Lambda Assay Kit (Lambda-LC)

Method: Immunoturbidity Method

Cat. No.	Package Size	Analyzer
EGSLamd-LC	R1: 1×60 ml R2: 1×20 ml	For Hitachi 917 Olympus AU640/400/600
EGBLamd-LC	R1: 1×60 ml R2: 1×20 ml	For Hitachi 717 Shimadzu CL7200/8000
EGHLamd-LC	R1: 1×45 ml R2: 1×15 ml	For Hitachi 902
EGDLamd-LC	R1: 12×3.8ml R2: 6×2.6 ml	For Siemens Dupont Siemens Behring Series
EGλLC460BS	R1: 1×18 ml R2: 1×6 ml	For Mindray BS120/180/190/200/220/230/240/430/460/830
EGGλLC	R1: 1×18 ml R2: 1×6 ml	For Semi Auto Analyzer

INTENDED USE

For in vitro quantitative determination of Lambda-LC in human serum or plasma.

CLINICAL SIGNIFICANCE

Immunoglobulins can be divided into two types: kappa and lambda. When plasma cells synthesize immunoglobulins, light chains are synthesized simultaneously with heavy chains. Since the synthesis speed of light chain is faster than that of heavy chain, in addition to part of the synthesized light chain forming a complete immunoglobulin molecule with the heavy chain, about 40% of the light chain is free. Therefore, it can be detected by detecting free light chains [1]. Under normal circumstances, each plasma cell clone produces a uniform κ or λ light chain immunoglobulin molecule. The ratio of kappa to lambda in serum is normally about 2:1. The abnormal increase in cell clones will lead to an increase in immunoglobulin fragments (free light chains), which will change the ratio of κ to λ. Elevated κ or λ are common in rheumatoid arthritis, systemic lupus erythematosus, acute and chronic hepatitis and cirrhosis, childhood viral encephalitis, primary Sjogren's syndrome, autoimmune diseases, infections, liver diseases and kidney diseases, etc.[1 , 2]; κ or λ reduction is seen in hypoimmunoglobulinemia

ASSAY PRINCIPLE

The detection is based on the reaction between the light chain lambda antibody and the light chain lambda antigen to form an immune complex. The change in turbidity is detected at a wavelength of 340nm, and the degree of change is proportional to the light chain lambda content in the sample.

REAGENT COMPOSITION

Contents	Concentration
Reagent 1 (R1)	
Tris	20 mmol/L
NaCl	150 mmol/L
Polyethylene Glycol	5%w/v
Preservative	
Reagent 2 (R2)	
Tris	20 mmol/L
Lambda-LC Antibody	5% v/v
Preservative	

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. Do not mix reagents of different batches.
3. The production date and expiry date are shown on the label.
4. Once opened, the reagents are stable for 28 days, when refrigerated on the analyzer or refrigerator.

APPLICABLE INSTRUMENT

This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering wavelength of 340nm/800nm.

It is recommended to use this kit on a biochemistry analyzer for testing according to laboratory conditions.

SAMPLE COLLECTION AND PREPARATION

Fresh Serum or Plasma (EDTA or Heparin Li)

ASSAY PROCEDURE

Test Condition (Hitachi 917)

Main wavelength	340 nm	Diluted Sample(S)	5 μl
Secondary wavelength	800 nm	Reagent 1 (R1)	150 μl
Reaction temperature	37℃	Reagent 2 (R2)	50 μl
Cuvette diameter	1cm	Reaction type	End Point

Operation Procedure

Add into Cuvette:	
Sample	8 μl
Diluted	120μl
Diluted Sample (S)	5 μl
Reagent 1 (R1)	150 μl
Mix well and incubate for 5 minutes at 37℃, read A1,	
Reagent 2 (R2)	50 μl
Mix well and incubate 5 minutes at 37℃, and read absorbance A2, △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 Lambda-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 once a week. 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 Lambda-LC control. The absorbance of quality control should be within the 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.

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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.

CALCULATION RESULT

According to the project-specific calibration mode, after the instrument automatically generates a calibration curve, the content of the test substance is calculated from the change in absorbance.

REFERENCE RANGE

Serum or Plasma Kappa-LC: 0.93-2.42 g/L
Kappa/Lambda Ratio: 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 ≤ 500 mg/dl, rheumatoid factors ≤ 300IU/mL, intralipid ≤ 500 mg/dL, is less than 10%.

ACCURACY

Compared with competitors, in the range of [0.3, 7.00] g/L, the correlation coefficient r≥0.975. In the range of [0.3, 1.75] g/L, the absolute deviation should not exceed ±0.175 g/L. In the range of (1.75, 7.00] g/L, the relative deviation should ≤ ±10%.

SENSITIVITY

When the sample concentration is 1.75 g/L, the change of absorbance should ≥0.1000.

LINEARITY

In the range of [0.3, 7.00] g/L, the correlation coefficient r≥0.990. In the range of [0.3, 1.75] g/L, the absolute deviation should not exceed ±0.175 g/L. In the range of (1.75, 7.00] g/L, the relative deviation should ≤ ±10%.

PRECISION

Refer to CLSIEP5-A2, repeatability 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 per day, and each batch was measured for 2 times for total 20 days. The results are as follows:

a) Repeatability (N=20)

	Mean (g/L)	CV %
Level 1	1.05	0.5
Level 2	1.73	0.6

b) Intermediate precision (N=80)

	Mean (g/L)	CV %
Level 1	1.05	1.54
Level 2	1.73	1.03

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. The calibrator and quality control product contain human serum. It has been tested for antibodies against HIV (HIV1, HIV2), hepatitis B surface antigen (HbsAg) and hepatitis C virus (HCV), and they are all negative. Although the detection method is highly accurate, there is no guarantee that all infected donors can be found, so quality control products should also be treated as infectious specimens.

REFERENCES

1. Chen Haifei, et al. Serum Free Light Chain Detection and Its Clinical Application Progress. 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
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention: See instruction for use
EC REP	Authorized Representative in the European Company

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