DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Albumin, BCG

(en) English

REF	Content			
D97202B	1	x	1 L	reagent
D09550	4	x	250 mL	reagent
D97203	5	x	100 mL	reagent
D00204	5	x	50 mL	reagent
D00205	5	x	25 mL	reagent
D00206	5	x	10 mL	reagent
D51911	10	x	50 mL	reagent
D0401917	9	x	65 mL	reagent
DA0801	5	x	50 mL	reagent
DT1001	4	x	50 mL	reagent
DK0701	5	x	50 mL	reagent
DE1801	10	x	50 mL	reagent
DB20301	10	x	50 mL	reagent

For professional in vitro diagnostic use only.

INTENDED USE

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

DIAGNOSTIC SIGNIFICANCE[1,2]

Albumin is an important binding and transport protein for various substances in plasma and the main contributor to plasma osmotic pressure. Measurement of albumin in the 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

Photometric test using bromocresol green. In the presence of bromocresol green at a slightly acid pH, serum albumin produces a colour change of the indicator from yellow- green to green- blue.

REAGENT COMPOSITION

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

MATERIAL REQUIRED BUT NOT PROVIDED

- Standard or Calibrator, eg.:

REF	Name	Content		
D95555	Albumin Standard	1	x	3 mL
D98485	Diacal Auto	5	x	3 mL
D98485SV	Diacal Auto	1	x	3 mL

- Controls, eg.:

REF	Name	Content			Description
D98481	Diacon N	12	x	5 mL	control normal
D14481	Diacon N	5	x	5 mL	control normal
D98481SV	Diacon N	1	x	5 mL	control normal
D98482	Diacon P	12	x	5 mL	control abnormal
D14482	Diacon P	5	x	5 mL	control abnormal
D98482SV	Diacon P	1	x	5 mL	control abnormal

- NaCl solution (9 g/L).
- Photometric device.
- General laboratory equipment.

REAGENT PREPARATION

The reagent provided is ready to use.

STORAGE AND STABILITY

Conditions:	Store at 2 – 25 °C. Protect from light Close immediately after use. Avoid contamination Do not freeze the reagent.
Stability:	18 months after first opening of the primary container
On-board stability:	6 weeks
Calibration stability:	6 weeks

WARNINGS AND PRECAUTIONS

1. The standard contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
2. In very rare cases, samples of patients with gammopathy might give falsified results[3].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
4. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations, and other findings.
5. In the event of an incident related to the device, report it to the manufacturer and your competent authority as required.
6. For professional use only!

SPECIMEN COLLECTION AND STORAGE

Use serum or heparin plasma.

Stability[4]:

10 weeks	at	20 – 25 °C
5 months	at	4 – 8 °C
3 months	at	-20 °C

Only freeze once! Discard contaminated specimens.

STANDARD

(not included in the kit; has to be ordered separately)
Concentration: 5 g/dL
Contains bovine serum albumin (5 - 10%)
Storage: 2 – 25 °C
Stability: up to the indicated expiration date
Protect from light. Close immediately after use. Do not freeze the standard.

TEST PROCEDURE

Method:	BCG, colorimetric
Wavelength	Hg 546 nm, 540 – 600 nm
Optical path	1 cm
Temperature	37°C
Measurement	End point, against reagent blank. Increasing reaction.

Pipette into test tubes	Blank	Sample / Standard / Calibrator
Reagent	1000 µL	1000 µL
Sample / Standard / Calibrator	-	10 µL
Distilled water	10 µL	-
Mix, incubate for approx. 10 minutes at 37 °C and read absorbance (A) against reagent blank within 60 minutes.		

Automation

Special adaptations for automated analysers are available on request.

INTERPRETATION OF RESULTS

Calculation

With Standard or Calibrator:

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

Unit Conversion

Albumin [g/dL] x 10 = Albumin [g/L]
Albumin [g/dL] x 144.9 = Albumin [µmol/L]

QUALITY CONTROL AND CALIBRATION

We recommend the DIALAB serum controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range). Each laboratory should establish corrective action in case of deviations in control recovery.

Calibration

The assay requires the use of an albumin standard or an albumin calibrator. We recommend the DIALAB **Albumin Standard** and the DIALAB multi-calibration serum **Diacal Auto**.

PERFORMANCE CHARACTERISTICS

Tests were performed on the instrument BioMajesty® JCA-BM6010/C.

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Precision

Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/dL]	3.26	4.03	4.48
CV [%]	1.00	0.63	1.02
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	3.96	4.53	2.46
CV [%]	0.73	0.98	1.42

Analytical sensitivity

Limit of detection**: 0.1 g/dL.

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n=20) of an analyte free specimen.

Linearity and measuring range

Measuring range up 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.

Analytical specificity

Interfering substance	Interferences ≤ 10% up to
Ascorbic acid	30 mg/dL
Bilirubin (conjugated)	60 mg/dL
Bilirubin (unconjugated)	60 mg/dL
Hemoglobin	300 mg/dL
Lipemia (Triglycerides)	1200 mg/dL

For further information on interfering substances refer to Young DS[5,6].

Clinical performance

Method comparison (n=100)	
Test x	Competitor Albumin (ALB)
Test y	DIALAB Albumin, BCG
Slope	0.987
Intercept	0.168 g/dL
Coefficient of correlation	0.997

TRACEABILITY

The assigned values of calibrator Diacal Auto have been made traceable to the reference material ERM-DA470.

EXPECTED VALUES[7]

	[g/dL]	[g/L]	[µmol/L]
Adults	3.5 – 5.2	35 – 52	507 – 756

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

LIMITATIONS

Eventual albumin carry-over to reagents Iron (Ferene) and UIBC (Ferene). The actual carry-over depends on the analyser.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 14-5.
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IVD