



α_1 -Acid Glycoprotein

REF 9500150 1x50ml

CE [IVD] For in vitro medical device

INTENDED USE

The α_1 -Ac Gly is a quantitative turbidimetric test for the measurement of α_1 -Ac Gly in human serum or plasma.

PRINCIPLE OF THE METHOD

Anti- α_1 -Ac Gly antibodies when mixed with samples containing α_1 -Ac Gly, form insoluble complexes. These complexes cause an absorbance change, dependent upon the α_1 -Ac Gly concentration of the patient sample, that can be quantified by comparison from a calibrator of known α_1 -Ac Gly concentration.

CLINICAL SIGNIFICANCE

α_1 -Ac Glycoprotein (also known as orosomucoid) is a glycoprotein synthesized by hepatic parenchymal cells, but granulocytes and monocytes may also contribute significantly to plasma levels in sepsis. It has long been known to bind a large number of basic and lipophilic compounds (progesterone and related hormones).

It is an acute phase response protein that shows a 3 to 4-fold increase in most conditions associated with inflammation or tissue necrosis, and may be one of the most reliable indicators of clinical activity of ulcerative colitis. Levels also are increased by glucocorticoid effect.

Synthesis and plasma levels are decreased by estrogens.

REAGENTS

Diluent (R1)	Tris buffer 20 mmol/L, PEG 8000, pH 8.3. Sodium azide 0.95 g/L.
Antibody (R2)	Goat serum, anti-human α_1 -Ac Glycoprotein, pH 7.5. Sodium azide 0.95 g/L.
Optional	Ref: 905CAL Serum Protein Calibrator

CALIBRATION

The assay has been standardized against the Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM). It must be used the PROT CAL to calibrate the reagent. The reagent (both monoreagent and bireagent) should be recalibrated every month, when the controls are out of specifications, and when changing the reagent lot or the instrument settings.

PREPARATION

Reagents: Ready to use.

Calibration Curve: Prepare the following Serum Protein Calibrator dilutions in C1Na 9 g/L as diluent. Multiply the concentration of the α_1 -Ac Glycoprotein calibrator by the corresponding factor stated in table below to obtain the α_1 -Ac Glycoprotein concentration of each dilution.

Calibrator dilution	1	2	3	4	5	6
Calibrator (μ L)	--	10	25	50	75	100
NaCl 9 g/L (μ L)	100	90	75	50	25	-
Factor	0	0.1	0.25	0.5	0.75	1.0

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.

Reagent deterioration: The presence of particles and turbidity.

Do not freeze; frozen Antibody or Diluent could change the functionality of the test.

ADDITIONAL EQUIPMENT

- Thermostatic bath at 37°C.
- Spectrophotometer or photometer thermostatable at 37°C with a 340 nm filter (320 - 360 nm).

SAMPLES

Fresh serum or plasma. EDTA or heparin should be used as anticoagulant. Stable 7 days at 2-8°C or 3 months at -20°C.

The samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolyzed or lipemic samples.

PROCEDURE

1. Bring the reagents and the photometer (cuvette holder) to 37°C.

2. Assay conditions:

Wavelength : 340 nm
 Temperature : 37 °C
 Cuvette light path : 1cm

3. Adjust the instrument to zero with distilled water.

4. Pipette into a cuvette:

Reagent R1 (μ L)	800
Sample or Calibrator (μ L)	10

5. Mix and read the absorbance (A_1) after the sample addition.

6. Immediately, pipette into the cuvette:

Reagent R2 (μ L)	200
-----------------------	-----

7. Mix and read the absorbance (A_2) of calibrators and sample exactly 4 minutes after the R2 addition.

Gesam has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

CALCULATIONS

Calculate the absorbance difference (A_2-A_1) of each point of the calibration curve and plot the values obtained against the α_1 -Ac Gly concentration of each calibrator dilution. α_1 -Ac Gly concentration in the sample is calculated by interpolation of its (A_2-A_1) in the calibration curve.

QUALITY CONTROL

Serum Protein Control are recommended to monitor the performance of manual and automated assay procedures. Gesam Serum Protein Control (Ref.:905CTL) is available. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES²

Between 50 - 120 mg/dL. Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

- Measurement range:** Up to 250 mg/dL under the described assay conditions. Samples with higher concentrations, should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit depends on the sample / reagent ratio. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
- Detection Limit:** Values less than 12.9 mg/dL give non-reproducible results.
- Prozone effect:** No prozone effect was detected upon 1000 mg/dL.
- Sensitivity:** Δ 5.0 mA / mg/dL.
- Precision:** The reagent has been tested for 20 days, using two levels of serum in an EP5-based study.

EP5	CV (%)	
		56.4 mg/dl
Total	3.3%	3.1%
Within Run	1.1%	1.6%
Between Run	3%	2.1%
Between Day	0.7%	1.6%

6. **Accuracy:** Results obtained using this reagent (y) were compared to those obtained using the method Immage from Beckman. 51 samples ranging from 50 to 120 mg/dL of α_1 -Ac Gly were assayed. The correlation coefficient (r) was 0.95 and the regression equation $y = 0.9304x + 6.5367$.

The results of the performance characteristics depend on the used analyzer.

INTERFERENCES⁵⁻⁶

Hemoglobin (10 g/L), bilirubin (20 mg/dL), rheumatoid factors (200 IU/mL) and lipemia (2.5 g/L), do not interfere. Other substances may interfere^{5,6}.

NOTES

1. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

- Clinical Guide to Laboratory Tests, Edited by NW Tietz W B Saunders Co., Philadelphia, 483, 1983.
- Dati F et al. Eur J Clin Chem Clin Biochem 1996; 34:517-520.
- Pesce AJ and Kaplan, LA. Methods in Clinical Chemistry. The CV Mosby Company, St. Louis MO, 1987.
- Bienvenue J et al. Clin Chem Clin Biochem 1981; 27: 721-726.
- Young DS. Effects of drugs on clinical laboratory tests, 4th ed. AACC Pres, 1995.
- Friedman and Young. Effects of disease on clinical laboratory tests, 3th ed. AACC Pres, 1997.