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CE IVD

EN

INSTRUCTIONS FOR USE

Reagents for professional use,
for *In Vitro* use only in clinical laboratory (IVD)

κλoneus® - S-FLC-K - TIA

Free Light Chains KAPPA - Serum
for *Turbidimetry* (2nd generation)

REF TD-42511-SK

(Product included in REF TD-42510-K)

INTENDED USE

Quantitative determination of Free Light Chains KAPPA (FLC-K) in human serum, by turbidimetric method, in automatic Clinical Chemistry Analyzers.

PRINCIPLE OF THE METHOD

The specific antibodies (Ab) of the reagent, bound to polystyrene particles, when combined with the antigens (Ag) of the patient sample, form insoluble compounds causing a change in the absorbance and dispersion of the light, proportional to the antigen concentration, which can be quantified by turbidimetric (TIA) or nephelometric (NIA) method, by comparison with calibrators of known concentration.

CONTENTS - COMPOSITION - PREPARATION

- Antiserum Reagent: REAG | Ab | S-FLC-K
  REF TD-42511-RSK — 100 test (*1) - 5 ml
  Polyclonal specific antibodies bound to polystyrene particles.
- Reaction Buffer: BUF | S-FLC-K
  REF TD-42511-BSK — 100 test (*1) - 20 ml
  TRIS buffer, with PEG.
- Serum Diluent: DIL | S-FLC
  REF TD-42511-DS — CONT 18 ml
  Serum matrix diluent, for samples, calibrators and controls.

Note (*1): with the recommended general assay parameters.

The reagents are ready for use and require no preparation.

Before each use it is convenient that the reagents are homogenized, shaking them gently avoiding the formation of foam or bubbles.

As preservative, the reagents contain <0.1% (1 g/l) Sodium Azide (NaN_3).

WARNINGS - PRECAUTIONS

- Sodium Azide is toxic. Even if sodium azide is not harmful at the concentration present in the reagents, take the necessary precautions to avoid accidental ingestion or contact with the eyes.
- Sodium Azide can react with lead or copper to give explosive compounds. For disposal it is recommended to rinse with plenty of running water to avoid accumulation in drains.
- Materials of human origin have been tested and found negative for the presence of HBsAg, HCV, and anti-HIV 1 and 2 antibodies.
- Since the absence of infectious agents can not be proven with absolute certainty, components containing materials of human or animal origin must be handled with caution, as potentially infectious, following the recommended safety standards for biological risk.
- Do not mix components belonging to different lot kits.
- Clinical diagnosis should not be based on the results of a single test, but should always integrate all relevant clinical and laboratory data.

STORAGE - SHELF LIFE

- Store refrigerated at +2...+8ºC. Do not freeze, as the functionality of the reagents may be altered.
- Properly stored and unopened, the reagents are stable until the expiration date indicated on the label.
- Once opened, the shelf life of the reagents is at least 4 weeks, provided that after each use they are stored immediately in the original containers, tightly capped and refrigerated at +2...+8ºC. This information should be taken as a guideline given that, obviously, the shelf life depends on the particular environmental and use conditions, which may differ from those of the stability studies carried out.

MATERIALS NEEDED, NOT SUPPLIED

- Automatic Clinical Chemistry Analyzer, capable of running photometric assays at 600...700 nm, and accessories: reagent containers, cuvettes, etc..
- κλoneus® - S-FLC-K - Cal-L Set — REF TD-42512-SK
- κλoneus® - S-FLC-K - Control — REF TD-42502-SK

SAMPLES

Fresh Serum.

Samples with presence of fibrin should be centrifuged.

Do not use hemolyzed, lipemic or contaminated samples.

In bibliography(1), it is reported a stability of 28 days in refrigerated (preferred) samples.

PROCEDURE

If necessary, carefully transfer the reagents to the containers used by the analyzer, preventing leakage and foaming or bubbles.

To program and calibrate assays, follow the instructions for use of the analyzer used, with the recommended general parameters that are detailed below. Please, contact the Customer Support Service (support@3diag.com - ☎ +34 93 244 86 79) for further information about applications to specific analyzers.

