Free Light Chain Kits

Line Presentation

Summary

New Scientific Company, S.r.l.

Via Dante Alighieri, 35 - 20032 Cormano (MI) (Italia)
Tel.: (+39) 02 61 52 021 - Fax: (+39) 02 61 52 154
http://www.newscientific.com

New Scientific Company España, S.r.l.

Valencia, 558 - 08026 Barcelona (España)
Tel.: (+34) 93 244 82 94 - Fax: (+34) 93 244 82 95

Introduction

This line, which is the result of specific internal work, is exclusive to the NSC who, as the world leaders, have been marketing it since 1988.

The objective of the kits is for the qualitative and/or quantitative determination of Free Light Chains in unconcentrated urine and cerebrospinal fluid.

The method is based upon the reaction of ImmunoPrecipitation in liquid phase with specific adsorbed antisera anti Free Light Chains – "Hidden" Determinants.

The turbidity produced by the reaction can be:

- Measured instrumentally: turbidimetry or nephelometry:
  - Quantitative determination:
    The signal produced by the specimen is interpolated into the curves obtained with the Calibrators.
  - Instrumental qualitative determination:
    The signal produced by the specimen is compared to that produced by the Calibrators with the dilution chosen as the minimum concentration retained significant (cut off).

- Evaluated visually with suitable lighting:
  - Non-instrumental qualitative determination
    The turbidity produced by the specimen is compared to that of the "Sample Blank" and to that of the calibrators with the dilution chosen as the minimum concentration retained significant (cut off).

Uses

Determination of Free Light Chains has many uses:

Bence Jones Proteinuria (BJP)
Monoclonal Free Light Chains in Urine

- Protocol in the case of:
  - Clinically-suspected immunoproliferative disease such as:
    Waldenström's Macroglobulinemia, Multiple Myeloma, Chronic Lymphatic Leukaemia, Primitive Amyloidosis etc.
  - Serum Electrophoresis which highlights a new monoclonal band.
  - Laboratory data which show suspected micromolecular myeloma.

- Follow-up in the case of:
  - Immunoproliferative disease.
  - Patients with monoclonal band in serum electrophoresis but without diagnosis of immunoproliferative disease (MGUS).

- Pre-contrastographic tests:
  The contraindications in the use of contrast media by injection include Waldenström's Macroglobulinemia and Multiple Myeloma.
  In order to exclude the fact that the patient may be affected by Multiple Myeloma, electrophoresis of the serum proteins is not sufficient but it is necessary to carry out detection of Bence Jones Protein in urine. In fact, in cases of Micromolecular Myeloma electrophoresis of the serum frequently shows no significant or specific alterations.

Polyclonal Free Light Chains in Urine

- Protocol in research for hyperimmune diseases such as:
  Lupus Erythematosus, Rheumatoid Arthritis, Secondary Amyloidosis, etc.

- Protocol in research for functionality of proximal tubule
  Here, the Free Light Chains have the same significance as that of other microglobulins.

Free Light Chains in Cerebrospinal Fluid

- Protocol for research for the diagnosis and control of diseases of the Central Nervous system, such as:
  Multiple Sclerosis and Other Inflammatory Diseases.

Test Values

The value of the test will depend upon the problem:

Bence Jones Proteins

- diagnosis:
  the test has two values:
  - Qualitative Screening
    Regardless of the reason for the research, the value of the test is, above all, for qualitative screening, since the monoclonality will in any case have to be verified with Electrophoresis or ImmunoFixation.
  - Quantitative Indication
    Quantitative determination, even though it has its limits, is useful for:
    - providing a guidance as to how much to concentrate the sample for further research
    - providing a starting point for evolution control.

- follow-up:
  the test has a predominantly quantitative significance.

Polyclonal Free Light Chains in Urine

The test has a predominantly quantitative significance.

Free Light Chains in Cerebrospinal Fluid

The test has a predominantly quantitative significance.

Applications

The application of the test can be outlined thus:

Qualitative

Screening test under “Bence Jones Protein” research protocol.

Quantitative

- “Bence Jones Protein” – Monoclonal Free Light Chains in urine
- Polyclonal Free Light Chains in urine
- Free Light Chains in cerebrospinal fluid

Method Characteristics

Specificity

Adsorbed antisera are used and these react exclusively with the “hidden” determinants of Free Light Chains.

The specificity is demonstrated by the absence of specific reaction when a normal human serum is used as sample.

Unconcentrated Sample

An “unconcentrated” sample with no prior treatment is used.

Sensitivity

It is evaluated for “internal standardisation” and the results are:

- kit with normal sensitivity : 0.5 mg/dl
- kit with high sensitivity (HS) : 0.2 mg/dl

Automation

Kits and operating procedures are available for:

- *Dade Behring BN™-Series (BNA*, *BNII* and *BN-ProSpec*) nephelometers and similar.
- *Beckman Coulter IMMAGE®* and *ARRAY®* nephelometers and similar.
- automatic analyzers of clinical chemistry

Quantitative Determination

The calibrators allow construction of the calibration curves in order to achieve quantitative determination.

