

Research Use Only
Human Serum Amyloid A Kit

RUO LZ TEST EIKEN SAA



Features

- Latex agglutination turbidimetric immunoassay
- Applicable to various biochemistry analysers
- Traceable to WHO International Standard

EIKEN CHEMICAL CO., LTD.

Introduction

Serum amyloid A protein (SAA), being synthesized in the liver and increases in blood levels in inflammatory conditions such as infections, malignant tumors, autoimmune diseases, and tissue necrosis, was being discovered in serum components as a precursor of deposited protein (amyloid A protein) in persistent amyloidosis associated with chronic inflammatory diseases such as tuberculosis and rheumatoid arthritis¹⁾.

Same as C-reactive protein (CRP), Serum amyloid A protein (SAA) is an acute phase protein which increases significantly during inflammation, but its amplification is greater than that of CRP, and SAA increases remarkably even in diseases such as viral infections and renal transplant rejection reactions, while CRP do not increase so much.

Therefore, it has been stated at studies that measuring serum SAA holds different aspect from CRP²⁾.

RUO LZ TEST EIKEN SAA, a latex agglutination turbidimetric immunoassay with high sensitivity, has a wide measurement range, prozone-adaptable, and is easily applicable to various automated biochemistry analysers.

Principle of Measurement

This method is an optical measurement method by using the latex agglutination reaction and automated analyser.

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 bound to the latex particles react with SAA in the sample, and cause agglutination.

This reaction is then measured as a change in the turbidity, which increases in proportion to 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.

Intended Use

For measurement of serum amyloid A (SAA) in serum or plasma

Assay Range

2 mg/L - 200 mg/L (or value of highest calibration point)

Analytical Performance Data^{3), 4)}

Analyser : Hitachi 7180 Clinical Analyser

◆ Repeatability

concentration in mg/L

	QC-SAA L	QC-SAA H
<i>n</i>	20	20
<i>Mean</i>	9.58	46.68
<i>S.D.</i>	0.13	0.43
<i>C.V. (%)</i>	1.39%	0.91%
<i>MAX.</i>	9.8	47.6
<i>MIN.</i>	9.3	46.0
<i>Range</i>	0.5	1.6

◆ Intermediate precision

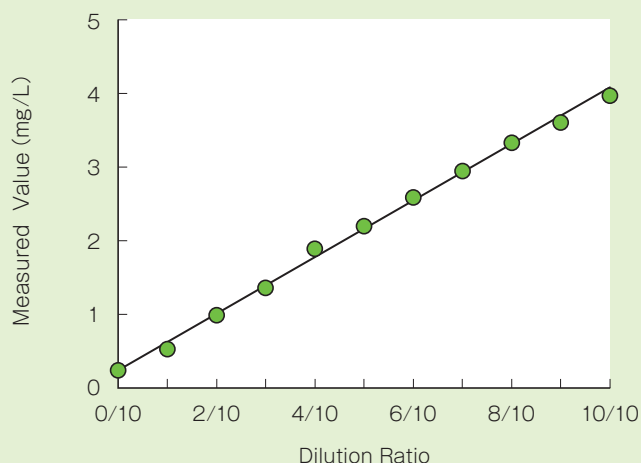
concentration in mg/L

	Days	Mean	Variation factor	C.V.
QC-SAA L	19	8.56	Total	4.31%
			Inter-day	4.00%
			Intra-day	1.59%
QC-SAA H	19	42.45	Total	1.66%
			Inter-day	0.73%
			Intra-day	1.49%

