# KAPPA / LAMBDA TOTAL LIGHT CHAINS CALIBRATOR
## (CALIBRATOR FOR IMMUNOCHEMICAL REACTIONS)

**Titred human serum useful as calibrator or control in immuno turbidinephelometrical and radial immunodiffusion reactions for urine tests**

### PRINCIPLE
The evaluation of suitable material in the sequence analysis, allows to verify the global inaccuracy of procedure adopted in.
The use of human serum as a control material, guarantees commutability of results obtained in the Quality Control process whit similar samples.
The serum concentrations are specially designed to be optimal for use in testing of the urine, and are calibrated against ERM-DA470k/IFCC.
(SEE POINT VALUES CALIBRATION).

### REAGENTS
Treated and titred human serum ready to use.

### STORAGE AND STABILITY
Calibrator is stored at 2-8°C and is stable until expiration dare on label if not contaminated during use.
Before opening wait and bring the vial at room temperature, and shake delicacy avoiding foam formation.

### VALUES CALIBRATION
The calibration values are specified for each lot and are indicated in the attached sheet values.
Kappa and Lambda values are calculated using the concentrations of individual proteins to IgG, IgA, and IgM determined by the average of the tests performed with immunoturbidimetric and radial immuno-diffusion methods using as a calibrator ERM-DA470k/IFCC and applying the following formula published by M.M. Lievens in J Clin Chem Clin Biochem 1989;27:519-23:

Kappa = [IgG] x 0,1983 + [IgA] x 0,1710 + [IgM] x 0,0975
Lambda = [IgG] x 0,1054 + [IgA] x 0,1206 + [IgM] x 0,0305

The extended uncertainty is calculated with k = 2 corresponds to a confidence level of 95%.

### CALIBRATION CURVE
To obtain a calibration curve, dilute the calibrator with saline solution at different concentrations.

Calibrators must be treated as if they were samples and test as indicated by the analytical procedure required by the reagent used.

### REFERENCE INTERVALS
Reference ranges for protein for healthy individuals.

| | |
|---|---|
| *In Serum* | |
| Kappa total light chains | 140 – 380 mg/dl |
| Lambda total light chains | 90 – 245 mg/dl |
| *In Urine* | |
| Kappa total light chains | < 4 mg/dl |
| Lambda total light chains | < 4 mg/dl |

Each laboratory should establish appropriate reference intervals related to its population.

### PRECAUTIONS
- Contains Sodium Azide 0.09 g/l.
- Each serum or plasma donor unit used in this product has been tested and found to be negative for HbsAg, HCV, HIV antibody, HCV-PCR and HIV-PCR by an FDA approved method.
- Considering that no known test can offer complete certainty that products derived from human blood will not transmit hepatitis, HIV or other infectious agents, must be taken all the necessary precautions for handling potentially infectious materials.

### NOTE
- Inaccurate results, or changes of color reagent could indicate a deterioration of the product. In any case, poor performance of the calibrator may also be due to other factors related to the dosage system.
- For in vitro diagnostic use only.

### WASTE DISPOSAL
Waste products must be handled as per relevant security cards and local regulations.

### PACKAGING
**CODE IC00900**

| | |
|---|---|
| Calibrator | 1 x 1 ml (liquid) |

### MANUFACTURER

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### REFERENCES

1. Blirup-Jensen S, Johnson AM, Larsen M. Protein standardization V: value transfer. A pratical protocol for the assignment of serum protein values from a reference Material to a Target Material. Clin Chem Lab Med 2008;46:1470–79.
2. Zegers I, Keller T, Schreiber W, Sheldon J, Albertini R, Blirup-Jensen S, Johnson M, Trapmann S, Emons H, Merlini G, Schimmel H. Characterization of the New Serum Protein Reference Material ERM-DA470k/IFCC: Value Assignment by Immunoassay. Clin Chem 2010;56:12:1880–88.
3. Blirup-Jensen S, Johnson AM, Larsen M. Protein standardization IV: value transfer. Procedure for the assignment of serum protein values from a reference preparation to a target material. Clin Chem Lab Med 2001;39:1110–22.
4. M.M. Lievens in J Clin Chem Clin Biochem 1989;27:519-23


### SYMBOLS

| | |
|---|---|
| IVD | Only for IVD use |
| LOT | Lot of manufacturing |
| REF | Code number |
| | Storage temperature interval |
| | Expiration date (year, month) |
| | Warning, read enclosed documents |
| | Read the directions |
| | Biological risk |

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