Cat. No 4-266 and 4-485

PRESTIGE 24i 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

	Cat. No 4-266 (24-TRAY)	**Cat. No 4-485 (36-TRAY)**
1-Reagent	1 x 38 ml	2 x 23 ml
2-Reagent	1 x 20 ml	2 x 12.5 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 analysers Prestige 24i, Biolis 24i, Sapphire 400 and Prestige 24i Premium, Biolis 24i Premium, Sapphire 400 Premium.
1-Reagent and 2-Reagent are ready to use.
1-Reagent put on basic position in reagent tray.
2-Reagent put on start position in reagent tray.
For reagent blank 0.9% NaCl is recommended.

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 or manual procedure 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	26.6	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 = 1.01 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).

2. Galvin J. P. et al.: Particle enhanced photometric immunoassay systems., Clin. Lab. Assays (Pap. Annu. Clin. Lab. Assays Conf.), 4th, 73 (1983).
3. Singer J. M. et al.: The latex fixation test. I. Application to the serologic diagnosis of rheumatoid arthritis, Amer. J. Med., 21, 888 (1956).
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.

APPLICATION for Prestige 24i, Biolis 24i and Sapphire 400

Item name	47	AFP

Data information

Units	**ng/ml**
Decimals	**1**

Analysis

Type	**RATE**
Main W.Length1	**570**
Sub W.Length2	**800**
Method	**Immuno**

Corr

Slope		Inter
Y= **1.000**	X+	**0.000**

Calibration

Type	**Spline**		
Standard			
#1	*	#4	*
#2	*	#5	
#3	*	#6	

Normal Range

	Male		Female	
	Low	High	Low	High
Serum	**0**	**15**	**0**	**15**
Urine				
Plasma				
CSF				
Dialysis				
Other				

Item name	47	AFP

Aspiration

Kind	**Double**

	Volume	
Sample	**25**	µl
Reagent1	**200**	
Reagent2	**100**	

Third Mix.	**ON**
R1 Blank	**Water-Blank**

Monitor

0 Level Point	**1**
Span	**3.000**

Data Process

Read

	Start	End
Main	**36**	**42**
Sub		

Absorbance Limit

Low	**-3.000**
High	**3.000**

Factor

Blank correction	**1.0000**	Endpoint Limit	**2.000**
		Linear Check (%)	**0**

Dilution

Diluent	**99:Dil 1**

Prozone Check

	Start	End	Limit (%)	
First				
Second				**Low**
Third				**Low**

Item name	47	AFP

Auto Rerun SW

OFF

Auto Rerun Range (Result)

	OFF	OFF
	Lower	Higher
Serum		
Urine		
Plasma		
CSF		
Dialysis		
Other		

Auto Rerun Condition (Absorbance)

Absorbance Range	
Lower	**OFF**
Higher	**OFF**

Prozone Range	**OFF**

APPLICATION for Prestige 24i Premium, Biolis 24i Premium and Sapphire 400 Premium

Item No.	47	Item Name	AFP	Optical

Data information

Units	**ng/ml**
Decimals	**1**

Analysis

Type	**RATE**
Main Wave Length	**570 nm**
Sub Wave Length	**800 nm**
Method	**Immuno**

Correlation

Slope		Intercept
Y= **1**	X+	**0**

Calibration

Type	**Spline 1**				
Std sample conc.					
Blank	**0**	#1	*	#2	*
#3	*	#4	*	#5	
#6					

Item No.	47	Item Name	AFP	Optical

Aspiration

Kind	**Double**
Vol.	

Kind	Vol.	Add	Units
Sample	**22**	**5**	µl
Reagent 1	**180**	**10**	µl
Reagent 2	**45**	**10**	µl

Blank value

Water Blank

Reaction Monitor

0 Level Point	**1**
Span	**3**

Third mixing

ON

Data Process

Read	Start	End
Main	**36**	**48**
Sub		

Abs.Limit Low **-3** ~ High **3**

Correction value

Blank correction	**1**
End Point Limit	**2**
Linear Check (%)	**0**

Prozone Check

	Start	End	Limit (%)	
First				
Second				**Low**

Item No.	47	Item Name	AFP	Optical

Normal Range

	Male		Female	
	Low	High	Low	High
Serum	**0**	**15**	**0**	**15**
Urine				
Plasma				
CSF				
Dialysis				
Other				

Panic Range

	Male		Female	
	Low	High	Low	High
Serum				
Urine				
Plasma				
CSF				
Dialysis				
Other				

Item No.	47	Item Name	AFP	Optical

Auto Rerun SW

OFF

Auto Rerun Range (Conc.)

	First Dil	Low			High		
		Re	Value	Dil	Re	Value	Dil
Serum							
Urine							
Plasma							
CSF							
Dialysis							
Other							

Auto Rerun Condition (Absorbance)

Lower	**OFF**
Higher	**OFF**

Auto Rerun Condition (Prozone)

OFF

Dilution

99:Dil 1

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MANUFACTURER

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