Kappa Light Chain Assay Kit
(κ -LC)

Method: Immunoturbidimetric Method

Cat. No.	Package Size	Analyzer
EGSK-LC	R1: 1×60 ml R2: 1×20 ml	For Hitachi917& OlympusAU640/400/600
EGBK-LC	R1: 1×60 ml R2: 1×20 ml	For Hitachi 717&ShimadzuCL7200/8000
EGHK-LC	R1: 1×45 ml R2: 1×15 ml	For Hitachi902
EGDK-LC	R1: 12×3.8 ml R2: 6×2.6 ml	For Siemens Dupont/Siemens Behring Series
EGK-LC460BS	R1: 1×18 ml R2: 1×6 ml	For Mindray BS120/180/190/200/220/230/240/430/460/830
EGGK-LC	R1: 1×18 ml R2: 1×6 ml	For Semi Auto Analyzer

INTENDED USE

For in vitro quantitative determination of Kappa light chain in human serum or plasma.

CLINICAL SIGNIFICANCE

There are two types of light chains,kappa and lambda. Each plasma cell synthesizes only one type of heavy chain and only one type of light chain. Heavy and light chains are then assembled to form immunoglobulins. The rest 40% light chains exist in the blood stream as free light chains. Therefore, the free lifght chains can be tested[1]. Under normal conditions, total κ/λ ratio should be normally around 2:1 in serum. In pathological conditions such as monoclonal gammopathies monoclonal immunoglobulin light chains would change the κ/λ ratio. κ/λratio increasing can be seen in rheumatoid arthritis, systemic lupus erythematosus, acute and chronic hepatitis and cirrhosis, childhood viral encephalitis, primary Sjogren's syndrome, autoimmune diseases, infections, liver disease and kidney disease[1, 2]. κ/λ ratio decreased can be seen in low immunoglobulinemia.

ASSAY PRINCIPLE

Kappa anti-body react with kappa antigen leading to formation of insoluble aggregates. The absorbance of these aggregates is directly proportional to lambda concentration in the sample at 340 nm.

REAGENT COMPOSITION

Contents	Concentration
Reagent 1	
Tris buffer Nacl polyethylene glycol Preservative	20mmol/L 150mmol/L >3% W/V
Reagent 2	
Tris buffer Kappa anti-body Preservative	20mmol/L >5% V/V

STABILITY AND PREPARATION OF REAGENTS

1. Stable up to the expiry date when the reagent is sealed and stored in dark at 2-8 ℃.
2. Reagents should not be frozen.
3. Do not mix reagents of different batches.
4.The production date and expiry date are shown on the label.
5.Once opened, the reagents are stable for 28 days when refrigerated on the analyzer or refrigerator.
6.Reagents should not be contaminated.

APPLICABLE INSTRUMENT

This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering the wavelength range of 340/800nm.
It is recommended to use this kit on a biochemistry analyzer for testing according to laboratory conditions.

SAMPLE COLLECTION AND PREPARATION

Fresh Serum, EDTA plasma or heparin plasma.

ASSAY PROCEDURE

Reagent preparation: reagent is ready to use.
Test Condition(Hitachi 917)

Main wavelength	340nm	Sample(S)	8 μl
Diluent	120 μl	Diluted Sample	3.3 μl
Secondary wavelength	800 nm	Reagent 1(R1)	150μl
Reaction temperature	37℃	Reagent 2(R2)	50μl
Cuvette diameter	1cm	Reaction type	End point assay

Operate procedure

Add into cuvette：	
Diluted Sample(S)	3.3μl
Reagent 1(R1)	150μl
Mix well and incubate for 5 minutes at 37℃, measure the original absorbance A1 at 340 nm.	
Reagent 2(R2)	50μl
Add 50 μl R2 into cuvette, mix well and incubate for 5 minutes at 37℃, read final absorbance A2 . Calculate △A=A2-A1	

Note: Parameters above are only introduced with Hitachi 917 as an example. The parameters of different biochemistry analyzers are slightly different. Please read the manual carefully before setting parameters.

