TURBITEST AA LINE

AGP

Immunoturbidimetric method for α-1-acid glycoprotein (AGP) serum protein (AGP/orosomucoid) determination

SUMMARY

The α-1-acid glycoprotein (AGP) serum protein, also called orosomucoid, is an early acute phase reactant. Its quantitative determination allows to monitoring tumor recurrence.

PRINCIPLE

The α-1-acid glycoprotein reacts with a specific antibody generating insoluble immune complexes. The turbidity produced by these immune complexes is proportional to the AGP concentration in the sample and can be measured spectrophotometrically.

PROVIDED REAGENTS

A. Reagent A: buffered saline solution, pH 7.5.
B. Reagent B: antibody monospecific anti-α-1-acid glycoprotein.

NON-PROVIDED REAGENTS

- Saline solution
- Wiener lab.'s **Calibrador Proteínas nivel alto Turbitest AA**.

INSTRUCTIONS FOR USE

Provided Reagents: ready to use.

WARNINGS

Reagents are for "in vitro" diagnostic use.
All samples from patients should be handled as capable of transmitting infection.
Use the reagents according to the working procedures for clinical laboratories.
The reagents and samples should be discarded according to the local regulations in force.

STABILITY AND STORAGE INSTRUCTIONS

Provided Reagents: stable at 2-10ºC until the expiration date stated on the box. Do not freeze.

SAMPLE

Serum or heparinized plasma
a) Collection: obtain the sample in the usual way.
b) Additives: if plasma is used, it is recommended to use heparin as anticoagulant.
c) Known interfering substances:
- Do not use contaminated or hemolyzed sera.
- No interferences have been observed with bilirubin up to 20 mg/dl, triglycerides up to 25 g/l and hemoglobin up to 1 g/dl.

See Young, D.S. in References for effect of drugs on the present method.

a) Stability and storage instructions: the sample should be preferably fresh. In case the test cannot be performed on the day, the sample can be stored for up to 1 week at 2-10ºC. In case it must be processed later than this period, store it at -20ºC.

REQUIRED MATERIAL (non-provided)

- Spectrophotometer.
- Spectrophotometric cuvettes.
- Micropipettes and pipettes for measuring the stated volumes.
- Kahn or hemolysis tubes.
- Stopwatch.

ASSAY CONDITIONS

- Wavelength: 340 nm
- Reaction temperature: room temperature (25ºC). Temperature control is not critical, it can range between 22 and 30ºC.
- Reaction time: 30 minutes

PROCEDURE

CALIBRATION CURVE
In Kahn tubes dilute the **Calibrador Proteínas nivel alto** with saline solution 1:10, 1:20, 1:40, 1:80 and 1:160, using saline solution as the zero point.

Diluted Calibrador Proteínas	80 ul
Reagent A	800 ul

Homogenize and measure absorbance of each dilution at 340 nm (OD_1), setting the instrument to zero with distilled water. Then, add:

Reagent B	120 ul

Mix and incubate for 30 minutes at room temperature. Measure absorbance at 340 nm (OD_2), setting the instrument to zero with distilled water.
Calculate the absorbance difference ($\Delta A = OD_2 - OD_1$) for each Calibrador Proteínas dilution, including the zero point.
Draw on graph paper the ΔA absorbance differences versus the Calibrador Proteínas concentration in mg/dl (g/l).

SAMPLES PROCEDURE
Dilute the samples 1:10 with saline solution.

Diluted Sample	80 ul
Reagent A	800 ul

Homogenize and measure absorbance at 340 nm (OD), setting the instrument to zero with distilled water. Then, add:

Reagent B	120 ul

Mix and incubate for 30 minutes at room temperature. Measure absorbance at 340 nm (OD_2), setting the instrument to zero with distilled water.

CALCULATIONS

Calculate the absorbance difference ($\Delta A = OD_2 - OD_1$) for each sample tested. Interpolate this ΔA in the calibration curve to determine the concentration in mg/dl (g/l) corresponding to the sample under study. Samples with an absorbance above that of the Calibrador Proteínas Nivel Alto must be diluted 1:2 with saline solution and processed again. Multiply the obtained result by 2.

QUALITY CONTROL METHOD

Wiener lab.'s **Control Inmunológico nivel 1** or **Control Inmunológico nivel 2 Turbitest AA**.
The Control should be processed in the same manner as the sample.

REFERENCE VALUES

50-120 mg/dl (0.50-1.20 g/l).
It is recommended that each laboratory establishes its own reference values.

SI SYSTEM UNITS CONVERSION

AGP (mg/dl) x 0.2439 = AGP (umol/l)

PROCEDURE LIMITATIONS

Turbidity and particles in the sample may interfere with the test. Therefore, the particles that may be the result of an incomplete coagulation or protein denaturalization must be removed by centrifugation before testing the sample.

PERFORMANCE

a) Reproducibility: simultaneously processing 20 replicates of one sample, the following results were obtained:

Level	S.D.	C.V.
27.9 mg/dl	± 1.30 mg/dl	4.66 %
71.2 mg/dl	± 0.81 mg/dl	1.14 %
149.8 mg/dl	± 3.67 mg/dl	2.45 %

b) Dynamic range: values can be obtained between the lowest and highest calibrator concentrations of the calibration curve (approximately 250 mg/dl).
c) Detection limit: the minimum detectable concentration change of AGP is 4 mg/dl.

PARAMETERS FOR AUTOANALYZERS

Refer to the specific applications of each autoanalyzer. For calibration must be use Wiener lab's **Calibrador Proteínas nivel alto Turbitest AA** following the autoanalyzer requirements.

WIENER LAB. PROVIDES

1 x 60 ml Reagent A
1 x 5 ml Reagent B
(Cat. 1413261)

1 x 60 ml Reagent A
1 x 5 ml Reagent B
(Cat. 1009341)

1 x 60 ml Reagent A
1 x 5 ml Reagent B
(Cat. 1009214)

1 x 60 ml Reagent A
1 x 5 ml Reagent B
(Cat. 1009638)

REFERENCES

- Ichihara, K. et al - J. Clin. Lab. Anal. 10:110 (1996).
- Itoh, Y. et al - J. Clin. Lab. Anal. 11:39 (1997).
- Maynard, Y. et al - Clin. Chem. 32/5:752 (1986).
- Dati, F - Journal of IFCC VIII/1:29 (1996).
- Young, D.S. - "Effects of Drugs on Clinical Laboratory Tests", AACC Press, 4th ed., 2001.

Symbols

The following symbols are used in packaging for Wiener lab. diagnostic reagent kits.

CE — This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices

EC REP — Authorized representative in the European Community

IVD — "In vitro" diagnostic medical device

Σ — Conteins sufficient for <n> tests

Use by

Temperature limitation (store at)

Do not freeze

Biological risks

Volume after reconstitution

Cont. — Contents

LOT — Batch code

Manufactured by:

Xn — Harmful

Corrosive / Caustic

Xi — Irritant

Consult instructions for use

Calibr. — Calibrator

CONTROL — Control

CONTROL + — Positive Control

CONTROL − — Negative Control

REF — Catalog number

Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 - Rosario - Argentina
http://www.wiener-lab.com.ar
Dir. Téc.: Viviana E. Cétola
Biochemist
A.N.M.A.T. Registered product
Cert. Nº: 3011/98

Wiener lab.

2000 Rosario - Argentina