Assay Parameters

- ①Dispense and mix:
  - Sample/Calibrator/Control: 3 µl (neat)
  - BUF | S-FLC-K 200 ul
- ②Incubate a fixed time between 1 and 5 minutes.
- ③Dispense and mix: REAG | Ab | S-FLC-K 50 µl
- ④Read absorbance A1 (Blank) at 600...700 nm.
- ⑤Incubate a fixed time of about 5 minutes.
- ⑥Read absorbance A2 (End Point) at 600...700 nm.
- ⑦Interpolate the absorbance increment (A2-A1) of the samples and controls in the curve obtained with the calibrators.
- ⑧Samples with concentrations higher than the upper limit of the assay range should be analyzed again, progresively diluted (for example in steps of 1:5 (recommended)), by programming a larger sample dilution in the analyzer, or manually, until a value close to the midpoint of the measurement range is recovered.
  Use always DIL | S-FLC as specific diluent for samples.

Calibration Parameters

- Calibrators: Use the κλoneus® - S-FLC-K - Cal-L Set.
- If the analyzer allows it, it is recommended to program two replicates of each calibration point.
- The calibration is Non-linear. For the calculation it is recommended to use a 3rd Order Polynomial, a Logit or a Polygonal adjustment.

The assay must be recalibrated, at least when a new batch of reagents is used, or when the internal quality control established procedures do not give the expected results.

PERFORMANCES OF THE METHOD

Detailed information on the characteristics and performances of the assay is given in the Technical Report, available on the website (www.3diag.com) or upon request to the Customer Support Service (✉ support@3diag.com - ☎ +34 93 244 86 79).

Antigen Excess

The Free Light Chains (FLC) of the sample, especially if they are monoclonal, can react in a way that is not proportional to the calibration (lack of linearity), just as it happens in the immunochemical quantification of monoclonal immunoglobulins.
Although the method does not enter into antigen excess until very high concentrations of FLC, as a precaution it is recommended to analyze patient samples, which, because of their history, clinical data or other laboratory results, are suspected of having FLC extreme values or whose reaction is non-proportional, at two dilutions, the usual working one and manually prediluted (for example 1:10). Recovered result of the prediluted sample significantly higher than that of the sample at the normal dilution is indicative of an eventual excess of antigen or non-linearity; in that case, to obtain a result as accurate as possible, it is recommended to dilute the sample progressively (for example in steps of 1:5) until a value close to the midpoint of the measurement range is recovered. Use always **DIL** **S-FLC** as diluent for samples.
The use of complementary assays, for example the determination of the FLC at the same time in serum and urine, the determination of the Total Light Chains (free+bound) together with the FLC, or electrophoretic assays, can be a useful alarm signal in case of obtaining discordant results.

QUALITY CONTROL

To monitor performances, it is recommended that internal controls be inserted into each analytical series. It is recommended to use the controls of κλoneus® - **S-FLC-K - Control**. Each laboratory should establish its own quality scheme and corrective actions if controls do not meet the assigned tolerances.
The reagents have been subjected to quality control checks and should react as described in these instructions. Therefore, as a general recommendation, in case the controls do not give the expected reaction, as a precaution all reagents should be considered unreliable until their operation has been checked.

TRACEABILITY

Given that certified reference materials are not available, in order to ensure traceability, the following procedure has been carried out:

- Values in U/ml have been referred to the *European Reference Material ERM-DA470k/IFCC* (*Institute for Reference Materials and Measurements*, *IRMM*), assuming by definition that its content in FLC-K and FLC-L is equal to 100 U/ml.
- Values in mg/l have been assigned based on the measurement of the Light Chains in the calibrators (pure solutions of FLC-K and FLC-L), with a nephelometric method standardized to the *ERM-DA470k/IFCC*, using the formula of *M.M. Lievens*[2].
- The values in mg/l are also referred to commercial calibrators *Freelite®* Kappa (Refs.: IC016.A-F, Lot: 418487) and Lambda (Refs.: IC018.A-F, Lot: 411486) (*Freelite®* is a registered trademark of *The Binding Site Group Ltd.*, Birmingham, U.K.).

Bibliography states that when changing the method additional sequential measures should be carried out to establish new baseline values that allow monitoring the evolution of patients.

