

Total Protein

(Biuret Method)

| Code | Product Name | Pack Size |
|-------|---------------|------------|
| VS206 | Total Protein | 10 x 32 ml |
| VS306 | Total Protein | 10 x 44 ml |

| |
|-----|
| IVD |
|-----|

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Total Protein in human serum and plasma.

CLINICAL SIGNIFICANCE

Total protein is useful for monitoring gross changes in protein levels caused by various disease states. It is usually performed in conjunction with other tests such as serum albumin, liver function tests or protein electrophoresis. An albumin/globulin ratio is often calculated to obtain additional information.

Increased levels of serum protein are observed in dehydration, multiple myeloma and chronic liver disease.

Decreased levels are encountered in renal diseases and terminal liver failure.

PRINCIPLE

Biuret method. The peptide bonds of protein react with copper II ions in alkaline solution to form a blue-violet ion complex, (the so called biuret reaction), each copper ion complexing with 5 or 6 peptide bonds. Tartrate is added as a stabiliser whilst iodide is used to prevent auto-reduction of the alkaline copper complex. The colour formed is proportional to the protein concentration and is measured at 546 nm (520-560).

REAGENT COMPOSITION

Reagent 1 Biuret Reagent

| | |
|---------------------------|-------------|
| Copper Sulphate | <15 mmol/L |
| Potassium Sodium Tartrate | >15 mmol/L |
| Potassium Iodide | >10 mmol/L |
| Sodium Hydroxide | >600 mmol/L |

REAGENT PREPARATION

Reagents are liquid, ready to use.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

On board stability: 30 days if refrigerated (2–10°C) and not contaminated.

SPECIMEN COLLECTION AND HANDLING

Use unheamolytic serum or plasma (heparin, EDTA)

It is recommended to follow standardized procedure.

Stability

| | |
|-------------------|------------|
| 6 days | at 20–25°C |
| 4 weeks | at 4–8°C |
| at least one year | at -20°C |

Discard contaminated specimens.

CALIBRATION

Calibration with Cfas calibrator is recommended.

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagent performance

EXPECTED VALUES

| | (gm/dl) |
|---------------|-----------|
| Adults: | 6.4 – 8.3 |
| Premature | 3.6 – 6.0 |
| Newborn | 4.6 – 7.0 |
| 1 week | 4.4 – 7.6 |
| 7 – 12 months | 5.1 – 7.3 |
| 1 – 2 years | 5.6 – 7.5 |
| > 2 years | 6.0 – 8.0 |

It is recommended that each laboratory verify this range or derive reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on vecsys system. Data obtained in your laboratory may differ from these values.

Limit of quantification: 0.37 gm/dl

Linearity: 10 gm/dl

Measuring range: 0.37 – 10 gm/dl

PRECISION

| Intra-assay precision Within run (n=20) | Mean (gm/dl) | SD (gm/dl) | CV (%) |
|--|-----------------|---------------|-----------|
| Sample 1 | 5.77 | 0.1 | 1.22 |
| Sample 2 | 7.31 | 0.1 | 0.69 |

| Inter-assay precision Run to run (n=20) | Mean (gm/dl) | SD (gm/dl) | CV (%) |
|--|-----------------|---------------|-----------|
| Sample 1 | 5.85 | 0.07 | 1.13 |
| Sample 2 | 7.34 | 0.04 | 0.57 |

COMPARISON

A comparison between vecsys Total Protein (y) and a commercially available test (x) using 20 samples gave following results:

$$y = 0.986x + 0.163 \text{ gm/dl}$$

$$r = 0.997$$

INTERFERENCES

Following substances do not interfere:

haemoglobin up to 7.5 g/l, bilirubin up to 40 mg/dl, triglycerides up to 1500 mg/dl.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.

R1 contains 2.4 % sodium hydroxide.

WASTE MANAGEMENT

Please refer to local legal requirements.

ASSAY PARAMETERS

| Parameter Screen window | VEC-150+ | VEC-200+ |
|--|---------------|---------------|
| Chemistry | Total Protein | Total Protein |
| Full Name | Total Protein | Total Protein |
| Decimal | 0.000 | 0.000 |
| Test Method | End Point | End Point |
| Direction | Increase | Increase |
| Unit | gm/dl | gm/dl |
| Primary Wavelength | 546 nm | 546 nm |
| Secindary Wavelength | - | - |
| Linearity | 10 gm/dl | 10 gm/dl |
| Calibration Method | Linear | Linear |
| Reagent Alarm No. | from 5 to 10 | from 5 to 10 |
| Sample Volume | 2 | 2 |
| R1 | 200 | 200 |
| R2 | | |
| Blank Cycle/Time (s) | 7-9 | 7-9 |
| Reaction Cycle/Time (s) | 18-19 | 23-25 |
| Linearity Limit (%) | | |
| Substrate Depletion Limit | | |
| Response Range | | |
| Auto Dilution Rerun Condition | | |
| Above Linearity Limit | ✓ | ✓ |
| Above Substrate Depletion Limit | | |
| Auto Dilution Rerun Set up: Dilution Ratio | 5 | 5 |
| Original Sample Volume | 40 | 40 |
| Calibration Validity | | |

ASSAY PARAMETERS

| Parameter Screen | VEC-300+ |
|------------------|---------------|
| Item | Total Protein |
| Full Name | Total Protein |
| Test Method | End Point |
| Filter | 546 nm |
| Decimal | 0.00 |
| Unit | gm/dl |
| Sub Filter | - |
| High Poluted | No |
| Reagent Blank | |
| Blank Medium | Reagent |
| Blank Value | Nil |
| Sample | |
| Sample Volume | 3 |
| Dilution | |
| Dilution Sample | |
| Dilution Rate | |
| Dilution Correct | |
| Reagent 1 Volume | 300 |
| Reagent 2 Volume | 0 |
| Assistance | |
| Linearity | 10 gm/dl |
| Test Point | 35-36 |
| Dilution | 0 |
| No. of Standard | 1 |

NOTE


The Program is only for VECSYS kits.


The program is made as per the in house testing, it can be modified as per requirements.


REFERENCES


1. Cornall, A. G., Bardawill, C. J., David, M. M.: J. Biol. Chem. 177, 751, 1949.
2. Dumas, B. T., Bayse, D. D. a kol.: Clin. Chem. 27, 1642, 1981.
3. Chromý, V., Fischer, J.: Clin. Chem. 23, 754, 1977.
4. Chromý, V., Fischer, J., Vozníček, J.: Z. Med. Labor.-Diagn. 21, 333, 1980.
5. Tietz Textbook of Clinical Chemistry and Molecular diagnostics. Burtis, C.A., Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders Company, 2012.

**SYMBOLS USED ON LABELS**


 Lot Number

 Manufacturer

 See Instruction for Use

 Expiry Date

 In Vitro Diagnostics

 8°C Storage Temperature
2°C