DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Protein Total Mono, Biuret

(en) English

REF	Content			
D12681B	1 x	1	L	reagent
D12680	5 x	100	mL	reagent
D13685	5 x	50	mL	reagent
D13686	5 x	25	mL	reagent
D13687	5 x	10	mL	reagent
D43911	10 x	50	mL	reagent
D0448917	9 x	65	mL	reagent
DA1353	5 x	50	mL	reagent
DT1353	4 x	50	mL	reagent
DK1346	5 x	50	mL	reagent
DE1853	10 x	50	mL	reagent

For professional in vitro diagnostic use only.

INTENDED USE

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

DIAGNOSTIC SIGNIFICANCE[1,2]

Measurement of total protein is a useful test in a variety of disorders. Decreased total protein concentrations can be detected in defective protein synthesis in the liver, protein loss due to impaired kidney function, intestinal malabsorption, or nutritional deficiency. Elevated protein levels occur in chronic inflammatory disorders, liver cirrhosis and dehydration.

TEST PRINCIPLE

Photometric test according to the Biuret method.
Proteins form a violet blue colour complex with copper ions in alkaline solution.
The absorbance of this colored complex is directly proportional to the protein concentration in the sample.

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Sodium hydroxide	180 mmol/L
Potassium sodium tartrate	30 mmol/L
Potassium iodide	15 mmol/L
Copper sulphate	6 mmol/L

MATERIAL REQUIRED BUT NOT PROVIDED

- Standard or Calibrator, eg.:

REF	Name	Content
D94683	Protein Total 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 is ready to use.

STORAGE AND STABILITY

Conditions: Reagent is stable up to the date of expiry indicated on the kit, if stored at 2 - 25°C and contamination is avoided. Close immediately after use. Protect from light.

WARNINGS AND PRECAUTIONS

1. Components contained in Protein Total Mono, Biuret are classified according to EC regulation 1272/2008 (CLP) as follows:

   Reagent : Warning

   H290: May be corrosive to metals.
   H315: Causes skin irritation.
   H319: Causes serious eye irritation.
   H373: May cause damage to organs through prolonged or repeated exposure.
   H412: Harmful to aquatic life with long lasting effects.
   P234: Keep only in original packaging.
   P273: Avoid release to the environment.
   P280: Wear protective gloves/protective clothing/eye protection.
   P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
   P314: Get medical advice/attention if you feel unwell.
   P390: Absorb spillage to prevent material damage.
   Special labelling: Contains Potassium iodide.

2. In serum or plasma from patients who have received large intravenous amounts of polydextrans, too high values can be measured with the biuret method. In such cases an alternative method (e.g. Kjeldahl) has to be used.
3. In very rare cases, samples of patients with gammopathy might give falsified results[3].
4. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents.
5. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
7. 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.
8. For professional use only!

SPECIMEN COLLECTION AND STORAGE

Use human serum or heparin plasma.

Only use suitable tubes or collection containers for specimen collection and preparation. When using primary tubes, follow the manufacturer's instructions.

Stability[4]:		
	at 20 – 25 °C	6 days
	at 4 – 8 °C	4 weeks
	at - 20 °C	at least 1 year

Freeze only once! Discard contaminated specimens.

STANDARD

(not included in the kit; has to be ordered separately)

Description	Protein Total Standard is an aqueous standard. The standard is used to calibrate the DIALAB test Protein Total, Biuret.
Storage:	The standard, both opened and unopened, must be stored at 2 – 25 °C. Avoid contamination and protect from light.
Stability:	Unopened: Up to the date of expiry indicated on the kit. Opened: 36 months. Proper storage and handling of this product must be observed.
Warnings and Precautions:	1. Contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes. 2. Contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice. 3. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of standards. 4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer. 5. 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. 6. For professional use only.
Preparation	The standard is ready to use.
Traceability	The standard value has been made traceable to the biuret method. Standard value has been determined under standardized conditions using the DIALAB Protein Total, Biuret reagent.
Concentration	**5 g/dL (50 g/L)**

TEST PROCEDURE

Method:	Colorimetric, Biuret
Wavelength	540 nm, Hg 546 nm
Optical path	1 cm
Temperature	20 – 25 °C / 37°C
Measurement	End point, against reagent blank. Increasing reaction.

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std./Cal.	Sample
Sample	-	-	20 µL
Standard/Calibrator	-	20 µL	-
Distilled water	20 µL	-	-
Reagent	1000 µL	1000 µL	1000 µL
Mix, incubate for 5 min. at 20 – 25 °C / 37 °C and read absorbance against the reagent blank within 60 min.			

Automation

Special adaptations for automated analysers can be made on request.

INTERPRETATION OF RESULTS

Calculation

With Standard or Calibrator

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

Unit Conversion

Total Protein [g/dL] x 10 = Total Protein [g/L]

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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). 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.

Calibration
We recommend the DIALAB multi calibration serum **Diacal Auto**. The DIALAB **Protein Total Standard** may be used alternatively for calibration.

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 [mg/dL]	4.78	6.17	7.40
CV [%]	0.57	0.52	0.35
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	5.97	6.63	7.13
CV [%]	1.00	1.00	1.15

Analytical sensitivity
Limit of detection*: 0.05 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 14 g/dL. When values exceed this range, samples 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 and unconjugated)	60 mg/dL
Hemoglobin	500 mg/dL
Lipemia (Triglycerides)	1000 mg/dL

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

Clinical performance

Method comparison (n=100)	
Test x	Competitor Protein Total
Test y	DIALAB Protein Total Mono, Biuret
Slope	1.00
Intercept	0.040 g/dL
Coefficient of correlation	0.998

TRACEABILITY

The assigned values of the calibrator Diacal Auto and Protein Total Standard are traceable to the Biuret method.

EXPECTED VALUES[1]

	[g/dL]	
	Females	**Males**
Adults:	6.6 - 8.8	6.6 - 8.8
Children:	**Females**	**Males**
1 - 30 day(s)	4.2 - 6.2	4.1 - 6.3
1 – 6 month(s)	4.4 - 6.6	4.7 - 6.7
6 months – 1 year	5.6 - 7.9	5.5 - 7.0
1 – 18 year(s)	5.7 - 8.0	5.7 - 8.0

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

LIMITATIONS

- Eventual Protein Total Mono (Biuret) carry-over to reagents CK-NAC (opt. DGKC/IFCC), CK-MB (opt. DGKC/IFCC), Uric Acid (AOX), and Uric Acid (TBHBA). The actual carry-over depends on the analyser.

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.

LITERATURE

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4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 42-3.
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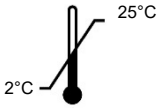
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