Instructions for Use
For *in vitro* diagnostic use

Alfa 1 – GLICOPROTEÍNA ÁCIDA

Alpha 1 – Acid Glycoprotein

Anvisa 80115310074

ORDER INFORMATION

Cat. No.	Kit size
4080050K	2 x 25 mL + Standard 1 x 1 mL

INTENDED USE

Quantitative determination of α1- Acid Glycoprotein (AGP) in human serum by turbidimetric immunoassay.

WARRANTY

These instructions for use should be read carefully before using the product and the information contained therein should be strictly adhered to. The reliability of the test results cannot be guaranteed if the instructions are not followed.

SUMMARY

As an early acute phase reactant, AGP is especially useful in monitoring tumor recurrence. Levels are also helpful in differentiating acute phase responses (elevated levels) from estrogen effects (normal or depressed levels). In addition it is an excellent protein to assay along with Haptoglobin in assessing *in vivo* hemolysis. An elevated AGP level but normal Haptoglobin suggests an acute phase response with mild to moderate *in vivo* hemolysis.

METHOD

Measurement of antigen-antibody reaction by the end-point method.

REAGENTS

Components and Composition

Monoreagent (R):
Polyclonal goat anti-human AGP antibody stabilized in saline solution.

Polyethylene glycol Enhancer	26 g/L
Sodium azide	0.95 g/L

Standard:
Human serum containing a predetermined concentration of AGP based on a reference preparation (CRM470) from the International Federation of Clinical Chemistry (IFCC).

Sodium azide	0.95 g/L

STANDARD VALUE

The analyte concentration value of the standard is specific and valid for the corresponding batch and is indicated on the bottle label.
* Each laboratory must establish corrective actions in case of deviations in the recovery of the standard.
** Changes in the analyte value defined in this standard may occur due to restandardization of the reference material.

REAGENT PREPARATION

The reagent and the standard are ready for use and are stable until the expiration date, if contamination is avoided and if they are stored at a temperature of 2 to 8ºC.

Stability on the instrument is at least 4 weeks, if contamination is avoided. Do not freeze!

WARNINGS AND PRECAUTIONS

1. *In vitro* diagnostic use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
3. Take the necessary precautions when handling laboratory reagents.
4. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA. Only donors with negative results were used in the manufacture. However, all products obtained from fluids of the human body must be handled with appropriate care in accordance with the recommended procedures for biologically hazardous materials, since the absence of infectious agents cannot be proven.

WASTE MANAGEMENT

Follow the requirements of the current guidelines about technical regulation for the management of healthcare service waste, as well as other equivalent biosafety practices.

MATERIALS REQUIRED, BUT NOT PROVIDED

1. NaCl solution 9 g/L.
2. General laboratory equipment.
3. Control Kovalent “Controle Multiparamétrico de Proteínas”.

SPECIMEN

Use fresh serum. If the test can not be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours. If stored for a longer period, the sample should be frozen.

ASSAY PROCEDURE

Applications for automatic systems are available upon request.

MANUAL PROCEDURE

1. Sample/Control: dilute 1:10 in 9 g/L saline.
2. Reference curve: generate a reference curve by diluting the Kovalent Standard Alfa 1-Glicoproteína Ácida provided in 1:10, 1:20, 1:40, 1:80 and 1:160 in 9 g/L saline. Use 9 g/L saline as the zero point.
3. Test: Mix 32 µL of the diluted samples, standards, and controls with 1000 µL of the monoreagent and incubate for 5 minutes at room temperature. Read the optical density (OD) of samples, standards, and controls at 340 nm. Build a reference curve and read the concentration of controls and samples.

PERFORMANCE CHARACTERISTICS

The studies below were conducted using Selectra 2 analyzer.

Measuring range:

Measuring Range:	0 – 299 mg/dL
Detection limit:	9 mg/dL
Hook Effect:	> 400 mg/dL
Sensitivity:	0.00158 units of ABS/Concentration unit

Specificity/interferences:

1. Specificity: Mono-specific
2. Interferences: No interference for: sodium citrate (1000 mg/dL), Heparin (50 mg/dL), Triglycerides (2500 mg/dL), EDTA (5 mg/dL).
3. Hemoglobin (250 mg/dL), Turbidity (> 2.5%), and Bilirubin (> 10 mg/dL) interfere with the test.
4. Limitations: None.

Precision [%CV]

	Low	Medium	High
Intra-assay	1.29	1.30	1.30
Inter-assay	2.23	2.08	2.17

Accuracy [mg/dL]

Controls	AGP (mg/dL)	
	Assigned	Measured
DADE BEHRING	71.7 (60.9 – 82.5)	63.4
CLINICA III	128 (109.2 – 147.2)	128.5

Method comparison:

Method comparison between Kovalent AGP Monoreagent and a commercial test (x) using 50 samples demonstrated the following results:

y = 0.9141x – 0.8383 / r = 0.9674

REFERENCE VALUES

	[mg/dL] (IFCC)
Men	50 – 130
Women:	40 – 120

This range is given for orientation only.

Each laboratory should establish its own reference value

LITERATURE

1. Schmid, K. In FW putman, Editor, The plasma Proteins, Vol 1, second editioin, Academic Press, New York, 2975, pp 184-288.
2. Jonhson, A.M. et al, J. Clin.. Invest, 48 (1969) 2293.
3. Dati, F. Et al., Lab. Med. 13 (1989) 87.)

CONSUMER INFORMATION

Symbols used:

	Manufacturer
	Temperature limit
	In vitro diagnostic device
	Caution
	Operating instructions
	Recycling material
	Do not discard directly into the environment
	Batch code
	Date of manufacture
	Use by date
	Biological hazards
	Highly toxic
	Corrosive
	Harmful

Manufacturer:
Kovalent do Brasil Ltda.
Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro
São Gonçalo – RJ – CEP 24722-414 – Brasil
www.kovalent.com.br
CNPJ: 04.842.199/0001-56

Kit sizes variations on demand:

Anvisa No.	Kit size
80115310074	4 x 25 mL + Standard 1 x 1 mL

Customer service: sac@kovalent.com.br - (21) 3907-2534 / 0800 015 1414

Expiration date and Lot no.: See label