Please use the reagent after reading this package insert

KL-6(K)

Quantitative turbidimetric latex assay for the measurement of KL-6

【General attention】

1. This reagent is for in vitro diagnostic use, and do not use for other purpose.
2. The doctor in charge along with clinical conditions and other laboratory results, etc. must judge the clinical diagnosis based on the result of a measurement overall.
3. Please use it according to use and the dosage regimen described in the package insert. The reliability of the result of a measurement cannot be guaranteed when use excluding described use and dosage regimen.

【Reagent Composition】

1. Buffer (R1) …… Liquid
2. Latex reagent (R2) …… Liquid

(Anti-human KL-6 (mouse) monoclonal antibody sensitized latex)

【Intended use】

Measurement of KL-6 in serum or plasma sample

【Principle】

1. Principle of measurement

Antibody adsorbed latex particles and KL-6 in the sample react immunologically, and causing the latex particles to agglutinate. This agglutination results in a change of turbidity, and the change in absorbance is a measure of the amount of KL-6 in the sample.

2. Feature

1. Measurement principle is latex immuno turbidimetric assay.
2. It is possible to adjust to various general-purpose automatic analyzers.
3. unnecessary for preparation of reagent
4. The preprocessing of the sample (dilution of the sample) is unnecessary.

【Handling Precautions】

1. Measurement sample

Please use the fresh serum or plasma as a specimen for measurement. Please be careful to not cause hemolysis at the specimen collection.

2. Interfering substance etc.

The following components hardly interfered with the test result: chyle (up to formazin turbidity 1650), bilirubin F ≤19.1mg/dL, bilirubin C ≤20.7mg/dL, Hemoglobin 510mg/dL and RF ≤450IU/mL.

3. Others

a. Storage reagents at (2-10℃), and the freezing preservation must be avoid.
b. Please request material separately about the adaptation example to various automated analyzers.

【Procedure】

1. Preparation of the reagents

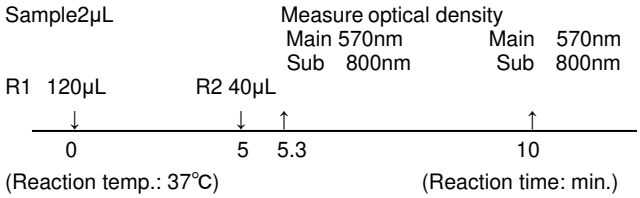
Buffer solution (R1) and Latex reagent (R2) are used as it is.

2. Stability

The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-10℃ and contaminations are prevented during their use.

3. Procedure

[Standard procedure]



4. Calibration

Using optional KL-6（K）calibrator and measure them as sample based on the above-mentioned procedure, and made the calibration line.

【Judgment method of result】

(1) Normal reference values

Normal range [4]	98～313 U/mL
Cut off [3]	500 U/mL

※Please set the normal range in each institution

(2)The nonspecific reaction can happen in various infectious diseases and autoimmune disease patients' serums. Please judge the diagnosis based on the result of a measurement overall in consideration of other inspections and clinical conditions.

【CLINICAL SIGNIFICANCE】

Sialylated carbohydrate antigen KL-6 found by Kohno in 1985 is one of the sialylated carbohydrate antigen located on MUC1, over 1 million molecular weight and transmembrane type glycoprotein expressed on epithelial cell line1 [1),3)]. At the beginning of his study he prepared monoclonal antibody by immunizing (VMRC-LCR) cell derived from human lung adenocarcinoma to mice with the aim of developing lung cancer marker. However, this antibody was specific to interstitial pneumonia and showed higher values in the active phase of interstitial pneumonia when react with patient sera, and was named KL-6 for the antigen and the antibody. In patients with interstitial pneumonia affected alveolar epithelium, KL-6 indicates remarkably higher values than in healthy people and other respiratory diseases. For this reason, KL-6 had been recognized as high diagnostic utility for interstitial pneumonia and pulmonary fibrosis, until then it was poor in specific markers for these diseases. Furthermore in active interstitial pneumonia cases KL-6 showed significantly higher value compared to the non-active cases and vary to reflect the disease after the start of treatment. Thus, measurement of the KL-6 are used for the purpose of differentiation of pathologies characterized by fibrosis of the lungs, pathological state of interstitial pneumonia (active and inactive of differentiation) and observation of treatment [3)].

