAY AFP CALIBRATORS kit (Cat. No 4-282) is recommended. The calibration curve should be prepared with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using an automatic analyser HITACHI 917. Results may vary if a different instrument is used.

- **Analytical range:** 7 – 250 ng/ml.
  For higher concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**
  Haemoglobin up to 0.3 g/dl, bilirubin up to 30 mg/dl and triglycerides up to 300 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [ng/ml]	SD [ng/ml]	CV [%]
level 1	9.9	0.4	4.03
level 2	22.6	0.3	1.37
level 3	96.5	0.7	0.71

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 78 samples gave following results:
y = 1.01x + 16.73 ng/ml;
R = 0.996 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. Bergstand C. G. et al.: Demonstration of a new protein fraction in serum from the human fetus., Scand. J. Clin. Lab. Invest., 8, 174 (1956).
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4. Pesce A. J., Kaplan L.A.: Methods in Clinical Chemistry, St. Louis, Mosby, 459-465 (1987).
5. Burtis CA, Ashwood ER, Bruns DE, editors. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 4th ed, St. Louis: W. B Saunders Company; 2006, 2269.

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