Serum Amyloid A Protein Assay Kit （SAA）

Method: Latex Immunoturbidimetric Method

Cat.No.	Package Size	Analyzer
EGSSAA	R1:1×60 ml R2:1×20 ml	For Hitachi917& OlympusAU640/400/600
EGBSAA	R1:1×60 ml R2:1×20 ml	For Hitachi 717 &ShimadzuCL7200/8000
EGHSAA	R1: 1×45 ml R2: 1×15 ml	For Siemens Dupont/Siemens Behring Series
EGD129T	R1: 12×3.8 ml R2: 6×2.6 ml	For Siemens Dupont/Siemens Behring Series
EGSAA460BS	R1: 1×45 ml R2: 1×15 ml	For Mindray BS120/180/190/200/220/230/240/430/460/830
EGGSAA	R1: 1×45 ml R2: 1×15 ml	For Semi Auto Analyzer

INTENDED USE

For in vitro quantitative determination of Serum Amyloid A in human serum.

CLINICAL SIGNIFICANCE

Serum Amyloid A Protein (SAA) is an acute phase protein. During inflammation, infectious and non-infectious diseases, its concentration in the blood can rise sharply within a few hours and can rise to 1000 times of the initial concentration; SAA and HDL are related to the regulation of HDL metabolism during inflammation. A particularly important feature of SAA is that its degradation products can be deposited in different organs in the form of amyloid A fibrils. This is a serious complication in chronic inflammatory diseases; elevated SAA is also seen in atherosclerosis, diabetic nephropathy, acute myocardial infarction, coronary heart disease, and chronic kidney disease. SAA has a similar effect with CRP in evaluating inflammation, monitoring its activity, and treatment. SAA testing is more conclusive than CRP testing in patients diagnosed with viral infection, renal transplant rejection (especially those treated with immune mechanisms) and adrenal cortical hormone-treated cystic fibrosis. The study found that SAA is most closely related to disease activity in cases of arthritis. Simultaneous detection of CRP and SAA can improve the diagnostic sensitivity of infection.

ASSAY PRINCIPLES

When the latex particles coated with Serum Amyloid A (SAA) antibodies are mixed with a sample containing SAA antigen, an agglutination reaction occurs, which causes a change in absorbance, the size of which is proportional to the SAA antigen content in the sample. Comparing the change in absorbance with a calibrator of known concentration can quantitatively determine the content of serum amyloid A in the sample.

REAGENT COMPOSITION

Contents	Concentration
Reagent 1 (R1)	
Tris buffer	≥50.0mmol/L
Preservative	≥0.05%
Reagent 2 (R2)	
Latex particles coated with anti-human serum amyloid A antibody	≥0.10%（W/V）
Preservative	≥0.05%

STABILITY AND PREPARATION OF REAGENTS

1. Stable up to the expiry date when the reagent is sealed and stored in dark at 2-8 ℃.
2. Reagents should not be frozen.
3.The production date and expiry date are shown on the label.

APPLICABLE INSTRUMENT

This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering the wavelength range of 546 / 800nm.
It is recommended to use this kit on a biochemistry analyzer for testing according to laboratory conditions.

SAMPLE COLLECTION AND PREPARATION

Fresh serum to avoid hemolysis,
Stable for one week when stored at 2 ℃ ～ 8 ℃.

ASSAY PROCEDURE

Test Conditions:（Hitachi 917）

Main wavelength	546 nm	Sample (S)	2.5 μL
Secondary wavelength	800nm	Reagent (R1)	200μL
Reaction temperature	37℃	Reagent (R2)	40μL
Cuvette Diameter	1cm	Reaction type	End point

Operate Procedure

Add into cuvette:	
Sample (S)	2.5μL
Reagent (R1)	200μL
Mix well and incubate for 300 seconds at 37℃.	
Reagent (R2)	40μL
Mix well and incubate for 60 seconds at 37℃, read initial absorbance A1, then incubate for another 120sec, read final absorbance A2, calculate ΔA=A2-A1	

Note:Parameters above are only introduced with Hitachi 917 as an example. The parameters of different biochemistry analyzers are slightly different. Please read the manual carefully before setting parameters.

CALIBRATION

It is recommended to use Gcell SAA calibrator.
Calibrator traces to the international reference materials NIBSC 92/680.
1. According to the requirements of the calibration procedure in the operation manual of biochemistry analyzer, each laboratory establishes its own calibration procedure according to the specific conditions.
2 Requirements for calibration and frequency: It is recommended to calibrate at least once every week. When the following situations occur, it is recommended

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to re-calibrate: change the reagent batch number, the indoor quality control runs out of control, the biochemistry analyzer carries out major maintenance or replaces the main parts such as light source or cuvette.

QUALITY CONTROL

It is recommended to use Gcell SAA control. The absorbance of quality control should be within the labeled value range. If the results deviate from the scope, please find out the reason by following steps:
1. Check the parameter setting and light source.
2. Check the cleanliness of the cuvette and sampling needle.
3. Check whether water is contaminated or not. Bacterial growth can lead to incorrect results.
4. Check the reaction temperature.
5. Check the validity of the kit.

CALCULATION OF RESULTS

According to the specific calibration mode of the project, the calibration curve is automatically generated by the instrument, and the content of the measured object is calculated from the absorbance change value of the measured object in the sample.

REFERENCE RANGE

Serum：≤10.0mg/**L**[1]
It is recommended that each laboratory establish its own reference interval based on age, gender, diet, and region.

INTERFERENCE

The effect of bilirubin ≤20mg/dL, Intralipid ≤500mg/dL, and hemoglobin concentration ≤300mg/dL, is less than10%.

ACCURACY

The kit is tested with NIBSC 92/680 international reference material. The deviation of the results should ≤± 15%.

SENSITIVITY

When the sample concentration is 20.0mg/L, its absorbance change should ≥0.0050.

LINEARITY

In the range of [5.0, 180.0]mg/L, the linear correlation coefficient r ≥ 0.990; in the range of [5.0, 40.0] mg/L,the absolute deviation should ≤ ± 6.0 mg/L; in the range of (40.0, 180.0] mg/L, the relative deviation should≤± 15%.

PRECISION

Repeatability precision was obtained by testing control or sample for 20 times of repeated measurement. Intermediate precision was obtained by testing human samples or control for 2 batches 5 days, and each batch was measured for 5 times.The results are as follows:
a）Repeatability Precision(N=20)

	Mean (mg/L)	CV(%)
Control 1	12.43	3.1
Control 2	34.47	1.6

b) Intermediate Precision (N=25)

	Mean (mg/L)	CV(%)
Control 1	7.62	2.9
Control 2	41.96	2.0

SAFETY PRECAUTIONS AND WARNINGS

1. The reagent contains preservatives. If it enters the eyes, mouth or contact on the skin, please rinse it thoroughly with clean water immediately and go to the hospital if necessary.
2. The reagent contains preservatives, which can react strongly with copper, lead and other metals to form azide metal. Therefore, please dilute the waste liquid and flush the drain pipe to avoid residual when disposal.
3. Do not mix or exchange reagents with different batches in the process of detection.
4. Opened reagents should be sealed and stored according to the specified method. Expired product should not be used.
5. Please dispose test tubes and other instruments that have touched the test sample according to the relevant medical waste disposal regulations.

REFERENCES

1. "National Clinical Laboratory Practice" (Fourth Edition), Department of Medical Affairs, Ministry of Health, People's Republic of China

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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