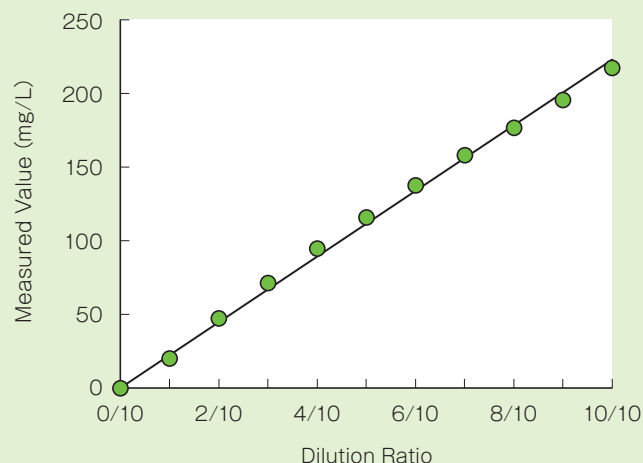
◆ Linearity

Linearity was tested at the low and high concentration range.
RUO LZ TEST EIKEN SAA has a linear range of 2 mg/L - 200 mg/L.

<Low concentration range>

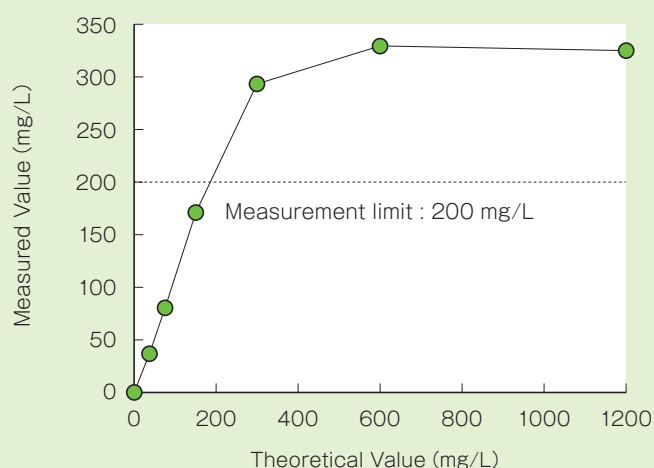


<High concentration range>



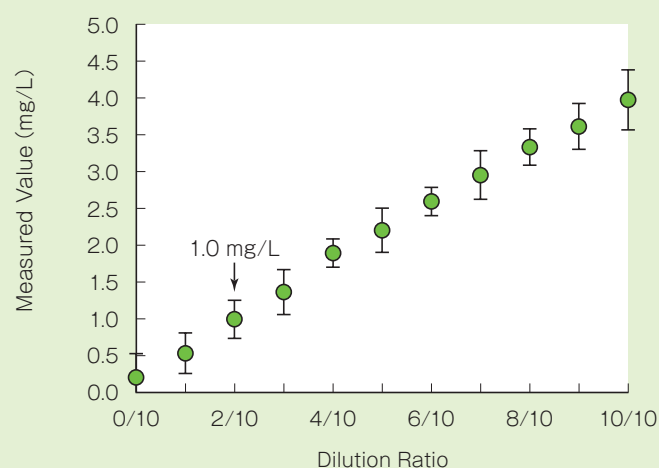
◆ Prozone

No hook effect was seen up to 1200 mg/L SAA.



◆ Limit of Detection

The Limit of Detection is 1.0 mg/L. This means that when SAA samples were diluted in 10 steps with saline and each sample was measured at n=10, the mean of 1.0 mg/L SAA -2.6 SD does not overlap with the mean of blank sample +2.6 SD.



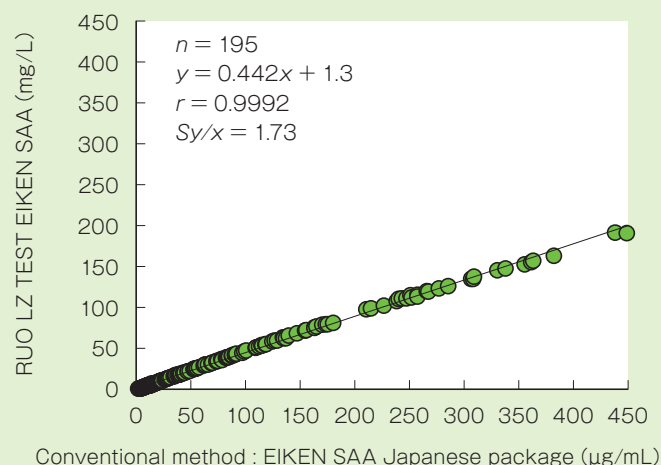
◆ Interfering substances

Almost no effect on the measured value was observed from the following co-existing substances at the indicated concentrations.

