DIAGNOSTICA PRODUCTS

Liquid Reagents – ready to use

ALBUMIN
BCG

Single Reagent

Diagnostic reagent for quantitative in vitro determination of Albumin in human serum or plasma on photometric systems.

Ref.No.	Kit Size	Content
DIA010292	5 x 25 ml	Single Reagent
DIA010293	5 x 50 ml	Single Reagent
DIA010294	5 x 100 ml	Single Reagent

Additionally offered:

DIA060190	1 x 3 mL	**Protein Total STANDARD**
DIA040012	1 x 3 mL	**Diacal Auto** (Calibrator)
DIA030012	1 x 5 mL	**Diacon N** (Control Normal)
DIA030022	1 x 5 mL	**Diacon P**(Control Abnormal)
DIA030030	1 x 5 mL	**Diacon Urine Level 1** (Control Normal)
DIA030035	1 x 5 mL	**Diacon Urine Level 2** (Control Abnormal)

TEST PARAMETERS

Method: Colorimetric, Endpoint, Increasing Reaction, BCG
Wavelength: 540-600 nm, Hg 546 nm
Temperature: 20 – 25°C, 37°C
Sample: Serum or heparin or EDTA plasma
Linearity: up to 6 g/dL
Sensitivity: Lower limit of detection: 0.2 g/dL

DIAGNOSTIC IMPLICATION [1,2]

Measurement of albumin in serum is used for diagnosis and monitoring of liver diseases, e.g. liver cirrhosis. Furthermore, albumin levels indicate the health and nutritional status of an individual and, therefore, are used for detecting malnutrition and for prognosis in elderly hospitalized patients.

TEST PRINCIPLE

In the presence of bromocresol green at a slightly acid pH, serum albumin produces a color change of the indicator from yellow-green to green-blue. The intensity of the blue-green color is proportional to the concentration of albumin in the sample.

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION	
Citrate buffer, pH 4.2	30	mmol/L
Bromocresol green	0.26	mmol/L

REAGENT PREPARATION

The reagent is ready to use.

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

REAGENT STABILITY AND STORAGE

Conditions: Protect from light.
Close immediately after use.
Do not freeze the reagents.
Avoid contamination.
Storage: at 2 – 25°C
Stability: up to the expiration date

SAMPLE STABILITY AND STORAGE

Stability [3]: at 15 – 25°C 10 weeks
at 4 - 8°C 5 months
at -20°C 3 months
Discard contaminated specimens.
Freeze only once!

STANDARD

(not included in the kit – has to be ordered separately)
Concentration 5 g/dL (50 g/L)
Storage: 2 – 8°C
Stability: up to the expiration date
Close immediately after use! Avoid contamination!

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std./Cal	Sample
Sample	-	-	10 µl
Standard/Calibrator	-	10 µl	-
Dist. water	10 µl	-	-
Reagent	1000 µl	1000 µl	1000 µl
Mix, Incubate for approx. 10 min. at 20 – 25 °C / 37 °C and read absorbance against reagent blank within 60 min.			

CALCULATION

$$\text{Albumin [g/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. Std/Cal [g/dL]}$$

UNIT CONVERSION

g/dL x 10 = g/L
g/dL x 144.9 = µmol/L

REFERENCE RANGE [4] * [g/dL]

	Females	Males
Adults:		
g/dL	3.5 – 5.2	3.5 – 5.2
g/L	35 - 52	35 - 52
µmol/L	507 - 756	507 - 756

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

PERFORMANCE CHARACTERISTICS

LINEARITY

The assay is linear from 0.2 to 6 g/dL.
Samples with albumin concentrations higher than 6 g/dL should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

PRECISION (at 37 °C)

Intra-assay n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	3.52	0.03	0.91
Sample 2	4.50	0.05	1.12
Sample 3	6.89	0.12	1.79
Inter-assay n = 20	**Mean [g/dL]**	**SD [g/dL]**	**CV [%]**
Sample 1	3.35	0.05	1.58
Sample 2	4.32	0.06	1.44
Sample 3	6.73	0.11	1.60

SPECIFICITY/INTERFERENCES

No interference up to:

Ascorbic acid	30 mg/dL
Bilirubin	40 mg/dL
Hemoglobin	400 mg/dL
Triglycerides	500 mg/dL

For further information on interfering substances refer to Young DS [5].

METHOD COMPARISON

A comparison between Diagnostica Albumin (y) with a commercially available test (x) using 59 samples gave following results: y = 1.00 x – 0.11 g/dL; r= 0.998.

AUTOMATION

Special applications for automated analysers can be made on request.

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CALIBRATION

The assay requires the use of a Albumin standard or calibrator.
We recommend the Diagnostica **Albumin Standard** and the Diagnostica multi calibration serum **Diacal Auto**.
The assigned values of Diacal Auto have been made traceable to the reference material ERM-DA470.

QUALITY CONTROL

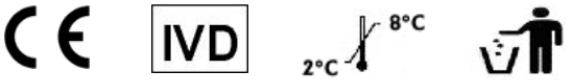
All control sera with Albumin values determined by this method can be used.
We recommend the Diagnostica serum controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range).

WARNINGS AND PRECAUTIONS

1. In very rare cases, samples of patients with gammopathy might give falsified results [5].
2. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
3. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.

WASTE MANAGEMENT

Please refer to local legal requirements.



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