Available Kits

The following types of kits are available:

- kits containing mixed reagent anti Free Light Chains kappa+lambda
  - normal sensitivity : up to 0.5 mg/dl
  - high sensitivity (HS): up to 0.2 mg/dl

- kits containing separate reagents anti Free Light Chains kappa and anti Free Light Chains lambda
  - normal sensitivity : up to 0.5 mg/dl

The following are available for each type:

- APS kit – ImmunoNephelometry: *Beckman Coulter ARRAY*® Nephelometer and similar.

  BNA kit – ImmunoNephelometry: *Dade Behring BN™-Series* (*BNA*, *BNII* and *BN-ProSpec*) Nephelometers and similar.

- IMG kit – ImmunoNephelometry: *Beckman Coulter IMMAGE*® Nephelometer and similar.

- ITA kit – ImmunoTurbidimetry - instrumental: Photometers and Automatic Photometric Analyzers.

- ITS kit – ImmunoTurbidimetry:
  - non-instrumental
  - instrumental: Photometers and Automatic Photometric Analyzers.

Kit Characteristics

All kits come complete with Calibrators/Controls.

Accessory reagents are separate.

Type

All components are liquid and ready to use.

Preservative

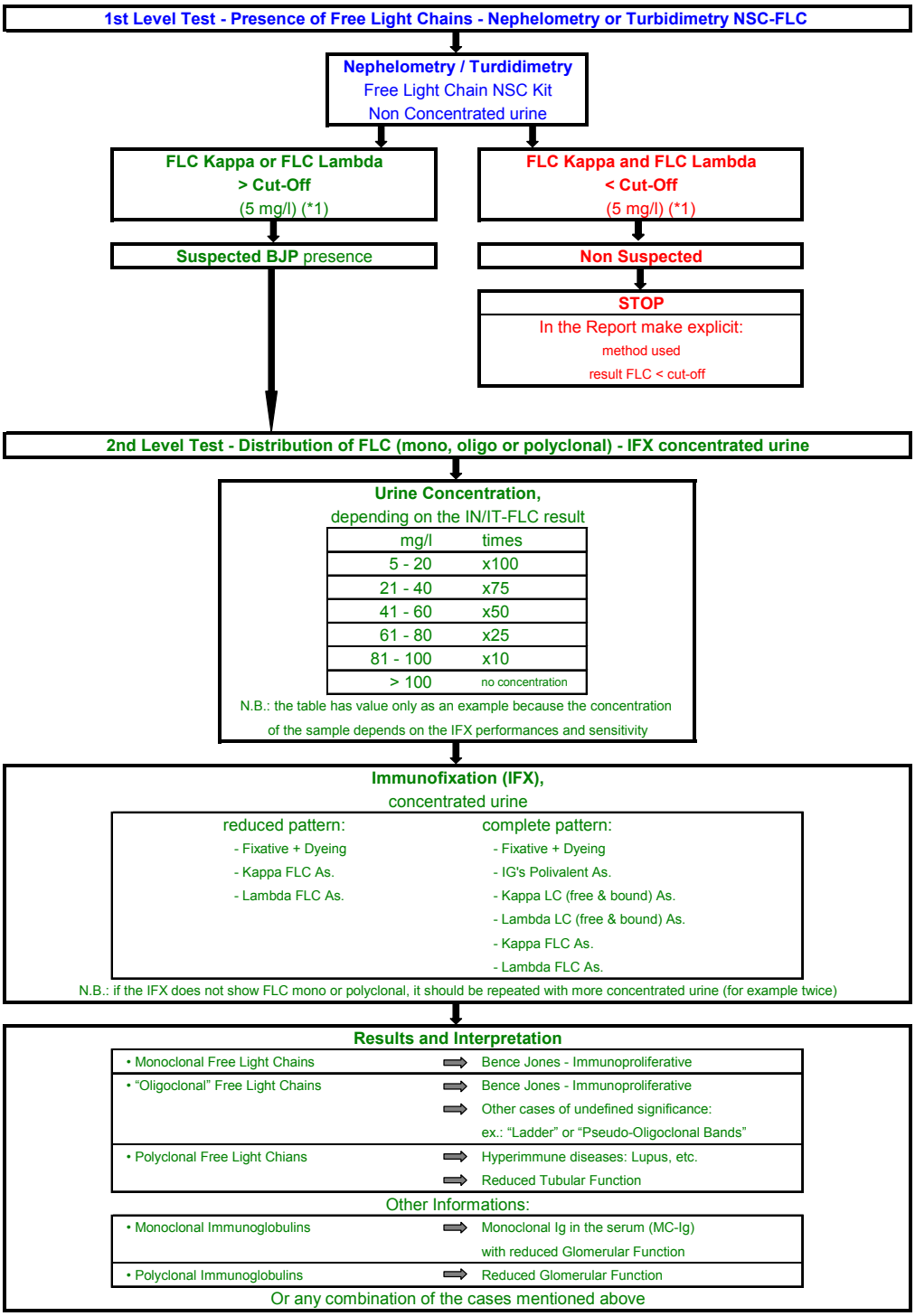
Sodium Azide < 0,1% (w/v).

Stability

Over 1 year at 2 - 8°C.

Operative Protocol in Urine - Example

The Operative Protocol which follows is an example of the utilization of the FLC kits in Urine in its initial diagnostic approach.



Note (*1): or other defined by the user