Instruction For Use

【Product Name】

Serum Amyloid A (eCLIA)

【Order Information】

REF NO.	Package Size
0320502001	50T
0320502002	2×50T
0320502003	100T
0320502004	2×100T

【Intended Use】

Immunoassay for in vitro quantitative determination of Serum Amyloid A (SSA) in human serum and plasma.

Serum amyloid A (SAA) is A precursor of the organization of serum amyloid A, belong to the acute instead should protein [1] [2] in infectious and non-infectious diseases during inflammation and its concentration in the blood can rise sharply in A few hours, mainly as A nonspecific inflammation index, it is mainly used for clinical auxiliary diagnosis of acute infectious disease, associated with CRP detection is used to identify the virus and bacteria infection, and kidney transplant rejection of auxiliary judgment. [3]

【Principles of the examination method】

Sandwich principle.Total duration of assay: 9 minutes.

After the user applies for testing,the system automatically aspirates the sample and sample diluent into the incubation cup at a rate of 1:9 and dilute it twice consecutively, that is, dilute it 100 times in total. The system automatically aspirates 6 μL of the diluted sample, 85 μL of biotinylated SAA monoclonal antibody, 85 μL of Ru complex-labeled SAA monoclonal antibody and 25 μL of streptavidin coated magnetic particles into the reaction cup. They are automatically incubated at 37℃ for 9 min to form antigen-antibody sandwich complexes, and then the whole complexes are bound to the magnetic particles under the interaction of biotin and streptavidin. After incubation, the system automatically aspirates the reaction mixture into the measuring cell, the magnetic particles are captured onto the surface of electrode, while the unbound substances are washed away by buffer, and the electrodes is applied with voltage to generate chemiluminescence. The generated optical signals are measured by the photomultiplier, and the measured results are automatically determined via the calibration curve specifically generated by the instrument (this curve is obtained by performing three-point calibration for the master calibration curve obtained by reading the reagent RFID)

【Main Components】

The reagent pack consists of MB, RA, RB, RD, calibrators and control materials(optional), and different components and reagents of lot numbers should not be used interchangeably.

Component	Ingredients	Volume (2×50T)	Volume (50T)	Volume (100T)	Volume (2×100T)
MB	streptavidin-coated magnetic beads, 0.75 mg/mL; ProClin™300	2×1.3 mL	1×1.3 mL	1×2.5 mL	2×2.5 mL
RB	Anti-SAA-Ab~biotin: 10mM HEPES; ProClin™300	2×4.3 mL	1×4.3 mL	1×8.5 mL	2×8.5 mL
RA	Anti-SAA-Ab~ $Ru(bpy)_3^{2+}$: 10mM HEPES; ProClin™300	2×4.3 mL	1×4.3 mL	1×8.5 mL	2×8.5 mL
RD	10 mM HEPES; ProClin™300	2×5.4 mL	1×5.4 mL	1×10.8mL	2×10.8mL
Calibrators	SAA antigen; ProClin™300; lyophilized	High: 1×1.0 mL Medium:1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	SAA antigen; ProClin™300; lyophilized	High: 1×1.0 mL Low: 1×1.0 mL			

Traceability: This method has been standardized against the international standard substances for WHO 92/680.

See the control material value sheet for the target values and ranges of control materials.

Supporting instruments and materials required but not provided in this pack (provided by Lifotronic)

Additional materials for Automated ECL Immunoassay Analyzers eCL8000, eCL8000i, eCL8000p, eCL8000x:

- REF 679005, Auffer, 480 mL, or REF 679004, Auffer, 6×480 mL
- REF 679007, Buffer, 480 mL, or REF 679006, Buffer, 6×480 mL
- REF 679009, Concentrated Washing Buffer, 1 L, or REF 679008, Concentrated Washing Buffer, 6×1 L
- REF 679011, Assay Cup, 300 T, or REF 679012, Assay Cup, 3000 T

Additional materials for Automated ECL Immunoassay Analyzer eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p:

- REF 0320501804, Auffer, 2×1 L, or REF 0320501805, Auffer, 4×1 L
- REF 0320501904, Buffer, 2×1 L, or REF 0320501905, Buffer, 4×1 L
- REF 0320507502, PreClean, 2×800 mL, or REF 0320507503, PreClean, 4×800 mL
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 0321201[illegible], Assay Cup/Assay Tip, 12×2×105