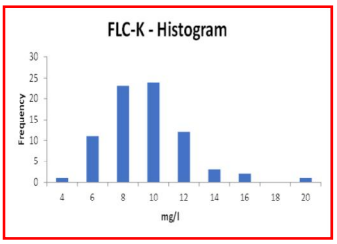
REFERENCE INTERVALS

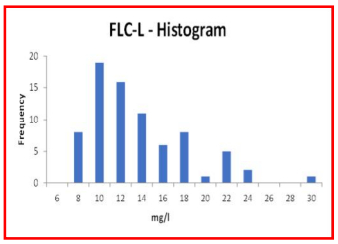
It is always advisable for each laboratory to establish its own reference values.
The bibliography[1][3] reports reference values of:

	mean	SD	range	95 percentile
S-FLC-K (mg/l)	8.36	---	- - -	**3.3 - 19.4**
S-FLC-L (mg/l)	13.43	---	- - -	**5.7 - 26.3**
κ/λ S-FLC	0.63	---	**0.26 - 1.65**	- - -

The validity of the transference of these intervals has been statistically verified by analyzing serum samples from 107 presumably healthy patients from the Barcelona area, obtaining results (see table and histograms) within the ranges of variability reported in the bibliography[3][4][5], obtained with the *Freelite®* method.

	mean	SD	range	95 percentile
S-FLC-K (mg/l)	8.42	2.61	3.09 - 18.3	**4.84 - 14.2**
S-FLC-L (mg/l)	12.6	4.53	6.10 - 29.2	**7.03 - 22.5**
κ/λ S-FLC	0.687	0.136	**0.426 - 1.05**	- - -





The above intervals transported to the *ERM-DA470k/IFCC* standardization result of:

- Bibliography range:

	U/ml (ERM)	mg/l (ERM)
S-FLC-K	48.2 - 284	1.41 - 8.29
S-FLC-L	53.6 - 248	0.643 - 2.97
κ/λ S-FLC	0.404 - 2.56	0.986 - 6.25

- Internal study range:

	U/ml (ERM)	mg/l (ERM)
S-FLC-K	70.7 - 208	2.07 - 6.07
S-FLC-L	66.2 - 212	0.793 - 2.54
κ/λ S-FLC	0.662 - 1.63	1.61 - 3.98

CLINICAL SIGNIFICANCE

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 (i.e. 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.
Quantities of FLC, both in serum and in urine, exceeding normal values or an abnormal κ/λ FLC ratio may be indicative of the presence of a monoclonal gammopathy, which should always be confirmed by electrophoretic techniques. Its quantification may also be useful in monitoring the monoclonal component.
In urine, specific guidelines[6] propose, as an alternative approach, the use of the quantitative measurement of urinary FLC as a screening method for the presence of Bence-Jones proteinuria (BJP), that may also be useful in monitoring and as BJP quantitative estimation, more precise and sensitive than the one made electrophoretically.

SYMBOLS

In addition to the harmonized symbols provided on the European Standard EN 980:2008, in the labels and instructions of use has been used the complementary symbology proposed[7] by the *EDMA* (*European Diagnostic Manufacturers Association*), whose meaning is detailed below.

REAG	Reagent
Ab	Antibody / Antiserum
S-FLC-K	Free Light Chains KAPPA - Serum
BUF	Buffer
DIL	Diluent
S-FLC	Free Light Chains - Serum
CONT	Contents

BIBLIOGRAPHY

(1) *Mayo Medical Laboratories* website (www.mayomedicalcliniclabs.com), date of consultation: 17th July 2020.

(2) M.M. Lievens: "*Medical and technical usefulness of measurement of kappa and lambda immunoglobulin light chains in serum with an M-component*" - J Clin Chem Clin Biochem 1989; 27; 519-23.

(3) J.A. Katzmann et al.: "*Serum Reference Intervals and Diagnostic Ranges for Free κ and Free λ Immunoglobulin Light Chains: Relativa Sensitivity for Detection of Monoclonal Light Chains*" - Clinical Chemistry 2002; 48:9 1437-1444.

