**ENVY® 500 TOTAL PROTEIN REAGENT KIT**

Product no. 55425  
For in vitro diagnostic use

**INTENDED USE**

Envoy®® 500 Total Protein Reagent is for the quantitative in vitro diagnostic determination of total protein in human serum and plasma on Envoy 500 Series Analyzers. Measurements of total protein are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders. It is not intended for use in Point of Care settings.

**CLINICAL SIGNIFICANCE**

In human plasma, albumin accounts for 50 to 60% of total proteins - the reminder fraction mainly contains globulins (α1, α2, β, and γ). Most plasmatic proteins are synthesized by the liver, except immunoglobulins. Increase of the plasmatic volume (salt retention syndrome, intoxication with water...) or its reduction (dehydration related to vomiting, diarrhoea...) induce respectively relative hypoprotenemia and relative hyperproteinaemia.

For a normal plasmatic volume, abnormal total protein rates only occur in the event of disorder affecting the concentration of albumin or immunoglobulins. Thus, severe proteinic insufficiency (malabsorption, malnutrition, dietary insufficiency), renal and hepatic diseases result in hypoprotenemia. If total protein concentration is lower than 40 g/L oedemas can be observed. Hypoprotenemia can be seen, for example, in case of hypoimmunoglobulinaemia (multiple myeloma, infection).

**METHODOLOGY**

Serum proteins form a coloured complex in the presence of copper salt in alkaline solution:

- Normal saline.
- Analyzer specific consumables.
- General Laboratory Equipment.

**PROCEDURE**

The Envoy 500 Total Protein Reagent is ready to use as packaged.

**STORAGE AND STABILITY**

Store this reagent at 2 to 25 °C and protected from light. Do not freeze. Unopened reagents are stable to the expiration dates on the bottle labels. The reagent is stable for 14 days onboard the Envoy 500 Analyzer.

**SPECIMENS**

COLLECTION AND STORAGE

Fresh unhemolized serum or lithium heparinized plasma is the preferred specimen. Samples must be free from haemolysis and lipemia. Do not analyze whole blood. Collect specimens by venipuncture according to accepted clinical protocols.

**MATERIALS PROVIDED**

The Envoy 500 Total Protein Reagent Kit includes the following components:

- 8 x 48.8 mL boats of Envoy 500 Total Protein Reagent.

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Envoy 500 Serum Calibrator (product no. 55111).
- Envoy 500 Serum Controls (product no. 55131).
- Normal saline.
- Analyzer specific consumables.
- General Laboratory Equipment.

**REAGENT INSTALLATION AND USE**

Program the instrument using the application parameters and programming instructions provided at the end of this Instructions For Use. Refer to the Operator Manual for additional information on installing reagents and programming the analyzer, and running samples, calibrators and controls.

**COMPOSITION**

Total Protein Reagent R contains 6 mmol/L Potassium iodide ; 21 mmol/L Potassium sodium tartrate ; 6 mmol/L Copper sulfate ; 490 mmol/L Sodium hydroxide.

**WARNINGS AND PRECAUTIONS**

- This reagent is for professional in vitro diagnostic use only.
- Total Protein Reagent is "Corrosive".

**WARRANTY**

Causes skin and serious eye irritations. May be corrosive to metals. Harmful to aquatic life with long lasting effects.

**CALIBRATION**

Calibrate the instrument after loading new reagent lot, after maintenance and whenever quality control results fall outside established limits. Under typical use conditions, calibration factors for this test are valid for 14 days.

**QUALITY CONTROL**

Quality control requirements should be established in accordance with local, state and/or federal regulations or accreditation requirements. Assay at least two levels of serum control daily. Serum Controls for Envoy 500 level 1 and level 2 may be used. Controls should also be assayed after performing a reagent blank, calibrating, maintaining the instrument and after loading a new reagent unit.

Controls may be assayed more frequently based on laboratory workflow and the discretion of the user.

**REFERENCE**

For further information, the Safety Data Sheet (SDS) is available on request for professional user.

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In very rare cases, monoclonal gammapathies (multiple myeloma), in particular IgM type (Waldenstrom’s macroglobulinemia) can cause unreliable results.

Other compounds may interfere.

REFERENCES

14. Interfering Substances Studies have been performed to determine the level of interference from different compounds according to CLSI EP7-A2 protocol and SFBC recommendations. Recovery is within ± 10% of initial value of total protein concentration of 4.06, 6.50 and 9.90 g/dL.
15. Unconjugated Bilirubin : No significant interference up to 30.0 mg/dL (513 μmol/L).
16. Conjugated Bilirubin: No significant interference up to 29.5 mg/dL (504 μmol/L).
17. Glucose: No significant interference up to 577 mg/dL (32.03 mmol/L).
18. Turbidity: No significant interference up to 577 mg/dl (32.03 mmol/L).
19. Hemoglobin: No significant interference up to 50 mg/dL, induces falsely high results at therapeutic concentrations.

Programming Instructions

Detailed instructions for programming reagent parameters are provided in the Envoy® 500 Operator Manual and Envoy®500 Settings Table. It is very useful if you have a total protein code must first be added before the parameters can be entered. On the menu bar, select «Test — Test Directory.» A new window will open up listing all the codes for the tests that are installed on the instrument. Click on the «New Code» button, type «PRO» into the Code field and select «Save.»

To program the application parameters, check the box next to the code for the total protein test, and select the «Parameters» button located at the bottom of the window. To program standard information, click the «Standards» button located at the bottom of the window.