


Albumin in Urine/CSF FS* (Microalbumin)

Order Information

Cat. No.

1 0242 99 10 921

Kit size

 400 (4 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of albumin in human urine or cerebrospinal fluid (CSF) on automated respons[®]910.

Summary

Albumin is a carbohydrate-free protein that constitutes a major part of total plasma proteins, accounting for approximately 60% of the total protein content in blood [1]. It is primarily synthesized in the liver at a rate of 12-25 g/day and is distributed in plasma, interstitial fluid, and various body compartments [2]. The main physiological role of albumin is to maintain oncotic pressure, facilitate the transport of various substances (such as hormones, fatty acids, and drugs), and serve as a source of amino acids [2,3]. Due to its size and charge, albumin is normally retained in the bloodstream, with only minimal amounts present in urine or cerebrospinal fluid (CSF). Any significant deviation from normal albumin levels in these fluids can indicate underlying pathological conditions [1,3]. The determination of albumin in urine is crucial in assessing renal function and detecting early-stage kidney diseases [4]. Even a slight increase in urinary albumin (microalbuminuria) serves as an early marker of diabetic nephropathy and hypertensive kidney damage, while higher levels of albumin in urine indicate more severe glomerular dysfunction [3,4]. In contrast, albumin measurement in CSF primarily assesses the integrity of the blood-brain barrier (BBB). Increased CSF albumin levels suggest BBB impairment, which can be associated with neurological disorders such as multiple sclerosis, meningitis, and traumatic brain injury [5]. Additionally, the CSF/serum albumin ratio is a valuable parameter for evaluating the degree of BBB dysfunction [6].

Method

Immunturbidimetric test

Determination of the albumin concentration via photometric measurement of antigen-antibody-reaction among antibodies against albumin and albumin present in the sample.

Reagents

Components and Concentrations

| | | | |
|------------|---|--------|------------|
| R1: | TRIS | pH 7.5 | 100 mmol/L |
| | NaCl | | 50 mmol/L |
| R2: | TRIS | pH 8.0 | 83 mmol/L |
| | NaCl | | 165 mmol/L |
| | Antibodies (goat) against human albumin | | < 1% |

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 2 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- The albumin concentration in serum samples is much higher than in urine samples. In order to avoid contaminations and carryover from serum samples into urine samples, cuvettes and other glassware must be cleaned thoroughly after being used for tests with serum.
- In very rare cases, samples of patients with gammopathy might give falsified results [7].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For

diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.

- For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human urine and CSF

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability in urine [8]:

| | | |
|----------|----|-----------|
| 7 days | at | 20 – 25°C |
| 1 month | at | 4 – 8°C |
| 6 months | at | -20°C |

Stability in CSF [8]:

| | | |
|----------|----|-----------|
| 1 day | at | 20 – 25°C |
| 2 months | at | 4 – 8°C |
| 1 year | at | -20°C |

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal Albumin U/CSF is recommended for calibration. DiaSys TruCal Albumin U/CSF high may be used alternatively for calibration. The calibrator values have been made traceable to the reference material ERM[®]-DA470/IFCC. Use DiaSys TruLab Albumin U/CSF Level 1 and Level 2 for internal quality control. TruLab Urine Level 1 and Level 2 may be used alternatively for internal quality control of urine/CSF determination. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

| | Cat. No. | Kit size |
|------------------------------|------------------|-----------|
| TruCal Albumin U/CSF | 1 9300 99 10 059 | 5 x 1 mL |
| TruCal Albumin U/CSF high | 1 9300 99 10 037 | 3 x 1 mL |
| TruLab Albumin U/CSF Level 1 | 5 9710 99 10 046 | 3 x 1 mL |
| TruLab Albumin U/CSF Level 2 | 5 9720 99 10 046 | 3 x 1 mL |
| TruLab Urine Level 1 | 5 9170 99 10 061 | 6 x 5 mL |
| TruLab Urine Level 1 | 5 9170 99 10 062 | 20 x 5 mL |
| TruLab Urine Level 2 | 5 9180 99 10 061 | 6 x 5 mL |
| TruLab Urine Level 2 | 5 9180 99 10 062 | 20 x 5 mL |

Performance Characteristics

| | |
|--|-----------|
| Measuring range from 20 mg/L up to 350 mg/L, depending on the concentration of the highest calibrator. Linearity is given within ± 10%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function. | |
| Limit of detection** | 1.81 mg/L |
| Limit of quantitation** | 20 mg/L |
| No prozone effect up to 60000 mg/L. | |
| Onboard stability | 14 days |
| Calibration stability | 7 days |

| Interference by | Interferences ≤ 10% up to | Analyte concentration [mg/L] |
|-------------------------------|------------------------------|------------------------------------|
| Bilirubin (conjugated) | 3 mg/dL | 24.2 |
| | 3 mg/dL | 42.5 |
| Hemolysis | 300 mg/dL | 110 |
| Urea | 50 g/L | 66.9 |
| | 55 g/L | 275 |

For further information on interfering substances, refer to the literature [9,10].

