Liquid Reagents – ready to use

# PROTEIN TOTAL MONO
# Biuret

Single Reagent

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

| Ref.No. | Kit Size | Content |
|---|---|---|
| **DIA010202** | 5 x 25 ml | Single Reagent |
| **DIA010203** | 5 x 50 ml | Single Reagent |
| **DIA010204** | 5 x 100 ml | Single Reagent |

**Additionally offered:**

| | | |
|---|---|---|
| **DIA060100** | 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, Biuret
**Wavelength:** 540 nm, Hg 546 nm
**Temperature:** 20 – 25°C, 37°C
**Sample:** Serum or plasma
**Linearity:** up to 15 g/dL(150 g/L)
**Sensitivity:** Lower limit of detection: 0.05 g/dL(0.5 g/L)

## SUMMARY [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 mal absorption 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 color 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 |

## REAGENT PREPARATION

The reagent is ready to use.

## 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 20 – 25°C 6 days
at 4 - 8°C 4 weeks
at -20°C at least 1 year
Discard contaminated specimens.
Freeze only once!

## MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

## 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** | - | - | 20 µl |
| **Standard/Calibrator** | - | 20 µl | - |
| **Dist. water** | 20 µl | - | - |
| **Reagent** | 1000 µl | 1000 µl | 1000 µl |
| Mix, incubate for 5 min. at 20-25°C/37°C andread absorbance against the reagent blank within 60 min. | | | |

## CALCULATION

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

## UNIT CONVERSION

g/dL x 10 = g/L

## REFERENCE RANGE [1] * [g/dL]

| | Females | Males |
|---|---|---|
| **Adults:** | 6.6 - 8.8 | 6.6 - 8.8 |
| **Children:** | | |
| 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.

## PERFORMANCE CHARACTERISTICS

### LINEARITY, MEASURING RANGE

The test has been developed to determine total protein concentrations within a measuring range from 0.05 – 15 g/dL (0.5 – 150 g/L).
If values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

### SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 0.05 g/dL (0.5 g/L).

### PRECISION (at 37 °C)

| Intra-assay n = 20 | Mean [g/dL] | SD [g/dL] | CV [%] |
|---|---|---|---|
| Sample 1 | 5.27 | 0.05 | 0.91 |
| Sample 2 | 7.05 | 0.07 | 1.01 |
| Sample 3 | 10.4 | 0.08 | 0.80 |
| **Inter-assay n = 20** | **Mean [g/dL]** | **SD [g/dL]** | **CV [%]** |
| Sample 1 | 5.24 | 0.06 | 1.06 |
| Sample 2 | 7.07 | 0.11 | 1.53 |
| Sample 3 | 10.4 | 0.14 | 1.32 |

### SPECIFICITY/INTERFERENCES

No interference up to:

| | |
|---|---|
| Ascorbic acid | 30 mg/dL |
| Bilirubin | 40 mg/dL |
| Hemoglobin | 500 mg/dL |
| Triglycerides | 1000 mg/dL |
| Dextran | 2000 mg/dL |

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For further information on interfering substances refer to Young DS [4].

**METHOD COMPARISON**

A comparison between Diagnostica Total protein (y) with a commercially available test (x) using 68 samples gave following results: y = 1.00 x – 0.07 g/dL; r= 0.997.

## CALIBRATION

The assay requires the use of a protein total standard or calibrator.
We recommend the Diagnostica **Protein Total Standard** and the Diagnostica multi calibration serum **Diacal Auto**.
The assigned values of the calibrator are traceable to the Biuret method.

## QUALITY CONTROL

All control sera with protein total 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).
Each laboratory should establish corrective action in case of deviations in control recovery.

## AUTOMATION

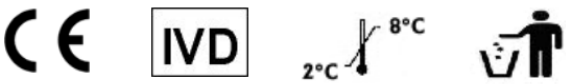
Special applications for automated analysers can be made on request.

## WARNINGS AND PRECAUTIONS

1. Reagent: Warning.
   H290: May be corrosive to metals.
   H315: Causes skin irritation.
   H319: Causes serious eye irritation.
   P234: Keep only in original container.
   P280: Wear protective gloves/protective clothing/eye protection/face protection.
   P302+P352: If on skin: Wash with plenty of water/soap.
   P305+P351+P338: In in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Contrinue rinsing.
   P309+P311: If exposed or if you feel unwell: call a poison center or doctor/physician.
   P390: Absorb spillage to prevent material damage.
2. The reagents contain sodium hydroxide. Do not swallow! If the reagents come in contact with skin or mucous membranes rinse immediately with water!
3. The Protein Total Standard contains biological material. The standard should be handled as potentially infectious and with the same precautions used for patient specimens.
4. 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.
5. In very rare cases, samples of patients with gammopathy might give falsified results [5].
6. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
7. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
8. For professional use only!

## WASTE MANAGEMENT

Please refer to local legal requirements.

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