BIOLABO
www.biolabo.fr

MANUFACTURER:
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TOTAL PROTEIN Biuret Method

Reagent for quantitative determination of total protein in human serum and plasma.

I REF K1016	**R1**	4 x 17 mL
I REF K2016	**R1**	4 x 25 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

I INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantitative determination of triglycerides in human serum and plasma.

I GENERALITIES (1)

The overall composition of a patient's plasma or serum should be studied first by determining its total protein content and then its composition by electrophoresis.
Decrease in the volume of plasma water (hemoconcentration), noted in dehydration (severe vomiting, diarrhea, Addison's disease, or diabetic acidosis), is reflected as relative hyperproteinemia. Hemodilution (increase in plasma water volume) occurring with water intoxication or salt retention syndromes, during massive intravenous infusions, and physiologically when a recumbent position is assumed, is reflected as relative hypoproteinemia. Hypoproteinemia due to low levels of albumin in plasma is also common and has many causes. Mild hyperproteinemia may be caused by an increased in the concentration of specific proteins (infection). Marked hyperproteinemia may be caused by high levels of monoclonal immunoglobulins produced in multiple myeloma and other malignant paraproteinemia.

PRINCIPLE (4) (5)

Colorimetric method described by Gornall and al. The peptide bonds of proteins react with Cu^{2+} in alkaline solution to form a colored complex which absorbance, proportional to the concentration of total protein in the specimen, is measured at 550 nm. The Biuret reagent contains sodium potassium tartrate to complex cupric ions and maintains their solubility in alkaline solution.

REAGENTS

R1 **TP2**	Biuret Reagent	
Sodium hydroxide	370	mmol/L
Na-K Tartrate	10	mmo/L
Potassium iodide	3	mmol/L
Copper II sulfate	3	mmol/L

Danger: Met Corr.1: H290 - May be corrosive to metals
Eye Dam.1: H318 - Causes serious eye damage
Skin Corr. 1B: H314- Causes severe skin burns and eye damage

P234: Keep only in original container, P264: Wash hands thoroughly after handling, P280 : Wear protective gloves/protective clothing/eye protection/face protection, P301+330+331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting, P303+361+353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water, P304+P340 : IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing, P305+351+338: IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing, P310: Immediately call a POISON CENTER or doctor/physician. Classification due to: Sodium Hydroxide 2,5-< 10%. For more details, refer to Safety data sheet (MSDS)

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 18-25°C, used and stored as described, reagent is stable:
Unopened:

- Until expiry date stated on the labe.

Once opened:

- Reagent is stable at least 1 year at 18-25°C

Discard reagent if cloudy or if absorbance at 546 nm > 0.150.

SPECIMEN COLLECTION AND HANDLING (2)

Serum or plasma.
Analyze fresh or store at 2-8°C less than 72 h.

Total protein in serum is stable for:
✓6 months at –20°C
✓Indefinitely at -70°C.

LIMITS (3)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

EXPECTED VALUES (2)

Serum or plasma	(g/dL)
In cord	4.8-8.0
Premature	3.6-6.0
Newborn	4.6-7.0
1 week	4.4-7.6
7 days-1 year	5.1-7.3
1 year-2 years	5.6-7.5
≥ 3 years	6.0-8.0
Adult, ambulatory	6.4-8.3
Adult, recumbent	6.0-7.8
≥ 60 years	Lower by 0.2

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On Kenza 240TX, at 37°C, 546 nm

Linearity Range: between 0.7 and 8.0 g/dL

Detection limit: approx. 0.01 g/dL

Precision:

Within-run N = 20	*Low level*	*Medium level*	*High level*
Mean (g/dL)	3.53	6.89	9.14
S.D. g/dL	0.03	0.07	0.08
C.V. %	0.8	1.0	0.9

Between run N = 20	*Low level*	*Medium level*	*High level*
Mean (g/dL)	3.54	6.87	9.06
S.D. g/dL	0.06	0.10	0.15
C.V. %	1.7	1.4	1.6

Comparison studies with commercially available liquid reagent:
Realized on human specimens (n=116) between 2.7 and 8.8 g/dL
y = 0.9652 x + 0.2395 r = 0.9895

Analytical sensitivity: approx. 0.057 abs (1 g/dL)

Interferences:

Turbidity	Positive interference from 0.114 abs
Total bilirubin	No interference up to 541 µmol/L
Direct bilirubin	No interference up to 397 µmol/L
Glucose	No interference up to 1059 g/dL
Ascorbic acid	No interference up to 2500 g/dL
Hemoglobin	Positive interference from 128 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration Stability: 2 months

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

Performances and stability data on Kenza 450TX/ISE and Kenza One are available on request.

CALIBRATION (6)

- REF 95015 Multicalibrator traceable *to SRM 927*

The calibration frequency depends on proper instrument functions and on the preservation of reagent

QUALITY CONTROL

- REF 95010 EXATROL-N Level 1
- REF 95011 EXATROL-P Level 2
- External quality control program

It is recommended to control in the following cases
- At least once a run
- At least once within 24 hours
- When changing vial of reagent
- After maintenance operations on the instrument

If control is out of range, apply following actions:
1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly final result.
Refer to the instruction of use of Kenza analyzer.

REFERENCES

(1) TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 477-530.
(2) Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 916-921
(3) YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-498 à 3-511
(4) GORNALL A. C., BARDAWILL C. J., DAVID M. M., J. Biol. Chem. 1949, 177, 751
(5) TIETZ N.W. Text book of clinical chemistry, 3d Ed. C.A. Curtis, E.R. Silverman L . M., Christensen R. H. (1995) p. 523-524.
(6) SRM: Standard Reference Material ®

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with