(4) A.R. Bradwell et al.: "*Higly Sensitive, Automated Immunoassay for Immunoglobulin Free Light Chains in Serum and Urine*" - Clinical Chemistry 2001; 47:4 673-680.

(5) G.P Mead et al.: "*Detection of Bence Jones myeloma and monitoriong of myeloma chemotherapy using immunoassays specific for free immunoglobulin light chains*" - British Journal of Haematology 2002: 117 (Suppl. 1) p69 No. 195.

(6) 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.

(7) EDMA Labelling Task Force: "*EDMA Symbols for IVD Reagents and Components - Revision, October 2009*".

TEXT REVISION DATE

4th November 2020.

Modifications highlighted in blue.

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INSTRUCTIONS FOR USE

Reagents for professional use,
for *In Vitro* use only in clinical laboratory (IVD)

κλoneus® - S-FLC-K - CAL-L SET

Free Light Chains KAPPA - Serum
Low Calibrators (6 lev.)
REF TD-42512-SK
(Product included in REF TD-42510-K)

INTENDED USE

Elaboration of the calibration curve for the quantitative determination of Free Light Chains KAPPA (FLC-K), in human serum, by immunochemical methods, with κλoneus® reagents.

PRINCIPLE OF THE METHOD

The specific antibodies (Ab) of the reagent, bound to polystyrene particles, when combined with the antigens (Ag) of the patient sample, form insoluble compounds causing a change in the absorbance and dispersion of the light, proportional to the antigen concentration, which can be quantified by turbidimetric (TIA) or nephelometric (NIA) method, by comparison with calibrators of known concentration.

CONTENTS - COMPOSITION - PREPARATION

• Level 1:	CAL	1	S-FLC-K	REF	TD-42512-SK1	CONT	1 ml
• Level 2:	CAL	2	S-FLC-K	REF	TD-42512-SK2	CONT	1 ml
• Level 3:	CAL	3	S-FLC-K	REF	TD-42512-SK3	CONT	1 ml
• Level 4:	CAL	4	S-FLC-K	REF	TD-42512-SK4	CONT	1 ml
• Level 5:	CAL	5	S-FLC-K	REF	TD-42512-SK5	CONT	1 ml
• Level 6:	CAL	6	S-FLC-K	REF	TD-42512-SK6	CONT	1 ml

The calibrators are human Free Light Chain solutions.
As preservatives, the calibrators contain <0.1% (1 g/l) Sodium Azide (NaN_3), <0.02% (0.2 g/l) Methylisothiazolone and <0.02% (0.2 g/l) Bromonitrodioxane.
The calibrators are ready for use and require no preparation.
Before each use it is convenient that the calibrators are homogenized, shaking them gently avoiding the formation of foam or bubbles.
It is always advisable to bring the calibrators to room temperature before use.
The values of the calibrators are lot dependent and are indicated in the table of values of their Instructions for Use.

WARNINGS - PRECAUTIONS

- Sodium Azide is toxic. Even if at the concentrations present neither Sodium Azide nor the other preservatives are harmful, take the necessary precautions to avoid accidental ingestion or contact with the eyes.
- Sodium Azide can react with lead or copper to give explosive compounds. For disposal it is recommended to rinse with plenty of running water to avoid accumulation in drains.
- Materials of human origin have been tested and found negative for the presence of HBsAg, HCV, and anti-HIV 1 and 2 antibodies.
- Since the absence of infectious agents can not be proven with absolute certainty, components containing materials of human or animal origin must be handled with caution, as potentially infectious, following the recommended safety standards for biological risk.
- Do not mix components belonging to different lot kits.
- Clinical diagnosis should not be based on the results of a single test, but should always integrate all relevant clinical and laboratory data.

STORAGE - SHELF LIFE

- Store refrigerated at +2...+8ºC. Do not freeze, as the functionality of the calibrators may be altered.
- Properly stored and unopened, the calibrators are stable until the expiration date indicated on the label.
- Once opened, the shelf life of the calibrators is at least 4 weeks, provided that after each use they are stored immediately in the original containers, tightly capped and refrigerated at +2...+8ºC. This information should be taken as a guideline given that, obviously, the shelf life depends on the particular environmental and use conditions, which may differ from those of the stability studies carried out.