| Precision | | | |
|----------------------|----------|----------|----------|
| Repeatability (n=20) | Sample 1 | Sample 2 | Sample 3 |
| Mean [mg/L] | 24.6 | 57.5 | 114 |
| CV [%] | 3.76 | 1.84 | 1.30 |
| Between day (n=20) | Sample 1 | Sample 2 | Sample 3 |
| Mean [mg/L] | 22.4 | 55.6 | 96.7 |
| CV [%] | 2.76 | 2.34 | 3.12 |

| Method comparison (n=125) | |
|----------------------------|---|
| Test x | DiaSys Albumin in Urine/CSF FS (Hitachi 917) |
| Test y | DiaSys Albumin in Urine/CSF FS (respons [®] 910) |
| Slope | 0.932 |
| Intercept | -0.675 mg/L |
| Coefficient of correlation | 0.999 |

** according to CLSI document EP17-A, Vol. 24, No. 34

Conversion Factor

Urine/CSF:

Albumin [mg/L] x 0.0152 = Albumin [µmol/L]

Urine:

Albumin [mg/g crea] x 0.113 = Albumin [g/mol crea]

Reference Range

Urine [3]:

Albumin excretion rate in urine: < 30 mg/24 h
 Albumin concentration (early morning urine): < 30 mg/L
 Albumin/creatinine ratio (early morning urine): < 30 mg/g Creatinine
 CSF/Serum albumin ratio (RALb) adults [3]: (5 – 8) x 10⁻³

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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* Fluid Stable

Albumin in Urine/CSF FS Urine Application

Application for urine samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

| Identification | |
|-------------------------------------|-------|
| This method is usable for analysis: | Yes |
| Twin reaction: | No |
| Name: | MALBu |
| Shortcut: | |
| Reagent barcode reference: | 700 |
| Host reference: | 700 |

| Technic | |
|---------------------------------------|------------|
| Type: | End point |
| First reagent:[μ L] | 200 |
| Blank reagent | Yes |
| Sensitive to light | |
| Second reagent:[μ L] | 40 |
| Blank reagent | No |
| Sensitive to light | |
| Main wavelength:[nm] | 405 |
| Secondary wavelength:[nm] | 700 |
| Polychromatic factor: | 1.0000 |
| 1 st reading time [min:sec] | (04:24) |
| Last reading time [min:sec] | 10:00 |
| Reaction way: | Increasing |
| Linear Kinetics | |
| Substrate depletion: Absorbance limit | |
| Linearity: Maximum deviation [%] | |
| Fixed Time Kinetics | |
| Substrate depletion: Absorbance limit | |
| Endpoint | |
| Stability: Largest remaining slope | |
| Prozone Limit [%] | |

| Reagents | |
|----------|--|
| Decimals | |
| Units | |

| Sample | |
|--------------------------------------|------------------|
| Diluent | DIL A (NaCl) |
| Hemolysis: | |
| Agent [μ L] | 0 (no hemolysis) |
| Cleaner | |
| Sample [μ L] | 0 |
| Technical limits | |
| Concentration technical limits-Lower | 20.0000 |
| Concentration technical limits-Upper | 350.0000 |
| SERUM | |
| Normal volume [μ L] | 10.0 |
| Normal dilution (factor) | 1 |
| Below normal volume [μ L] | |
| Below normal dilution (factor) | |
| Above normal volume [μ L] | 10.0 |
| Above normal dilution (factor) | 6 |
| URINE | |
| Normal volume [μ L] | 10.0 |
| Normal dilution (factor) | 1 |
| Below normal volume [μ L] | |
| Below normal dilution (factor) | |
| Above normal volume [μ L] | 10.0 |
| Above normal dilution (factor) | 6 |
| PLASMA | |
| Normal volume [μ L] | 10.0 |
| Normal dilution (factor) | 1 |
| Below normal volume [μ L] | |
| Below normal dilution (factor) | |
| Above normal volume [μ L] | 10.0 |
| Above normal dilution (factor) | 6 |
| CSF | |
| Normal volume [μ L] | 10.0 |
| Normal dilution (factor) | 1 |
| Below normal volume [μ L] | |
| Below normal dilution (factor) | |
| Above normal volume [μ L] | 10.0 |
| Above normal dilution (factor) | 6 |
| Whole blood | |
| Normal volume [μ L] | 10.0 |
| Normal dilution (factor) | 1 |
| Below normal volume [μ L] | |
| Below normal dilution (factor) | |
| Above normal volume [μ L] | 10.0 |
| Above normal dilution (factor) | 6 |

| Results | |
|---------------------------|--------|
| Decimals | 1 |
| Units | mg/L |
| Correlation factor-Offset | 0.0000 |
| Correlation factor-Slope | 1.0000 |

| Range | |
|-------------|-----|
| Gender | All |
| Age | |
| SERUM | |
| URINE | # |
| PLASMA | |
| CSF | |
| Whole blood | |
| Gender | |
| Age | |
| SERUM | |
| URINE | |
| PLASMA | |
| CSF | |
| Whole blood | |

| Contaminants | |
|---|--|
| Please refer to r910 Carryover Pair Table | |

| Calibrators details | |
|---------------------|----------------|
| Calibrator list | Concentration |
| Cal. 1/Blank | 0 |
| Cal. 2 | * |
| Cal. 3 | * |
| Cal. 4 | * |
| Cal. 5 | * |
| Cal. 6 | |
| | Max delta abs. |
| Cal. 1 | 0.0100 |
| Cal. 2 | 0.0100 |
| Cal. 3 | 0.0100 |
| Cal. 4 | 0.0100 |
| Cal. 5 | 0.0100 |
| Cal. 6 | 0.0200 |
| Drift limit [%] | 2.00 |

| Calculations | |
|--------------|--------------|
| Model | Cubic Spline |
| Degree | |

* Enter calibrator value

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