Additional materials for Automated ECL Immunoassay Analyzer eCL9000, eCL9600, eCL9900, eCL9900i:

- REF 0320501801, Auffer, 2×2 L, or REF 0320501806, Auffer, 4×2 L
- REF 0320501901, Buffer, 2×2 L, or REF 0320501906, Buffer, 4×2 L
- REF 0320507501, PreClean, 2×2 L, or REF 0320507504, PreClean, 4×2 L
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 0320510002, Assay Cup/Assay Tip, 1×6×105

【Storage and Shelf Life】

Store at 2℃-8℃.

Do not freeze.

Store the reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Damaged, expired or contaminated reagents should be discarded.

Stability of the reagents	
Unopened store at 2℃~8℃	18 months
Store at 2℃~8℃ after opening	8 weeks
Store on the analyzers at 2℃~15℃	8 weeks

The calibrators and control materials are stable up to the stated expiration date.

Stability of the calibrators and control materials	
Unopened store at 2℃~8℃	18 months
Store at 2℃~8℃ after resolution	7 days
Store at -25℃~-15℃ after resolution	3 months (freeze only once)

Store calibrators and control materials upright in order to prevent the calibrators and control materials from adhering to the cap of the vial.

【Applicable Instrument】

Automated ECL Immunoassay Analyzers: eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p, eCL9000, eCL9600, eCL9900, eCL9900i.

【Specimen collection, handling and storage】

It is recommended to use serum samples or plasma samples collected from EDTA-3K, EDTA-2K, sodium citrate,heparin lithium and heparin sodium blood collection tubes.

Blood samples should be collected in accordance with the standard operation of venous puncture; After the sample is completely coagulated, centrifugation should be performed to remove residual cellular substances. The sample should be free of air bubbles during testing. Lipid layer covering the sample after centrifugation should be removed. It is not recommended to use hemolyzed samples.

Samples can be stored for 8 hours at 18~28℃,7 days at 2~8℃, and 30 days at -15℃ or below. Freezing and thawing cycle is permitted only once.

【Testing Procedure】

Testing procedure and precautions

Before testing, the system operation manual of the measuring instrument should be carefully read, so as to obtain relevant information such as system operating procedures, sample management, safety precautions and maintenance, and materials required for testing should be prepared. SAA testing procedures should be called and set up in accordance with the system operating procedures.

Before using the reagent, put it into the analyzer 30 minutes in advance to automatically stir the magnetic bead particles and keep them in suspension.

Recommended environment temperature for testing: 10~30℃; relative humidity: ≤ 80%.

Calibrator and Control Material handling :

Handing of lyophilized calibrators and control materials:

Carefully dissolve the contents of one bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 10~15 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer aliquots of the reconstituted calibrators or control materials to the additional bottles. After bottles is marked and dispensed. If you do not test immediately, you need to store the aliquots immediately at -20 °C (± 5 °C) .

Calibration

Calibration should be performed using lot-matching reagent and calibrators.

Before calibration, the reagent and main curve information should be imported into the analyzer via radio frequency identification reagent card (refer to instrument user manual). The analyzer adjusts the main curve to produce working curve according to the calibrator results, and identifies validity of the working curve automatically.

Recalibration is recommended when:

(1) The reagents of different lot are used;

(2) The same lot of reagents were used on the analyzer beyond 28 days;

(3) Quality control findings outside the defined limits.

(4) The Buffers of different lot are used.

Quality Control procedure

For quality control, use SAA control materials.

In addition,other suitable control material can be used.

Control materials for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and

following each calibration.
The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.
If necessary, repeat the measurement of the samples concerned.
Follow the applicable government regulations and local guidelines for quality control.
Please make sure that the correct values are used.

Calculation

The system software automatically calculates the concentration of the analyte, and the result unit is μg/mL. 1μg/mL=1mg/L.

【Biological reference interval】

According to serum test results of 288 heathy human serum samples , the percentile 95 gives reference range <10.47 μg/mL.
Due to differences in the region, race, gender and age, laboratories are recommended to set up their own reference ranges.

