

R1: 1x 50 mL **REF** A-R1100003701  
R2: 1x 9 mL



**SUMMARY AND EXPLANATION OF THE TEST**

The determination of Kappa/lambda in human serum is important for the diagnosis and subtyping of monoclonal gammopathies.

Whereas polyclonal immunoglobulins (normal or enhanced concentration) exhibit both Kappa and lambda types of light chains in a roughly constant ratio of 2:1, monoclonal immunoglobulins exhibit only one type of light chain. Increased production of monoclonal immunoglobulins or free monoclonal light chains leads to a Kappa/lambda quotient outside the reference range indicating the existence of a monoclonal gammopathy.

**PRINCIPLE OF THE TEST**

Measurement of antigen-antibody reaction by the end-point method.

**Reagent Kit**

**Lambda Light Chain**

Code A-R1100003701

**Reagent 1 (R1) - Buffer - 1 x 48.5 mL/vial**

**Reagent 2 (R2) - 1 x 8.5 mL/vial**

Each vial is ready to use and contains:

Reagent 1:	Conc.	U.M.
Phosphate buffered saline (pH 7.43)	/	/
Polyethylene glycol	60	g/L
Sodium azide	0,95	g/L
Reagent 2:	Conc.	U.M.
Phosphate buffered saline (pH 7.43)	/	/
Polyclonal goat anti-human Kappa Light Chain (variable)	/	/
Sodium azide	0,95	g/L

**Reagent Preparation:**

Liquids reagents ready for use.

**Storage and Stability:**

If stored at 2 - 8°C avoiding direct light, the reactants remain stable until the expiration date printed on the label.

Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Do not freeze the reagents.

**EQUIPMENT / ACCESSORIES REQUIRED AND NOT SUPPLIED**

General laboratory equipment

Saline (9 g/L)

Calibrators and/or Control

(Pooled human serum, liquid and stabilized. Contains 0.95 g/L sodium azide. Value is stated in the insert)

**PRECAUTIONS AND LIMITATIONS**

**For *in vitro* diagnostic use.**

**Only experienced laboratory personnel should use this test and handling should be in agreement with Good Laboratory Practice (GLP).**

**Reagents from different lots must not be interchanged.**

**Safety Precautions**

- Each donor unit used in the preparation of the reagents, standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA
- Do not pipet by mouth.
- Do not smoke, eat or apply cosmetics in areas in which patients' samples or kit reagents are handled.
- Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
- Take care to avoid self-inoculation, splashing of mucous membranes or generation of aerosols.
- Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
- In addition to the eventual risk indications regarding the active components, the reagents contain inactive components such as preservatives (e.g. sodium azide or others) and detergents. The total concentrations of these components is lower than the limits reported by the current directive and following modification and amendments. However, it is recommended to handle reagents carefully, to avoid ingestion and contact with eyes, skin and mucus membranes and to use laboratory reagents according to good laboratory practice.
- All human samples must be handled and disposed of as potentially infectious materials.
- For information about safe handling, read carefully the Material Safety Data Sheet (MSDS).

**Disposal of Reagents**

Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

**SPECIMEN COLLECTION AND STORAGE**

Use fresh serum.

If the test can not be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours.

If stored for a longer period, the sample should be frozen.

**Quality control**

It's necessary, each time the kit is used, to perform the quality controls and to check that values

obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

**Automation**

All applications not explicitly approved by ISE S.r.l. cannot be guaranteed in terms of performance, and must therefore be established by the operator.

**Procedures**

**Sample/Control/standard: dilute 1:2 in saline 9g/L**

**Reference curve:** generate a reference curve by diluting the standard high level Ref R1300002501 1:1, 1:2, 1:4, 1:8, 1:16 in saline 9 g/L. Use saline 9 g/L as zero point.

**Method for automated instrumentation**

<b>Analyzer:</b>	MiuraFamily	
<b>Analyte Name :</b>	Kappa Light Chain	Ref.: A-R1100003701
<b>Method Code:</b>	KAP	
<b>Type:</b>	Different. Sample Blk.	
<b>Unit:</b>	mg/dL	
<b>Filter F1:</b>	340 nm	
<b>Blank in calculation:</b>	Not Used	
<b>Step</b>	<b>Reaction volume</b>	<b>U.M.</b>
<b>Sample volume:</b>	3	µL
<b>Volume Reagent 1:</b>	240	µL
<b>Volume Reagent 2:</b>	55	µL
<b>Incubation Time</b>	60	Sec.
<b>Reading Time:</b>	300	Sec.
<b>Calibration</b>	See Reference Curve	

**EXPECTED VALUES**

200 - 440 mg/dL (IFCC)

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

**PERFORMANCE CHARACTERISTICS**

The performance characteristics for the Kappa Light Chain reagents were measured on a clinical chemistry analyzer.

**Measuring Range:** 0 - 800 mg/dL

**Detection Limit:** 40 mg/dL

**Hook effect:** No risk

**Sensitivity:** 0.0005 ABS units/concentration unit

**Precision:**

	Low	Medium	High
Intra-Run [%CV]	3.55	2.83	2.03
Inter-Run	/	2.65	3.72

**Accuracy:**

	Control	Assigned	Measured
Bio-Rad 1	233 (186 - 280)	251	
Bio-Rad 2	711 (569 - 853)	696	

**Specificity:** Monospecific

**Interferences:** No interference for: Hemoglobin (1000 mg/dL), Bilirubin (20 mg/dL), Turbidity (5%).

**Limitations:** None

**Comparison with Nephelometry:**  $y = 0.8998x + 44.745 / r = 0.9923$

**Stability at 4°C:** at least 3 years after production

**BIBLIOGRAPHY**

- Lievens, M. M., J. Clin. Chem. Clin. Biochem. 27, 519-523 (1989)
- Boege, F. et al., Lab. Med. 13, 369-374 (1989)
- Dati, F. et al., Lab. Med. 13, 87-90 (1989)



Numero lotto / Lot numer



Consultare la metodica operativa / consult instructions for use



Per uso diagnostico in-vitro / For in-vitro diagnostic use



Prodotto da / manufactured by



Data di scadenza / expiry date



Temp. Di Conservazione / storage temperature

