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CE IVD

Free Light Chains (FLC), in urine for *BN™ Series*

General information: structure, function ...

Immunoglobulin molecules are composed of two identical heavy chains (HC) of the same type and two identical light chains (LC) of the same type, linked by a variable number of disulphide bridges and non-covalent links. The amount of LC and HC produced by plasma cells is unbalanced, resulting in an excess of LC (FLC = Free Light Chains) that are secreted in the serum and, given their low molecular weight (approx. 22-25 KDa for the monomers), are almost completely eliminated by the kidney.

In the so-called monoclonal gammopathies, plasma cells frequently generate large (sometimes huge) quantities of FLC, which have the particular characteristic of being monoclonal (ie produced by a single clone). This hyperproduction of monoclonal FLC causes, in addition to the increase of its concentration in the serum, to overcome the tubular reabsorption capacity in the kidney and then FLC are also found in the urine, which is normally known as Bence-Jones Proteinuria (BJP). The amount of FLC in serum is determined by the balance between their production and their renal clearance (glomerular filtration), which depends on their degree of polymerization. The amount in urine will also depend on their tubular reabsorption rate.

Clinical Significance

The measurement of serum FLC levels and the calculation of its ratio (free K/L), as well as the determination of the urinary excretion of monoclonal FLC, have an important clinical significance, both in diagnostic and prognostic terms, in multiple pathological conditions, such as Multiple Myeloma, Waldenström's Macroglobulinemia, AL Amyloidosis, Light chain deposition disease (LCDD) and, in general, in all monoclonal gammopathies. The importance of its determination lies not only in revealing these pathologies but also in its harmful effect on tissues and organs, mainly on the kidney, which is the cause of different clinical manifestations. Periodic quantitative estimation, both in serum and in urine, is also important for monitoring and controlling the evolution of all those pathologies in which FLC are present.

In urine, specific guidelines (Graziani et al. for the IFCC Committee on Plasma Proteins: "Guidelines for the Analysis of Bence Jones Protein" - Clin Chem Lab Med 2003; 41(3): 338-346) propose, as an alternative approach for the presence of Bence-Jones proteinuria (BJP), the use of the quantitative measurement of FLC as a screening method, that may also be useful in monitoring and as BJP quantitative estimation, more precise and sensitive than the one made electrophoretically. For this purpose, at least 10 mg/L of Kappa and Lambda FLC should be detected.

Assay Performances and Characteristics

- **Particle Enhanced Nephelometric Immunoassay (PENIA),** based on specific **polyclonal antibodies,** specifically developed for their use on Siemens Healthcare's *BN™ Series* nephelometers.
- Good correlation with the densitometric estimation of Bence-Jones Proteinuria (BJP).
- Reagents, Calibrators and Controls, at 3 levels, in ready-to-use containers
- Values traced to the ***European Reference Material ERM-DA470k/IFCC*** *(Institute for Reference Materials and Measurements, IRMM),* to ensure lot to lot consistent results.
- No Antigen Excess until extreme values (controlled using the pre-reaction feature).

Catalogue

κλoneus® - U-FLC - BNs

REF TD-42505 Σ 100 test

EAN/GTIN: 8434477201066 SMN: 11309431

Contains Free Kappa Reagents, Free Lambda Reagents, Calibrator and Controls (3 levels)

Assay also available for other analytical platforms. For further information, please contact the Customer Support Service at support@3diag.com