



PROTEIN STANDARD

REF 1578-1190

Packaging: 5 x 1 mL

INTENDED USE

Material for the preparation of reference curves for the quantitative determination of a1-antitrypsin, a2-macroglobulin, a1-acid glycoprotein, ceruloplasmin, haptoglobin, transferrin, IgA, IgG, IgM, C3, C4, prealbumin, kappa light chains, lambda light chains using the corresponding Medicon reagent with Diatron Pictus® P700 and P500 analyzers. For in vitro diagnostic use only by trained laboratory professionals.

COMPOSITION

Variable amounts of the following human proteins in a filtered, defibrinated, liquid human plasma base:

a1-antitrypsin, a2-macroglobulin, a1-acid glycoprotein, ceruloplasmin, haptoglobin, transferrin, IgA, IgG, IgM, C3, C4, kappa light chains, lambda light chains, Prealbumin

Stabilizers and preservatives

Actual concentrations are lot dependent. Please verify your calibrator lot before programming the analyzer



WARNINGS – PRECAUTIONS

- To avoid the possible built up of azide compounds, flush waste pipes with water after the disposal of material. Dispose of all waste materials in accordance with local guidelines.
- Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1 and 2 using FDA approved methods and were found to be non-reactive. As there is no known test method that can offer complete assurance that products derived from human blood will not transmit infectious agents this product should be handled as a potentially infectious material.
- A Material Safety Data Sheet is available for this product by MEDICON.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!



PREPARATION

Materials are ready to use. Swirl each vial gently prior use. Avoid foaming. Replace cap immediately after use and store at 2-8°C. Unsuitable storage, handling, or errors during the analytical procedure may give erroneous results.

Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

No other materials are required than the chemistry analyzer, reagents and controls

CALIBRATION STORAGE - STABILITY

The materials are stable, unopened up to the stated expiry date when stored at 2-8°C. Once opened the material is stable for 6 weeks stored at 2-8°C.



DETERIORATION

The material should not be used:

- After prolonged exposure to high temperatures.
- After deep freeze.



WASTE DISPOSAL

This product contains sodium azide (NaN₃), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes. Dispose of all waste material in accordance with local guidelines. Safety data sheet is available for professional use on request.

ASSIGNED VALUES – Lot specific

Please refer to the value sheet for the specific lot available at <https://medicondoc.com>.

BIBLIOGRAPHY

1. Blirup-Jensen S, Johnson AM, Larsen M. Protein standardization IV: value transfer procedure for the assignment of serum protein values from a reference preparation to a target material. Clin Chem Lab Med 2001; 39:1110-1122.
2. Baudner S, Bienvenu J, Blirup-Jensen S, Carlström A, Johnson AM, Milford Ward A, et al. The certification of a matrix reference material for immunochemical measurement of 14 human serum proteins. CRM 470. EUR 15243 EN, 1993

SYMBOLS



Manufacturer



In vitro diagnostic medical device



Temperature Limit



Catalogue Number



Caution



Biological Risks