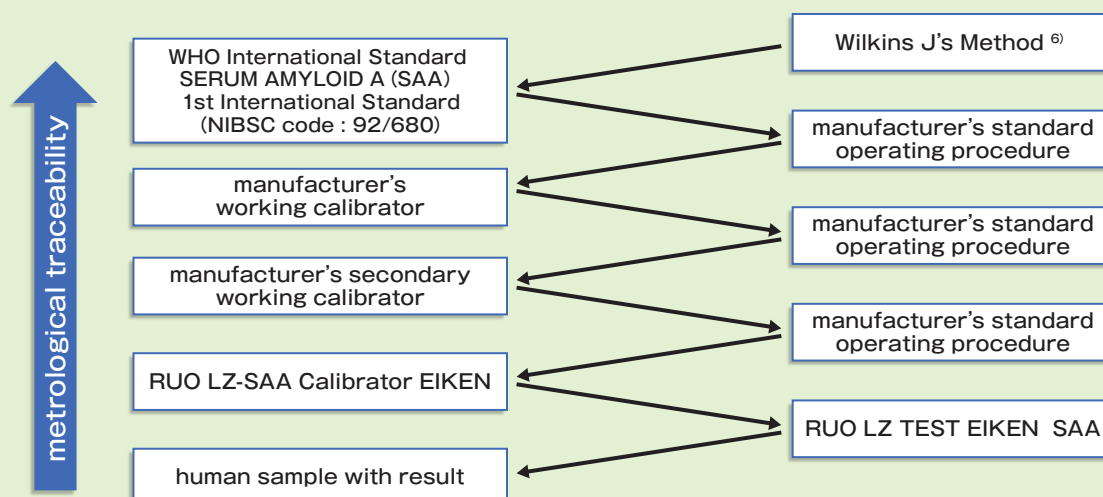
Conjugated Bilirubin	25 mg/dL
Unconjugated Bilirubin	25 mg/dL
Haemoglobin	500 mg/dL
Chyle	2000 FTU
Rheumatoid Factor	1000 IU/mL
Sodium Fluoride	1000 mg/dL
Sodium Citrate	500 mg/dL
Heparin Sodium	20 mg/dL
Disodium EDTA	200 mg/dL

FTU : Formazin Turbidity Unit

◆ Correlation



◆ RUO LZ TEST EIKEN SAA Calibration hierarchy^{3), 4), 5)}



◆ Contents • Storage • Shelf life

Product Name	Contents	Product Code	Storage	Shelf life
RUO LZ TEST EIKEN SAA	R1 : 20 mL x 2 R2 : 20 mL x 2	V-SZ11	2-8℃	12 Months

(Separately Sold : Calibrator)

Product Name	Contents	Product Code	Storage	Shelf life
RUO LZ-SAA Calibrator EIKEN	1 mL x 6 (6 concentrations)	V-SZ12	2-8℃	12 Months

(Separately Sold : Control Serum)

Product Name	Contents	Product Code	Storage	Shelf life
RUO QC-SAA L EIKEN	2 mL x 5	V-SZ13	2-8℃	36 Months
RUO QC-SAA H EIKEN	2 mL x 5	V-SZ14		

Reference

- 1) Benditt, E.P. Eriksen, N.: Proc. Soc. Natl. Acad. Sci. USA., 74 : 4025-4028, 1977.
- 2) Maury, C.P: Clin. Sci., 68 : 233-238, 1985.
- 3) Qin Y, et al. The journal of clinical laboratory instruments and reagents 2020 ; 43 (4) : 404-409
- 4) Internal data
- 5) ISO 17511 : 2020
- 6) Wilkins J, et al. Clin.Chem.1994 ; 40 (7) : 1284-1290

For precautions and operation of this product, please refer to Instructions for Use and other related documents.



Corporate website
(Product information)



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