MATERIALS NEEDED, NOT SUPPLIED

The calibrators are intended to be used in conjunction with the Reagents (available separately or included in the kits) and Controls:

- κλoneus® - S-FLC-K - TIA — REF TD-42511-SK
- κλoneus® - S-FLC-K - CONTROL — REF TD-42502-SK

PROCEDURE

Follow the Instructions for Use of the analyzer used to program and calibrate an assay, with the general parameters recommended in the Instructions for Use of Reagents.
For those analyzers where the dilution of the calibrators is performed, the use of the specific diluent DIL S-FLC included in the reagent kits is mandatory.

TRACEABILITY

Given that certified reference materials are not available, in order to ensure traceability, the following procedure has been carried out:

- Values in U/ml have been referred to the *European Reference Material ERM-DA470k/IFCC* (*Institute for Reference Materials and Measurements*, *IRMM*), assuming by definition that its content in FLC-K and FLC-L is equal to 100 U/ml.
- Values in mg/l have been assigned based on the measurement of the Light Chains in the calibrators (pure solutions of FLC-K and FLC-L), with a nephelometric method standardized to the *ERM-DA470k/IFCC*, using the formula of *M.M. Lievens*[1].
- The values in mg/l are also referred to commercial calibrators *Freelite*® Kappa (Refs.: IC016.A-F, Lot: 418487) and Lambda (Refs.: IC018.A-F, Lot: 411486) (*Freelite*® is a registered trademark of *The Binding Site Group Ltd.*, Birmingham, U.K.).

SYMBOLS

In addition to the harmonized symbols provided on the European Standard EN 980:2008, in the labels and instructions of use has been used the complementary symbology proposed[2] by the *EDMA* (*European Diagnostic Manufacturers Association*), whose meaning is detailed below.

CAL	Calibrator
n	Level n (n=1..6)
S-FLC-K	Free Light Chains KAPPA - Serum
CONT	Contents
DIL	Diluent
S-FLC	Free Light Chains - Serum

BIBLIOGRAPHY

(1) M.M. Lievens: "*Medical and technical usefulness of measurement of kappa and lambda immunoglobulin light chains in serum with an M-component*" - J Clin Chem Clin Biochem 1989; 27; 519-23.

(2) EDMA Labelling Task Force: "*EDMA Symbols for IVD Reagents and Components - Revision, October 2009*".

TEXT REVISION DATE

8th November 2020.

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INSTRUCTIONS FOR USE

Reagents for professional use,
for *In Vitro* use only in clinical laboratory (IVD)

κλoneus® - S-FLC-K CONTROL

Free Light Chains KAPPA - Serum
Controls (3 lev.)
REF **TD-42502-SK**
(Product included in REF TD-42510-K)

INTENDED USE

Internal controls, with assigned values, for the quantitative determination of Free Light Chains KAPPA (FLC-K), in human serum, by immunochemical methods, with κλoneus® reagents.

PRINCIPLE OF THE METHOD

The specific antibodies (Ab) of the reagent, bound to polystyrene particles, when combined with the antigens (Ag) of the patient sample, form insoluble compounds causing a change in the absorbance and dispersion of the light, proportional to the antigen concentration, which can be quantified by turbidimetric (TIA) or nephelometric (NIA) method, by comparison with calibrators of known concentration.

CONTENTS - COMPOSITION - PREPARATION

- FLC-L High: CONTROL | H | S-FLC-K — REF TD-42502-SKH — CONT 1 ml
- FLC-L Med.: CONTROL | M | S-FLC-K — REF TD-42502-SKM — CONT 1 ml
- FLC-L Low: CONTROL | L | S-FLC-K — REF TD-42502-SKL — CONT 1 ml

The controls are human Free Light Chain solutions.
As preservatives, the controls contain <0.1% (1 g/l) Sodium Azide (NaN_3), <0.02% (0.2 g/l) Methylisothiazolone and <0.02% (0.2 g/l) Bromonitrodioxane.
The controls are ready for use and require no preparation.
Before each use it is convenient that the controls are homogenized, shaking them gently avoiding the formation of foam or bubbles.
It is always advisable to bring the controls to room temperature before use.
The values of the controls are lot dependent and are indicated in the table of values of their Instructions for Use.

