REF G-SZ71

LZ Test 'Eiken' SAA

For measurement of Serum Amyloid A protein

INTRODUCTION

Serum amyloid A protein (SAA) was discovered in blood serum components as a precursor to the deposited protein (amyloid A protein) which occurs in secondary amyloidosis accompanying tuberculosis, rheumatoid arthritis, and other chronic inflammatory diseases. SAA is synthesized by the liver, and its concentrations in the blood increase with infectious diseases, malignant tumors, autoimmune diseases, and tissue necrosis.
Similar to C-reactive protein (CRP), it is an acute-phase protein that increases significantly when inflammations occur. The amount of the increase is larger than with CRP, and SAA increases significantly in cases of viral infections, kidney transplant rejections, and other ailments where CRP increases little. For this reason, measurement of SAA in blood is considered significant in a different capacity than CRP.
LZ Test 'Eiken' SAA is a reagent developed for highly sensitive and accurate measurement of SAA. This measurement utilizes a latex agglutination reaction, and the change in turbidity caused by this reaction is measured optically to determine the concentration.

CONTENTS OF THE KIT

1. Reagent 1
   Buffer solution
   (Contains 50mmol/L of Good's buffer.)
2. Reagent 2
   Latex reagent
   (Contains 40 vol % of latex sensitized with anti-human SAA antibodies*.)

* This is an abbreviation of the following: latex sensitized with anti-human SAA rabbit polyclonal antibodies and anti-human SAA mouse monoclonal antibodies.

APPLICATION

Measurement of serum amyloid A protein (SAA) in blood serum

TEST PRINCIPLE

This method is an optical measurement method using a latex agglutination reaction and an automated analyzer.
The latex reagent is prepared by bonding anti-SAA antibodies to the surface of the latex particles. When this reagent is mixed in a cell to react with the sample, the anti-SAA antibodies that were bonded to the latex particles react with the SAA in the sample, causing agglutination.
This reaction is then measured as a change in the turbidity, with the amount of the change increasing in proportion to higher concentrations of SAA in the sample.
Measurement using LX Test 'Eiken' SAA applies this principle to find a calibration curve from standards of known concentration. The amount of SAA in the sample is then found relative to this standard.

TEST PROCEDURE

1. Preparation of reagents
   - Reagent 1: Use the buffer solution as-is.
   - Reagent 2: Use the latex reagent as-is.
   - Standards: Separately obtain the SAA Standard, and prepare the standard solutions. Use the LZ-SAA Standard Q 'Eiken' as the standard.
2. Measurement procedure
   - Follow the instructions in the instruction manual to operate the automated analyzer.
   - Dispense the sample and standards into sample cups, and set them in the designated positions.
   - Set reagent 1 and reagent 2 in the designated positions.
   - Enter the parameters into the analyzer.
   - Press the analyzer "Start" key to begin analysis and output the measurement results (by printout or other means).
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(Example showing Hitachi 7170)

Reagent 1: 150 μL
Reagent 2: 150 μL
Sample: 3 μL

Measurement
Measurement wavelength: 570 nm
(Minutes)

Note: For details concerning the use of this product with various analyzers, please request the separately supplied printed information.

PRECAUTIONS FOR USE

1. Measurement sample properties and sample collection methods
   Collect blood serum by normal means and perform the measurement while the sample is fresh. If the sample is to be stored for a long period of time, store it at -20°C or below.
2. Interfering substances
   Almost no effect on the measurement value was found from bilirubin (20mg/dL), hemoglobin (500mg/dL), chyle (2000 formazine turbidity units), and rheumatoid factor (RF positive sample 1000 IU/mL).

WARNINGS AND PRECAUTIONS

1. Store the reagents under the designated conditions. Do not use reagents that have passed their expiration date.
2. Mix the latex reagent before using by gently inverting the vial several times.
3. Measurement errors may result if bubbles are present on the surface of the sample after it is dispensed into the sample cup. Therefore remove all bubbles. If fibrin is present in the sample cup, remove it. Fibrin can cause clogging of the sample nozzle.
4. Create a calibration curve for each day of measurement. Also be sure to create a new calibration curve when a reagent from a different vial or lot is used.
5. The test sample may be contaminated with the HB virus, HIV, or other pathogens. Therefore, use caution when handling.
6. If the sample concentration exceeds the measurement range, dilute with a normal saline solution or similar solution and perform measurement again.

7. If a reagent enters the eye or mouth, rinse it out with large volumes of running water, and perform other required first aid. If necessary, seek medical attention.
8. Use the reagents as quickly as possible after they are opened. If they are to be stored, be sure to close the caps and store them using the prescribed method.
9. There is the danger of infection from all tools, reagents, and reagent containers that contact the sample. Disinfect them using an autoclave or other means, or soak them in hypochlorous acid or other disinfectant solution.
   Example of treatment: Soak for 60 minutes or longer in a sodium hypochlorite solution (available chlorine concentration 1000 ppm or greater). (Neutralize any substances that contain acids before soaking.)
   Alternatively, treat in an autoclave at 121°C for 20 minutes. (Do not treat in this way any items to which sodium hypochlorite has adhered.)
10. Incinerate containers after they are used, or else separate and dispose of them in accordance with regulations related to waste materials.
11. If the product is used in any way other than that specified here, the reliability of measurement results cannot be guaranteed. Be sure to follow the procedure as specified here.
12. A clinical diagnosis based on the measurement results must be a comprehensive judgment made by the attending physician, including factors such as clinical symptoms and other test results.

STORAGE AND EXPIRATION DATE

Store at 2 - 10°C. Expiration date is 1 year.

PERFORMANCE

1. Normal reference value of this method is less than 8 μg/ml/
2. Assay range of this method is 5 ~ 500 μg/ml.
3. Accuracy - When the known concentration sample is measured the accuracy of this method is 85 ~ 115 %.
4. Reproducibility - When the same sample is measured 10 times simultaneously, the coefficient of variation (C.V) is less than 10%.
5. Correlation - When 57 samples are measured by this method and in-house reference method, the correlation coefficient (r) is r= 0.981, and the regression line is y = 0.971x +2.7.(y: this method, x: reference method)

REF G-SZ75

LZ-SAA Standard Q 'Eiken'

For measurement of serum amyloid A protein

Product name	Packaging	Storage method	Expiration date	Product code
LZ-SAA Standard Q	1 mL × 6	2 – 8°C	1 year	G-SZ75

INTRODUCTION

LZ-SAA Standard Q 'Eiken' is a calibration standard utilized with LZ Test 'Eiken' SAA.

PROCEDURE FOR USE

LZ-SAA Standard Q 'Eiken' is prepared 6 different concentration liquid calibrator.
Pour the optimum amount to the sampling cup.

PRECAUTIONS FOR USE

1. Store under the designated conditions.
2. Do not use reagents that have passed its expiration date.
3. This product contains 20% of 2-Methoxyethanol.
4. Handle with care under putting protection goggle and glove.
5. Rinse it out with large volume of running water, if reagent enters in the eye or mouth.
6. Wash out with large quantity of water when disposal.