【Interpretation of Results】

For explaining the result, the patient's overall clinical manifestation should be referred to, including symptoms, medical history and other relevant data and information.

【Limitations】

The test results are only for clinical reference and cannot be used alone as the basis for diagnosis or exclusion of cases.
The detection range of the kit is 0.2 μg/mL~400 μg/mL. If the SAA concentration in the sample is lower than the lower limit of detection, the result is reported as < 0.2 μg/mL; if the SAA concentration in the sample is higher than the upper limit of detection, the result is reported as > 400 μg/mL.
When bilirubin is ≤30 mg/dL, hemoglobin is ≤1000mg/dL, lipid is ≤2000 mg/dL, biotin is ≤80 ng/mL, total protein is ≤10 g/dL, HAMA is ≤100 ng/mL in the sample, the interference deviation of the measurement results is within ±10%. When the concentration of rheumatoid factor in the sample is ≤ 1100 IU/mL, the relative recovery of the test results is between 90% and 110%.

【Analytical Performance】

Lower limits of measurement

Limit of detection (LoD) ≤ 0.2 μg/mL

Accuracy

The national standard is tested, and the relative deviation of the test results of is within ±15%.

Linearity

Within the range of 0.2 μg/mL~400 μg/mL, the correlation coefficient (r) of the kit should not be less than 0.9900.

Within-run imprecision (repeatability)

The coefficient of variation (CV) is less than 8%.

Between-lot imprecision

The coefficient of variation (CV) is less than 10%.

Accuracy of calibrators

The supporting calibrators of the kit are tested, the relative deviation of the test results of is within ±15%.

Homogeneity of calibrators and control materials

In-bottle homogeneity: coefficient of variation (CV) ≤ 8%.
Between-bottle homogeneity: coefficient of variation (CV) ≤ 10%.

Method comparison

A comparison of the Lifotronic SAA assay (y) with the bycommercial SAA reagent kit (x) using clinical samples gave the following correlations:
Number of samples measured: 135
Linear regression:
Y=0.9988X+0.2112
r =0.9972
The sample concentrations were between approx 1.11 μg/mL to 384 μg/mL.

【Precaution and Warning】

The kit is only used for in vitro diagnostics.
Exercise the normal precautions required for handling all laboratory reagents.
All reagents and samples including specimen, reagents, calibrators and control materials should avoid foaming before and during test.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.
This product contains animal-sourced materials and may have potential biological risk. All samples and test wastes should be treated as the source of infection, and all wastes must be disposed according to local regulations.
Any serious incident that would be occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
The preservative ProClin™300 which contain Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1): May cause an allergic skin reaction. thus, proper personal protection should be adopt while handling the reagent: avoid breathing dust/fume/gas/mist/vapours/ spray, wear protective gloves and contaminated work clothing should not be allowed out of the workplace. If skin irritation or rash occurs: get medical advice/attention, take off contaminated clothing and wash it before reuse, and dispose of contents/container to an approved waste disposal plant.

【Symbols Explanation】

Symbol	Title of Symbol	Symbol	Title of Symbol
	Manufacturer		Consult instructions for use
	Use-by date	IVD	In vitro diagnostic medical device
LOT	Batch code	Σ	Sufficient for <n> tests
SN	Serial number		Biological risks
	Temperature limit		This way up
EC REP	Authorized representative in the European Community	CE	Indicates this device is in compliance with Europe Directive.
REF	Catalogue number	P/N	Material code
	Warning		Date of manufacture
UDI	Unique device identifier		

【Reference】

1. Uhlar CM,Whitehead AS,Serum amyliod A,the major vertebrate acute-phase reactant【J】.Eur J Biochem,1999,265(2):501-523.
2. Coetzee GA,Strachan AF,van der Westhuyzen DR,et al.Serum amyliod A-containing human high density lipoprotein 3.Density,size and apolipoprotein composition【J】. J Biol Chem , 1986, 261(21) : 9644-9651.
3. Research progress of Yang Xuejuan, Feng Xiying, Zhang Man, et al on serum amyloid A and respiratory diseases [J].Journal of clinical lung, 2014,19 (8) : 1052-1054

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