WARNINGS - PRECAUTIONS

- Sodium Azide is toxic. Even if at the concentrations present neither Sodium Azide nor the other preservatives are harmful, take the necessary precautions to avoid accidental ingestion or contact with the eyes.
- Sodium Azide can react with lead or copper to give explosive compounds. For disposal it is recommended to rinse with plenty of running water to avoid accumulation in drains.
- Materials of human origin have been tested and found negative for the presence of HBsAg, HCV, and anti-HIV 1 and 2 antibodies.
- Since the absence of infectious agents can not be proven with absolute certainty, components containing materials of human or animal origin must be handled with caution, as potentially infectious, following the recommended safety standards for biological risk.
- Do not mix components belonging to different lot kits.
- Clinical diagnosis should not be based on the results of a single test, but should always integrate all relevant clinical and laboratory data.

STORAGE - SHELF LIFE

- Store refrigerated at +2...+8ºC. Do not freeze, as the functionality of the controls may be altered.
- Properly stored and unopened, the controls are stable until the expiration date indicated on the label.
- Once opened, provided that they are handled with adequate precautions to avoid contamination, the shelf life of the controls is at least 4 weeks, provided that after each use they are stored immediately in the original containers, tightly capped and refrigerated at +2...+8ºC. This information should be taken as a guideline given that, obviously, the shelf life depends on the particular environmental and use conditions, which may differ from those of the stability studies carried out.
- During storage, controls may develop a slight turbidity, which is not due to microbial contamination and has no effect on the results.

MATERIALS NEEDED, NOT SUPPLIED

The controls are intended to be used in conjunction with the Reagents and Calibrators (available separately or included in the kits):

- κλoneus® - S-FLC-K - TIA — REF TD-42511-SK
- κλoneus® - S-FLC-K - CAL-L SET — REF TD-42512-SK

PROCEDURE

Follow the Instructions for Use of the analyzer used to program and calibrate an assay, with the general parameters recommended in the Instructions for Use of Reagents.
For those analyzers where a dilution of the controls is performed, the use of the specific diluent DIL | S-FLC included in the reagent kits is mandatory. Stability of dilutions is limited to their immediate use.

TRACEABILITY

Given that certified reference materials are not available, in order to ensure traceability, the following procedure has been carried out:

- Values in U/ml have been referred to the *European Reference Material ERM-DA470k/IFCC* (*Institute for Reference Materials and Measurements*, *IRMM*), assuming by definition that its content in FLC-K and FLC-L is equal to 100 U/ml.
- Values in mg/l have been assigned based on the measurement of the Light Chains in the calibrators (pure solutions of FLC-K and FLC-L), with a nephelometric method standardized to the *ERM-DA470k/IFCC*, using the formula of *M.M. Lievens*[1].
- The values in mg/l are also referred to commercial calibrators *Freelite®* Kappa (Refs.: IC016.A-F, Lot: 418487) and Lambda (Refs.: IC018.A-F, Lot: 411486) (*Freelite®* is a registered trademark of *The Binding Site Group Ltd.*, Birmingham, U.K.).

SYMBOLS

In addition to the harmonized symbols provided on the European Standard EN 980:2008, in the labels and instructions of use has been used the complementary symbology proposed[2] by the *EDMA* (*European Diagnostic Manufacturers Association*), whose meaning is detailed below.

CONTROL	Control
X	Level X (H=High, M=Medium and L=Low)
S-FLC-K	Free Light Chains KAPPA - Serum
CONT	Contents
DIL	Diluent
S-FLC	Free Light Chains - Serum

BIBLIOGRAPHY

(1) M.M. Lievens: "*Medical and technical usefulness of measurement of kappa and lambda immunoglobulin light chains in serum with an M-component*" - J Clin Chem Clin Biochem 1989; 27; 519-23.

(2) EDMA Labelling Task Force: "*EDMA Symbols for IVD Reagents and Components - Revision, October 2009*".

TEXT REVISION DATE

10th January 2023.

Modifications highlighted in blue .