CALIBRATION

It is recommended to use Gcell κ-LC calibrator.
Calibrator traces to the international reference materials ERM-DA470k/IFCC.
1. According to the requirements of the calibration procedure in the operation manual of biochemistry analyzer, each laboratory establishes its own calibration procedure according to the specific conditions.
2 Requirements for calibration and frequency: It is recommended to calibrate at least once every two weeks. When the following situations occur, it is recommended to re-calibrate: change the reagent batch number, the indoor quality control runs out of control, the biochemistry analyzer carries out major maintenance or replaces the main parts such as light source or cuvette.

QUALITY CONTROL

It is recommended to use Gcell κ-LC control**.** The absorbance of quality control should be within the

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labeled value range. If the results deviate from the scope, please find out the reason by following steps:
1 Check the parameter setting and light source.
2 Check the cleanliness of the cuvette and sampling needle.
3 Check whether water is contaminated or not. Bacterial growth can lead to incorrect results.
4 Check the reaction temperature.
5 Check the validity of the kit.

RESULT CALCULATION

Setting calibration curve by calibrator concentrations against the corresponding ΔA values. The concentration of κ-LC in the sample is obtained by ΔA value read from the calibration curve.

REFERENCE RANGE

Normally serum or plasma: 1.38-3.75 g/L.

κ/λ：1.17-2.93

Laboratories are suggested to establish its own reference interval according to age, sex, diet and region.

INTERFERENCE

The effect of bilirubin ≤ 60mg / dl, hemoglobin ≤ 500mg / dl, rheumatoid factor ≤ 300iu / / ml, Intralipid ≤ 500mg / dl, is less than 10%.

ACCURACY

Compared with competitors, in the range of [0.50, 12.00] g / L, the correlation coefficient R ≥ 0.975, the absolute deviation measured in the range of [0.50, 3.00] g / l should ≤ ± 0.30g/l, and the relative deviation measured in the range of (3.00, 12.00] g / l should ≤ ± 10%.

SENSITIVITY

When the sample concentration is 3.00g/L, the absorbance change should ≥ 0.1000.

LINEARITY

In the range of [0.50, 12.00] g/L, the linearity correlation coefficient r ≥ 0.990. In the range of (3.00, 12.00] g/L, the absolute deviation should ≤ ±0.30 g/L; In the range of (3.00, 12.00] g/L, the relative deviation should ≤ ±10%.

PRECISION

Refer to CLSIEP5-A2, repeatability precision was obtained by testing control or sample for 20 times of repeated measurement. Intermediate precision was obtained by testing human samples or control for 2 batches 5 days, and each batch was measured for 5 times. The results are as follows:

A)Repeatability (N=20)

	Mean	CV(%)
Level 1	2.91	0.71
Level 2	6.77	0.55

B)Intermediate precision (N=80)

	Mean	CV(%)
Level 1	1.92	1.61
Level 2	1.91	1.66

SAFETY PRECAUTIONS AND WARNINGS

1. The reagent contains preservatives. If it enters the eyes, mouth or contact on the skin, please rinse it thoroughly with clean water immediately and go to the hospital if necessary.
2. The reagent contains preservatives, which can react strongly with copper, lead and other metals to form azide metal. Therefore, please dilute the waste liquid and flush the drain pipe to avoid residual when disposal.
3. Do not mix or exchange reagents with different batches in the process of detection.
4. Opened reagents should be sealed and stored according to the specified method. Expired product should not be used.
5. Please dispose test tubes and other instruments that have touched the test sample according to the relevant medical waste disposal regulations.
6. Calibrator and control use human matrix serum, passed the detection of HIV (HIV 1, HIV 2) antibodies, hepatitis B surface antigen (HbsAg) and hepatitis C virus (HCV). All of them are negative. Although the detection method is highly accurate, it can not be guaranteed that all infected donors are found, so the control should also be treated as infectious specimens.

REFERENCES

1. Chen Haifei, et al. Detection of serum free light chain and its clinical application. International Journal of Blood Transfusion and Hematology. 2007, 30 (1): 74-77.
2. Bradwell AR, Carr-Smith HD, Mead GP, et al. Highly Sensitive, Automated Immunoassay for Immunoglobulin Free Light Chains in Serum and Urine. Clin Chem, 2001, 47: 673-680.
3. Lievens M. 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, 27:519-523.

INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	European Representtative

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