



LAMBDA LIGHT CHAINS L



Turbidimetric method for the determination of
Lambda light chains in urine



ORDER INFORMATION

REF	Kit size
GD8465 00	2x20 ml
KL8465 00	2x20 ml
BK8465 00	1x60 ml

INDICATION

The determination of Kappa/Lambda light chains in urine is important for the typing of the monoclonal gammopathy. Polyclonal immunoglobulins (normal and elevated concentration) show both of type of Kappa/Lambda light chains in a constant ratio 2:1; the monoclonal immunoglobulins show only one type of light chains. The increased production of monoclonal immunoglobulins or monoclonal free light chains determines a relationship Kappa/Lambda different to references ranges, indicating the existence of monoclonal gammopathy.

METHOD PRINCIPLE

Mixing a sample with a precise Antigen to a solution having the corresponding Antibody, in a well defined ratio, it is possible to have turbidity that can be read at 340 nm. The reagent is specific for LAMBDA chains in urine.

COMPOSITION

REAGENT A (liquid):

Goat anti-Lambda antibody
in PBS buffer >25 mmol/l

REAGENT B (liquid):

Modified PBS buffer, pH 7.4 >25 mmol/l

REAGENT C (liquid):

1x0.6 ml
Calibrator, calibrated against Beckman Coulter Proteins Calibrator*. Lambda concentration is stated on the label.

* A significant correlation exists between Beckman Coulter values and Dako-Roche values:
Beckman Coulter 300 mg/dl = Dako Roche 100 mg/dl

Storage and stability

Store at 2-8 °C. Reagents are stable until the expiry date stated on the labels, if contamination and evaporation are avoided, protected from light. The above conditions are valid if the vials are opened just only for the time to take the reagent, closed immediately with their cap and stored at the indicated conservation temperature.

ANCILLARY EQUIPMENT

- Automatic pipettes
- Photometer
- Analysis cuvettes (optical path = 1 cm)
- lambda Light Chains Positive Control (REF GD6803 00)

SAMPLES

Undiluted urine. Turbid samples have to be centrifuged or filtered.

Stable six days at 2-8 °C.

Stability of the calibrator after the first opening:
4 months at 2-8 °C.

INTERNAL QUALITY CONTROL

It is recommended to use Lambda Light Chains Positive Control (REF GD6803 00) to check the correspondence of the obtained results with those expected and validate the data.

ANALYTICAL PROCEDURE

Working temperature	25-30-37 °C
Wavelength	340 nm
Optical path	1 cm
Reaction	End point

Allow the reagents to reach working temperature before using.

Pipette into disposable or well clean cuvettes :

	Reagent Blank	Calibrator	Sample
Reagent A	500 µl	500 µl	500 µl
Distilled H ₂ O	20 µl	-	-
Calibrator	-	20 µl	-
Sample	-	-	20 µl

Kindly mix. After 20 minutes read absorbance values of calibrator and samples against Reagent Blank.
Read within a short time.

Note:

- If it is a problem to pipette 20 µl, it is possible to dilute samples and calibrator 1:2 (0.5+0.5) with Reagent B and pipette a double volume (40 µl).
- Reaction volumes can be proportionally modified.
- For concentration higher than 960 mg/dl, dilute the sample 1:20 with Reagent B, repeat the determination and multiply the result by 20.

CALCULATION OF RESULTS

Utilize the following formula:

$$\text{Lambda, mg/dl} = \frac{\text{A sample}}{\text{A calibrator}} \times \text{mg/dl calibrator}$$

REFERENCE VALUES

Lambda Light Chains **absent** in normal urine.

For the screening considerate 1 mg/dl value as minimum significant concentration.

Positive results have to be confirmed by immunofixation.

Each laboratory should establish reference ranges for its own patients population.

ANALYTICAL PERFORMANCES

Linearity

The assay is linear up to 960 mg/dl.

Sensitivity

Test sensitivity of the method, in terms of limit of detection, is 1 mg/dl.

Correlation

The method is correlated to immunofixation.

Interferences

Particular attention must be given to interfering substances: some drugs and other substances are able to influence levels of Lambda chains or their determination ⁽²⁾.

PRECAUTIONS IN USE

The reagents contain inactive components such as preservatives (Sodium azide or others), surfactants etc. The total concentration of these components is lower than the limits reported by 67/548/EEC and 88/379/EEC directives about classification, packaging and labelling of dangerous substances. However, the reagents should be handled with caution, avoiding swallowing and contact with skin, eyes and mucous membranes. The use of laboratory reagents according to good laboratory practice is recommended.

Waste Management

Please refer to local legal requirements.

REFERENCES

1. Textbook of Clinical Chemistry, Ed. by N.W. Tietz, W.B. Saunders Co., Philadelphia (1999)
2. Young D.S. et al., Clin. Chem. 21, 302D (1975)
3. EU-Dir 1999/11 Commission Directive of 8 March 1999 adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC