Instructions for Use

380348-B

English | For Research Use Only

RUO LZ TEST EIKEN SAA REF V-SZ11

INTENDED USE
RUO LZ TEST EIKEN SAA is intended for use with RUO LZ-SAA Calibrator EIKEN (REF V-SZ12), RUO QC-SAA L EIKEN (REF V-SZ13) and RUO QC-SAA H EIKEN (REF V-SZ14) for measurement of Serum Amyloid A (SAA) in serum or plasma. For research use only, not for use in diagnostic procedures.

INTRODUCTION
SAA is an apolipoprotein associated in HDL and has 11.4 kDa molecular weight. It is observed as an acute phase protein that increases by viral and bacterial infection, malignant tumors, autoimmune diseases, tissue necrosis, and other inflammation. SAA concentrations rise 10-1000 folds in response to acute phase reaction and decline rapidly after synthesis ceases.
RUO LZ TEST EIKEN SAA is a reagent developed for highly sensitive and accurate measurement of SAA. It utilizes a latex agglutination reaction, and the change of turbidity caused by this reaction is measured optically to determine the concentrations.

PRINCIPLE OF THE METHOD
This method is an optical measurement method by using the latex agglutination reaction and automated analyzer.
The latex reagent is prepared by binding anti-SAA antibodies to the surface of the latex particles. When this reagent is mixed in a cell to react with the sample, anti- SAA antibodies which are bounded to the latex particles react with SAA in the sample, and cause agglutination.
This reaction is then measured as a change in the turbidity, with the amount of the change increasing in proportion to higher concentration of SAA in the sample.
Measurement using RUO LZ TEST EIKEN SAA applies this principle to find a calibration curve from calibrator of known antigen concentration. The amount of SAA in the sample is then found relative to this calibrator.

CONTENTS OF THE KIT
1. Reagent-1 ・・・・・・・・・・・・2 x 20 mL
   (Contains 50 mmol/L of Good's buffer)
2. Reagent-2 ・・・・・・・・・・・ 2 x 20 mL
   (Contains 40 vol% of latex sensitized with anti-human SAA antibodies)

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

WARNINGS AND PRECAUTIONS
1. For research use only.
2. Use the fresh serum or plasma. When samples are stored, they should be kept at -20 °C. Repeated freezing and thawing of sample should be avoided.
3. Store the reagents under the designated conditions. Do not use reagents that have passed their expiration date.
4. Mix the latex reagent before using by gently inverting the vial several times.
5. 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.
6. 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.
7. The test sample may be contaminated with the HBV, HCV, HIV, or other pathogens. Therefore, use caution when handling.
8. If the sample antigen concentration exceeds the measurement range, dilute with a normal saline solution or similar solution and perform measurement again.
9. 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.
10. There is a 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.)
11. Disposal of used reagents and containers should be handled as infectious waste in accordance with applicable regulations.
12. 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.
*13. The product contains Guanidinium chloride (CAS No.50-01-1) and ProClin 300 (CAS No.55965-84-9) which are classified under the Classification, Labelling and Packaging (CLP) Regulation as Skin irritation (Category 2), Eye irritation (Category 2), Skin sensitisation (Category 1) and Acute toxicity, oral (Category 4).



Warning

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash skin/hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/ face protection.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/ attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

SAMPLE COLLECTION
1. Use serum or plasma as test sample (specimen).
2. Collect samples in usual manner and test them while fresh.
3. If test samples are to be stored over a long period of time, preserve them frozen at -20 °C or lower (avoid repeated freezing and thawing).
4. If a frozen stored test sample is to be used, thaw it at room temperature and then mix it by inversions before running the test.
5. Dialyzed blood-derived serum samples, in which fibrin is likely to be separated, should be defibrinated before used in the test.

TEST PROCEDURE
1.Preparation of reagents
   1) Reagent-1: Use the Reagent-1 as-is.
   2) Reagent-2: Use the Reagent-2 as-is.
   3) Calibrators: Separately obtain RUO LZ-SAA Calibrator EIKEN (REF V-SZ12) as the calibrators.

2. Measurement procedure
   1) Follow the instructions in the instruction manual to operate the automated analyzer.
   2) Dispense the sample and calibrators into sample cups and set them in the designated positions.
   3) Set Reagent-1 and Reagent-2 in the designated positions.
   4) Enter the parameters into the analyzer.
   5) Press the analyzer "Start" key to begin analysis and output the measurement results (by printout or other means).

INTERFERING SUBSTANCES
Almost no effect on the measurement value was found from conjugated bilirubin (25 mg/dL), free bilirubin (25 mg/dL), hemoglobin (500 mg/dL), chyle (2,000 formazine turbidity units), and rheumatoid factor (RF positive sample 1,000 IU/mL). As an anticoagulant almost no effect on the measurement value was found from EDTA-2Na (200 mg/dL), sodium citrate (500 mg/dL) and heparin sodium (20 mg/dL).

INTERNAL QUALITY CONTROL
A quality control program to monitor the performance of RUO LZ TEST EIKEN SAA is recommended to each laboratory.
The following relevant products are being recommended for the quality control program.
RUO QC-SAA L EIKEN (REF V-SZ13)
RUO QC-SAA H EIKEN (REF V-SZ14)

PERFORMANCE CHARACTERISTICS
1. Sensitivity
   When SAA calibrators of 0 mg/L and 2.2 mg/L were measured, the difference of absorbance change amount was 0.0015 or more.
2. Accuracy
   When control samples of known concentration were measured, the value obtained was within ±15 % of indicated value.
3. Within-run reproducibility
   When the same sample was measured 10 times within the same run, the coefficient of variation (CV) for the values obtained was 10 % or less.
4. Measurement range
   2 - 200 mg/L
5. Correlation
   Correlation with this product and reference product:
   $y = 0.4420\ x + 1.3$, $r = 0.9992$, n=195 human serum samples.
   (*y*: RUO LZ TEST EIKEN SAA, *x*: Japanese package EIKEN SAA)

	y: RUO LZ TEST EIKEN SAA	x: Japanese package EIKEN SAA
Reference material	WHO International Standard (human SAA, NIBSC code: 92/680)	In-house material

*PRODUCT CODE, PRODUCT NAME & STORAGE

Product code	Product name	Contents	Storage
V-SZ11	RUO LZ TEST EIKEN SAA	2 x 20 mL 2 x 20 mL	2-10 °C
V-SZ12	RUO LZ-SAA Calibrator EIKEN	6 x 1 mL	2-8 °C
V-SZ13	RUO QC-SAA L EIKEN	5 x 2 mL	2-10 °C
V-SZ14	RUO QC-SAA H EIKEN	5 x 2 mL	2-10 °C

REFERENCE
1. Sack GH Jr.: Mol Med., 24(1):46, 2018.

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