

**Free Light Chains (FLC),
in serum and urine, for *IMMAGE*® 800**



TRIMERO Diagnostics, SL

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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

- ➔ **Non-competitive Nephelometric Assays:**
Kinetic UDR Immunoassays, enhanced with polystyrene particles, for their use on *Beckman Coulter's IMMAGE*® 800 Immunochemical Systems.
- ➔ Antigen Excess control assays for a safer use.
- ➔ Values traced to the **European Reference Material ERM-DA470k/IFCC** (*Institute for Reference Materials and Measurements, IRMM*), to ensure lot to lot consistent results.
- ➔ Reagents, Calibrators and Controls, at 3 levels, in ready-to-use containers.

Catalogue

κλoneus® - S-FLC-K - 800 Kit

Free Light Chains KAPPA - SERUM - for *IMMAGE*® 800 (2nd generation)

REF TD-42500-K ▾ 100 test

P/N *Beckman Coulter*: **B28093**

Contents: Free Kappa Reagents,
Calibrators (6+4 levels) and Controls (3+3 levels)

κλoneus® - S-FLC-L - 800 Kit

Free Light Chains LAMBDA - SERUM - for *IMMAGE*® 800 (2nd generation)

REF TD-42500-L ▾ 100 test

P/N *Beckman Coulter*: **B28105**

Contents: Free Lambda Reagents,
Calibrators (6+4 levels) and Controls (3+3 levels)

κλoneus® - U-FLC - 800 KIT

Free Light Chains - URINE - for *IMMAGE*® 800 (2nd generation)

REF TD-42500 ▾ 100+100 test

P/N *Beckman Coulter*: **B28035**

Contents: Free Kappa and Free Lambda Reagents,
Calibrators (6+4 levels) and Controls (3 levels)

κλoneus® - FLC - CAL SET

Free Light Chains - Calibrators - Serum + Urine

REF TD-42501

P/N *Beckman Coulter*: **B28050**

Contents: Calibrators for serum (2x(6+4) levels)
and urine (6+4 levels)

κλoneus® - FLC - CONTROL

Free Light Chains - Controls - Serum + Urine

REF TD-42502

P/N *Beckman Coulter*: **B28058**

Contents: Controls for serum (3+3 levels) and urine (3 levels)

κλoneus® Free Light Chain assays
are also available for other analytical platforms

For further information, please contact the
Customer Support Service at support@3diag.com

κλoneus®

Free Light Chains

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by  **TRIMERO**
DIAGNOSTICS

Free Light Chains urine and serum.

Reagents based on polyclonal antibodies and immunogens.

Particle-enhanced assays for serum and urine.

Values referred to the European Reference Material ERM-DA470k/IFCC to ensure lot-to-lot traceability.

Nephelometric assays for IMMAGE® systems.

Turbidimetric assays for AU® platforms.

Good correlation with the densitometric estimation of Bence-Jones proteinuria.



Compatible with

 **BECKMAN
COULTER**
systems

Alternative Approach for the determination of Bence Jones Proteinuria (BJP), based on the IFCC Guidelines^{*1a}

Screening Test

Quantification of Free Light Chains in non-concentrated urine (ur-FLC)

Recommended Sample^{*1b}:

2nd morning void and expressing the results relative to creatinine

with **κλoneus[®]** assays
by Nephelometry (NIA) or Turbidimetry (TIA)

Recommended Detection Limit^{*1c}:
< 10 mg/L

Kappa or Lambda
>10 mg/L

Kappa and Lambda
<10 mg/L

BJP Suspicion

STOP

Confirmation Test

to determine the electrophoretic, mono, oligo or polyclonal distribution of the quantified ur-FLC by **κλoneus[®]** assays

by Immunofixation (IF)
of concentrated urine
Recommended Sensitivity^{*1e}: < 10 mg/L

the quantitative result obtained by **κλoneus[®]** is an objective guide to establish the urine concentration factor and it can also be useful in monitoring and quantitative estimation of the urinary monoclonal component ^{*1f} which is more precise and sensitive than densitometrically dosed

1. "Guidelines for the Analysis of Bence Jones Protein"

M. Graziani et al. for the IFCC Committee on Plasma Proteins
and the SIBioC Study Group on Proteins
Clin Chem Lab Med 2003; 41(3):338-346

1a. page 339:

"Alternative approaches

Immunochemical methods (nephelometry, turbidimetry) for the quantification of FLCs in urine can be used for BJP detection as an initial screening to exclude BJP, thus reducing the number of samples to process further."

1b. page 339:

"Sample

...

... we recommend the use of the second morning void (5) and expressing the concentration of BJP relative to urinary creatinine."

1c. page 340:

"Alternative approaches

...

... it is mandatory to control and avoid antigen excess and to document a detection limit below 10 mg/l."

1d. page 340:

"Alternative approaches

...

... A positive test should be followed by immunofixation (IF) for the following reasons: ..."

1e. page 339:

"Sensitivity

The indication of a detection limit for BJP can only be approximate since there is no way of obtaining an accurate quantification of the protein. However, since the indicated amount for polyclonal LC excretion is approximately 10 mg/l (10, 11), a method with a sensitivity down to this limit is suggested."

1f.

page 340:

"Quantification

...

Despite all these drawbacks, the immunochemical estimation of BJP may be of clinical value to monitor the clone during treatment, but it is necessary to utilize the same antisera and calibrators throughout the follow-up and to keep in mind all the caveats listed above."