Serum Amyloid A (SAA) PETIA kit

Catalogue number: 51910

For the quantitative determination of Serum Amyloid A
in human serum and plasma

This package insert must be read in its entirety before using this product
Use only the current version of product data sheet enclosed with the kit

Website: www.immunodiagnostics.com.hk
E-mail: info@immunodiagnostics.com.hk
Tel: (+852) 3502 2780
Fax: (+852) 3502 2781

FOR RESEARCH USE ONLY
NOT FOR USE IN DIAGNOSTIC PROCEDURES

Version: 5.22

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INTRODUCTION

Serum Amyloid A (SAA) is a family of apolipoproteins associated with high-density lipoprotein in blood stream. SAA are produced predominantly by the liver. The main functions of SAA include the transport of cholesterol to the liver for secretion into the bile, the recruitment of immune cells to inflammatory sites, and the induction of enzymes that degrade extracellular matrix.
SAA is a major acute phase protein in human beings. In normal conditions, SAA concentration in serum is approximately 1-10 μg/ml. However, during an acute-phase reaction, the concentration can rise to 1 mg/mL or even higher. SAA can be used in diagnosis, predicting outcomes and assessing the efficacy of treatment in patients with inflammation. Specifically, it has been demonstrated in a number of studies that SAA concentration reflects the disease activity and grade of inflammation in patients with rheumatoid arthritis. SAA is a sensitive biomarker of acute renal allograft rejection and it can be used to monitor SAA in kidney transplant patients for the early detection of acute rejection episodes. In patients with myocardial infarction, SAA concentration is elevated to extremely high values and correlates with post infarction complications and the mortality rate. Elevated SAA concentrations were observed in patients with bacterial infections caused by different pathogens. In patients with urinary tract infections, the monitoring of the SAA level is useful for the evaluation of antimicrobial therapy efficiency

PRINCIPLE OF THE ASSAY

This assay is a turbidimetric immunoassay for the quantitative measurement of SAA in human serum and plasma. A standard or sample is added into a cuvette and mixed with the reaction buffer R1. After a short incubation, the test reagent R2, which is a suspension of microparticles coated with SAA antibodies, is added into the cuvette and mixed. The presence of SAA in the standard or sample causes the immune-particles to aggregate. The extent to which the microparticles aggregate is quantified by the amount of light scattering measured as absorbance by a chemistry analyzer. The concentration of SAA in unknown samples can be interpolated from a reference curve using the standards provided.

REAGENTS SUPPLIED

R1 – Reaction buffer, 30 ml, a ready-to-use buffer solution containing salt, polyether compound and preservative

R2 – Test reagent, 10 ml, a ready-to-use suspension of polymer microparticles coated with rabbit anti-SAA polyclonal antibodies in storage buffer

OTHER MATERIALS REQUIRED, BUT NOT PROVIDED

1. Clinical chemistry analyzer
2. Serum Amyloid A calibrators and controls
3. Deionized water
4. Analyzer-specific reagent containers for R1 and R2

STORAGE

The kit should be stored at 2-8°C upon receipt. Once opened, the reagents may be stored at 2-8°C for up to 4 weeks.

SAMLE HANDLING

This kit can be used to determine SAA in human serum and plasma samples. Blood specimens should be collected aseptically into appropriate tubes. Plasma should be prepared by standard techniques for laboratory testing. The prepared specimens should be stored in closed vessels. If the assay cannot be performed within 24 hours or specimens are to be shipped, the specimens should be frozen at −20°C or below. For long-term storage of specimens, −70°C or below is recommended. To avoid freeze-thaw cycles, specimens should be aliquoted. Do not use hemolyzed, hyperlipemic, heat-treated or contaminated specimens. No dilution of the sample is required in this assay.