【PERFORMANCE】

1. ANALYTICAL PERFORMANCE

1. Sensitivity

(a) When measured saline liquid as the sample, absorbance change (⊿OD) is below 0.002/min.
(b) When measure standard solution of KL-6 concentration of 1,000 U/mL, absorbance change is between 0.004 to 0.03/min.

2. Accuracy
When measured the control serum of known concentration is measured, measurement value is within ±15% of the known value.
3. Reproducibility
When measure the same sample five times at the same time, the C.V of the absorbance value is 10% or less.
4. Measurement range
Measurement range of the KL-6 in the sample is 70-10,000U /mL.

2. Correlation

Correlation performance study were conducted with commercially available LIA reagents (x) and obtained good correlation as below.

Reference kit①	n	Correlation coefficient	Regression equation
Commercially available LIA kit	54	r = 0.993	y = 0.9491x +30.24

y : This reagent（U/mL） x : Reference kit ①（U/mL）

【Attention in handling for use】

1. Attention in handling (dangerous prevention)
(1) An infectious microorganism such as hepatitis B viruses might exist in the sample, please handle it assuming that there is a risk for infection.
(2) Sodium azide of 0.09w/v% is contained in the reagents as preservative. When entering eyes and mouths or adhering to the skin by mistake, flushing enough them with water as a stop-gap measure. If there is a necessity receive the doctor's treatment.
2. Directions
(1) Do not use the reagents after the expiration date.
(2) After open the reagents, use them as early as possible. When preserve them, please close the lid and preserve on a specified condition.
(3) Please do not use the bottle and the accessory in this kit for other purposes.
(4) Please set the buffer and the latex reagent at the position correctly after gently mixing by invert the bottle before measure. Please remove the bubble when bubbling.
(5) When the measurement value exceeds the measure range, please dilute with saline liquid, and measure the specimen material. Those obtained by multiplying the dilution factor in value is the measured value.
(6) Please do not use the reagent with different lot.
(7) Please make the working curve at each measurement. Moreover, please measure the calibration sample for two times or more respectively.
(8) Please use the calibrator sold separately, and refers to the manual of the goods before use.
(9) Preserve the reagent at refrigerated condition (2-10℃)and avoid the freezing.
3. Attention for Disposal
(1) Sodium azide of 0.09w/v% is contained is contained in the reagents as preservative. The sodium azide might generate the metallic azide that it reacts with the lead pipe and the copper pipe and explosiveness is strong, and flush it in volumes of water, please when you abandon it.
(2) An infectious microorganism such as hepatitis B viruses might exist in the sample, and process a used sample, the reagent container, and apparatus, etc. by sterilization, disinfection (0.5% solution of sodium hypochlorite), and incineration, etc.
(3) Please process it according to regulations of Wastes Disposal and Public Cleaning Law and Water Pollution Control Law, etc. when you abandon and apparatus, etc.

【Storage and validity period】

1. Storage ： 2～10℃
2. Validity period： 1.5 year after production
Expiration date is displayed on the outer box and bottle labels.

【Package】

Product Name	Contents
KL-6（K）reagent	
Buffer (R1)	30mL ×1
Latex reagent (R2)	10mL ×1

〔Optional goods〕
(Product Name) (Contents)
KL-6（K）Calibrator 5 concentration
KL-6（K）Control 2 concentration

【References】

1. Kohno N : *Med J Hiroshima Univ* 1985; 33, 971
2. Kohno N : *Resp* 1997; 16, 391
3. Kohno N, et al : *Clin and Res* 1998; 75, 217
4. SHIMA LABORATORY's internal data

【Inquiries】

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【Manufacturing and distribution】

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