CORMAY ALPHA-FETOPROTEIN

DIAGNOSTIC KIT FOR DETERMINATION OF α- FETOPROTEIN CONCENTRATION

Kit name	Kit size	Cat. No
CORMAY ALPHA-FETOPROTEIN	1 x 42 ml	6-305

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 29 ml
2-Reagent	1 x 13 ml

The reagents are stable up to the kit expiry date printed on the package when stored at 2-10°C. On board stability of the reagents depends on type of analyser used for analysis. Protect from light and avoid contamination!

Concentrations in the test

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

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.

ADDITIONAL EQUIPMENT

- automated clinical chemistry analyser capable of accommodating two-reagent assays;
- general laboratory equipment;

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

The reagents are ready to use.
These reagents may be used in automatic analysers according to their user manual. Applications for analysers are available on request.
These reagents may be used directly in Hitachi 911/912 analysers.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

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.
Calibration stability depends on type of analyser used for analysis. 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 the automatic analysers Hitachi 912 and 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 = 10	Mean [ng/ml]	SD [ng/ml]	CV [%]
level 1	25.14	0.93	3.69
level 2	106.24	2.44	2.30

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 78 samples gave following results:
y = 1.01 x + 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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