ASSAY PROCEDURE

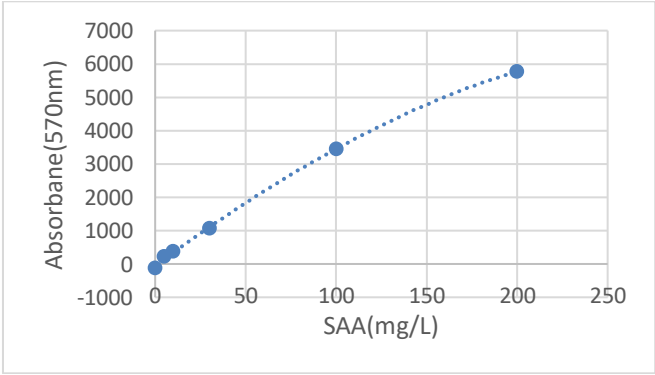
Assay procedures may vary depending on the automated chemistry analyzer to be used. A general example of assay procedures is stated as follow:

1. Dispense 150µl of R1 into a clean cuvette
2. Add 1.5µl of sample and incubate at 37˚C for 5 minutes
3. Further add 50µl of R2
4. Read change of absorbance at Main Wavelength 570 nm for 8 minutes after the addition of R2
5. Calculate the concentration of SAA in unknown sample by interpolation from a reference curve using the standards provided

TYPICAL STANDARD CURVE

The following standard curve is provided for demonstration only. A standard curve should be generated for each assay.

SAA (mg/L)	Absorbance
0	-0.0126
5	0.0221
10	0.0378
30	0.1072
100	0.3457
200	0.5777



CALCULATION

1. Subtract the absorbance of the blank from that of standards and samples.
2. Generate a standard curve by plotting the absorbance obtained (y-axis) against SAA concentrations (x-axis). The best fit line can be generated with any curve-fitting software by regression analysis. 4-parameter curve fitting can be used for calculation.
3. Determine SAA concentration of samples from standard curve.

ASSAY CHARACTERISTICS

A. Sensitivity

The sensitivity is defined as the lower limit of detection and is estimated as the mean of the blank sample plus three times the SD obtained from the blank sample. The sensitivity of SAA assay is 0.123mg/L.

B. Precision

Within-run Imprecision:

The precision of the SAA assay is < 10% CV. Three samples consisting of serum based panels were assayed 20 times separately.

Sample	Theoretical Value	Test 1	Test 2	Test 3	AVG	Recovery
Panel 1	5	5.16	5.28	5.25	5.23	95%
Panel 2	10	9.93	9.3	10.1	9.77	97%
Panel 3	30	30.27	30.01	29.33	30.1	96%

Between-day Impression:

The precision of the SAA assay is < 10% CV. Three samples consisting of serum-based panels were assayed separately on each of the 5 consecutive days.

Sample	Mean SAA (mg/L)	SD (mg/L)	CV
Panel 1	1.53	0.04	2.6%
Panel 2	5.55	0.10	1.8

Panel 3	20.13	0.59	2.9%

C. Linearity

The SAA assay is linear between 5 mg/L to 200 mg/L.

D. Traceability

Comparison to SAA standard obtained from 1st International Standard (NIBSC

Sample	Theoretical Value	Test 1	Test 2	Test 3	AVG	Recovery
WHO STD	156	149.1	153.5	155	152.8	98%
WHO STD (1/2 diluted)	78	82.0	82.6	81.3	80.8	96%
WHO STD (1/4 diluted)	39	37.0	36.4	37	37.4	96%

（code: 92/680)

E. Interference

No interference was detected with hemoglobin up to 5 g/L, conjugated bilirubin up to 300 mg/L, free bilirubin up to 300 mg/L, and up to 5g/L lipid emulsion.

F. Storage and Stability

Unopened: Stable for 12 months when stored all components at 2-8°C.

Opened: Stable for 4 weeks when stored all components at 2-8°C.

ImmunoDiagnostics Limited

5F, Biotech Centre 2 (11W), No. 11 Science Park
West Avenue, Hong Kong Science Park, Shatin. NT, Hong Kong
Website: www.immunodiagnostics.com.hk
E-mail: sales@immunodiagnostics.com.hk
Tel: (+852) 3502 2780
Fax: (+852) 3502 2781