**Intended Use**

*For in vitro diagnostic use only*

When a CARESIDE Analyzer™ operator performs both a CARESIDE Total Protein test and a CARESIDE Albumin test on a single patient sample, the CARESIDE Analyzer automatically calculates the Globulin measurement and the Albumin to Globulin ratio (A/G Ratio). Both calculations aid in the diagnosis and treatment of patients with numerous illnesses including severe liver and renal disease, multiple myeloma, and other disorders of blood globulins.

**Test Summary**

Plasma proteins (primarily albumin and the globulins) constitute approximately 7 percent of the total plasma, with albumin the most abundant protein in human plasma (55 to 65% of total protein) and globulins the second. In healthy individuals, the plasma protein concentration usually remains stable with about twice as much albumin as globulin (A/G ratio = 2)\(^1\).

Albumin concentration changes in plasma have significant effects on the relative amounts of the bound and free concentration of the ligands carried by the albumin. As a result, albumin levels can influence the receptor interaction and metabolism of endogenous and exogenous ligands, such as drugs and hormones\(^2\).

Globulin concentration may be quantified by either direct measurement or by calculation. Globulins are elevated in chronic infections, most acute and chronic liver diseases, collagen disorders such as rheumatoid arthritis and lupus erythematosis, and neoplastic diseases such as multiple myeloma, macroglobulinemia, and leukemia.

**Test Explanation**

When the CARESIDE Analyzer user selects a Globulin test, the instrument prompts the user to perform both the CARESIDE Total Protein and the CARESIDE Albumin test. Refer to the CARESIDE Total Protein and CARESIDE Albumin package inserts for relevant operation information.

**Test Principle**

The CARESIDE Analyzer uses the CARESIDE Total Protein and CARESIDE Albumin cartridge test results from a single patient sample to determine the globulin concentration and A/G Ratio. Globulin is calculated as the difference between the total protein and albumin concentrations.

**Test Warnings and Precautions**

- For *in vitro* diagnostic use only.
- Handle all patient samples, QC materials of human origin, and dosed test cartridges using universal precautions\(^3\).
• Protect reagent film from contamination or excessive light. Do not touch the film; touching the film can cause optical errors.
• Do not reuse cartridges.
• Specimens should be free from precipitates.

**Test Calibration**

No routine user calibration is required. Each cartridge lot is factory calibrated and the calibration information is read automatically by the CARESIDE Analyzer.

**Specimen Collection**

In order to determine Globulin concentration and the A/G ratio, collect at least 180 ± 20µL of a single patient sample: both the CARESIDE Total Protein and CARESIDE Albumin test cartridges require 90 ± 10µL per test cartridge. When using a single patient sample on both the CARESIDE Total Protein and CARESIDE Albumin cartridges, use heparinized whole blood, heparinized plasma or serum. Do not use hemolyzed serum or plasma. Follow specimen collection instructions indicated in the CARESIDE Total Protein test cartridge package insert.

**Note:** Results obtained from plasma will be higher than serum due to fibrinogen (a plasma protein) that remains in the plasma. An increase of 0.2 to 0.4 g/dL may be expected.

**Patient Preparation**

No special patient preparation is necessary. Albumin results from recumbent patients may be approximately 0.3 g/dL lower than if the patient were standing.

**Test Procedures**

1. In the Test Selection Menu order the Glob calc panel; this will automatically select TP and ALB
2. Perform the CARESIDE Albumin and CARESIDE Total Protein tests as indicated in their respective package inserts.

**Quality Control**

Each CARESIDE test cartridge barcode contains all required calibration information. The CARESIDE Analyzer scans the barcode, continuously performs quality control self-checks during operation, and alerts and prevents the user from proceeding if an unacceptable condition exists.

Follow the QC recommendations described in both the albumin and the total protein test cartridge package inserts. Each institution should establish quality control ranges using the CARESIDE Analyzer and monitor total protein, and albumin test performance using a Levey-Jennings chart (See CARESIDE Operator’s Manual).

**Results**

Results require no user calculation and appear on the CARESIDE Analyzer screen, as they become available.

**Globulin**

- Reporting Units: g/dL
- Conversion Factor: g/L = 10 x g/dL

**Expected Values (Reference Interval)**

The following reference intervals were obtained by calculation based upon the results of total protein and albumin analysis of plasma specimens from a population of 68 ambulatory, healthy adult workers in the United States (males, n=27, mean age 38; females, n= 41, mean age 38) using the CARESIDE Analyzer.

**Globulin**

2.7 to 4.2 g/dL

**A/G Ratio**

0.9 to 1.6

Expected values may vary depending upon the population of subjects. It is recommended that each institution establish these values for the population they serve.

**Limitations**

An abnormal globulin or A/G Ratio may be due to an analytical error in the measurement of total protein or albumin (refer to individual package inserts).
Performance Characteristics

CARESIDE Albumin and CARESIDE Total Protein test cartridge performance characteristics are indicated in their respective package inserts.

Bibliography


Technical Assistance

If questions arise concerning the CARESIDE Analyzer or test cartridges, please contact CARESIDE Technical Service.

Telephone: (888) 698-CARE (2273)  
(310) 338-6767

Fax: (310) 338-6789

Ordering Information

For product ordering or general information, please contact CARESIDE Customer Service.

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