

Quantitative determination of α_1 -Acid Glycoprotein (α_1 -Ac GLY) IVD

Store 2 - 8°C.

PRINCIPLE OF THE METHOD

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

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

| | |
|------------------------|---|
| R1 | Tris buffer 20 mmol/L, PEG 8000, pH 8.2. Sodium azide 0.95 g/L. |
| R2 | Goat serum, anti-human α_1 -Ac Glycoprotein, pH 7.5. Sodium azide 0.95 g/L. |
| Saline Solution | NaCl 9% (for samples predilution) |

CALIBRATION

The assay has been standardized against the Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM).

PREPARATION

Reagents: Ready to use.

Samples and Controls Pre-Dilution: Before the use, samples and/or controls must be diluted in this way:

- 25 μ L sample or control + 250 μ L NaCl 9 g/L (1:11)

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

- Pipette 100 - 1000 μ L
- Pipette 10 - 100 μ L
- Cuvettes and microstirrers (ref. code ACC16-037)

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.

TEST PARAMETER

Filter: set filter on position B

Reading time: 240 seconds

PROCEDURE

1. Pipette into an appropriate number of cuvettes:

| kind of reagent | μ L |
|-------------------------------|---------|
| R1 | 500 |
| Pre-diluted sample or control | 50 |

2. Incubate the cuvettes in positions 1-4 for at least 1 minute
3. Transfer each cuvette in the reading channel and, when requested on the display, add 25 μ L of R2
4. Read the result which will appear automatically on the reader's display after 240 sec

QUALITY CONTROL

Control sera are recommended to monitor the performance of manual and automated assay procedures. Vital Diagnostics SERUM PROT CONTROL BILEVEL (Ref.:ACC16-038) 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

1. Linearity: Up to 180 mg/dL (Note1), 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.
2. Detection Limit: Values less than 12.9 mg/dL give non-reproducible results.
3. Prozone effect: No prozone effect was detected upon 1000 mg/dL.
4. Sensitivity: Δ 5.0 mA / mg/dL.
5. Precision:

| | Mean | SD | CV% |
|--------------------|------|-----|-----|
| Intra-assay (n=10) | 33.1 | 1.1 | 3.3 |
| Inter-assay (n=10) | 44.2 | 1.5 | 3.4 |

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. Linearity limit depends on the calibrator concentration.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

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

PACKAGING

| | | |
|-----------------|-------|-----------------------------|
| Ref.: ACC16-022 | Cont. | : 1 x 50 mL R1 |
| | | : 1 x 2 mL R2 |
| | | : 1 x 50 mL Saline Solution |