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SAA
Fast Test Kit
(Immunofluorescence Assay)

IF1044 for Getein1100
IF3044 for Getein1180
IF2044 for Getein1600
IF5044 for Getein1160
REF IF4044 for Getein1200
IF6044 for Getein208

User Manual

INTENDED USE

SAA (Serum Amyloid A) Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of SAA in human serum, plasma, whole blood and fingertip blood samples. It can be used as a sensitive index in the diagnosis of infection and inflammation.

SUMMARY

SAA proteins comprise a family of small (12-14 kDa.104-112 amino acid residues), differentially expressed proteins that are highly conserved among vertebrates. SAA proteins are involved in the acute phase responses, these are the immediately early host respones to inflammation. SAAs have been implicated several disease states including rheumatoid arthritis, atherosclerosis, AA amyloidosis and coronary artery disease.

Liver is the major site of SAA synthesis, although extrahepatic expression also has been reported. In humans, four SAA genes and three protein products have been identified: human SAA1 and SAA2 are designated the acute phase SAA (A-SAA) isoforms, while SAA4 is constitutively expressed and SAA3 is a pseudogene.

SAA is released into bloodstream where it immediately binds the HDL particles. There are a number of important homeostatic functions associated with the circulating SAA-HDL complexes, these functions are categorized as immune modulation, lipid transport and anti-inflammatory. It is an acute phase marker responds rapidly, similar to CRP, levels of SAA increase within hours after inflammatory stimulus, and the magnitude of increase may be greater than CRP. It has been suggested that SAA levels correlate better with disease activity in early inflammatory joint disease than do ESR and CRP.

PRINCIPLE

The test uses an anti-human SAA monoclonal antibody conjugated with fluorescence latex coated nitrocellulose membrane and another an anti-human SAA monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled antihuman SAA monoclonal antibody binds with the SAA in sample and forms a marked antigen-antibody complex. This complex moves to the test detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by anti-human SAA antibody. The fluorescence intensity of test line increases in proportion to the amount of SAA in sample.

Then Insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/ Getein208 Hand-held Integrated System /automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein208, Getein1200 and Getein1600), the concentrations of SAA in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein208/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180/Getein208 contains:

Package specifications: 25 tests/box, 10 tests/box
1) Getein SAA test card in a sealed pouch with desiccant
2) Capillary pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card: 1 piece/box

2. A kit for Getein1200/Getein1600 contains:

Package specifications: 2×24 tests/box, 2×48 tests/box
1) Sealed cartridge with 24/48 Getein SAA test cards
2) User manual: 1 piece/box

Materials required for Getein1200/Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box

3. Sample diluent composition:

Phosphate buffered saline, proteins, surfactant, preservative and stabilizer.

4. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with fluorescence latex-labelled anti-human SAA
monoclonal antibody, the test lines is coated with another antihuman SAA antibody, and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICES

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein208 Hand-held Integrated System
Getein1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100/Getein1160/Getein1180/Getein208 within 1 hour once the foil pouch is opened.

For test card of Getein1200/Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

Store the sample diluent at 0~30℃ with a valid period of 24 months.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma, whole blood and fingertip blood samples. Heparin, EDTA and sodium citrate*** can be used as the anticoagulant forplasma. Samples should be free of hemolysis.
2. Suggesting serum or plasma for better results.
3. The test should be performed within 4 hours after whole blood collection. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2-8℃).
4. Refrigerated or frozen sample (only serum or plasma) should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples or hemolysis samples.
6. SAMPLE VOLUME ***(for Getein1100/Getein1160/Getein1180/ Getein208): 10 μl.***

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
4. Enter testing interface of Getein1100.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***10 μl*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μl*** of the sample mixture into the sample port on the test card.
8. ***Reaction time: 5 minutes***. Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

9. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
10. Enter testing interface of Getein1160/Getein1180.
11. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
12. Put the test card on a clean table,horizontally placed.
13. Using sample transfer pipette, deliver ***10 μl*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μl*** of the sample mixture into the sample port on the test card.
14. ***Reaction time: 5 minutes***. Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shoe on the screen and printed automatically.

For Getein208:

15. Long press the Power Button to start the analyzer
16. The system will enter (Test) menu.
17. Insert the MEMo memory chip which is with the same batch number as the test card.
18. Select (Test) menu, press (OK) to enter [Read Calibration Card] interface.
19. Press (OK) to automatically obtain the test item, batch number, serial number and sampling volume. Select the sample type by pressing＜or＞buttons.
20. Press (OK). The screen then prompts [Insert test card] and starts counting down from 60 sec. Insert test card within the 60 sec.

Note: Do not move the test card after it is inserted.

21. Add sample within 120 sec when the screen prompts [Wait for sample]. Then draw ***10 μL*** of sample and drop it into 1000 μL of sample diluent. Then drop ***60 μL*** of sample mixture into the sample port on the test card.
22. After sample adding, the system starts react-time countdown automatically.
23. After the countdown is over, the system starts testing automatically. Please check and record test results then.

Note: Test results are saved automatically in the system.

24. Long Press (OK)to return to the main interface. Take out

and discard the test card.

For Getein1200/Getein1600:

25. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
26. Place the sample diluent at the correct position in Getein1200/Getein1600.
27. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180/Getein208.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein208/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein208/Getein1200/Getein1600.

Others: Dilute the sample which concentration is higher than the upper limit with negative samples or sample diluent, and the dilution ratio should be less than 5 times.

EXPECTED VALUE

The expected normal value for SAA and was determined by testing samples from 400 apparently healthy individuals. The reference range of SAA is 10.0mg/L calculated by using normal distribution methods (95% confidence interval).

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	5.0~200.0 mg/L
Lower Detection Limit	≤5.0 mg/L
Within-Run Precision	≤10%
Between-Run Precision	≤15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferent may influence the results. The table below listed the maximum allowance of these potential interferent.

Interferent	Rheumatoid factors	Triglyceride	Bilirubin
Concentration (Max)	1620 IU/mL	22 mmol/L	888 umol/L

REFERENCES

1. Kivity S, Danilesko I, Benzvi I, et al. Serum amyloid A levels in kidney-transplanted patients with familial Mediterranean fever-amyloidosis. Isr Med Assoc J, 2011; 13(4):202-205.
2. Clinical and Laboratory Standards Institute. Protocols for determination of limits of quantitation; approved guideline-second edition. EP17-A, CLSI, 2004.
3. Clinical and Laboratory Standards Institute. Evaluation of precision performance of quantitative measurement method; approved guideline-second edition. EP17-A, CLSI, 2004.
4. National Committee for Clinical Laboratory. Method comparison and bias estimation using patient samples; approved guideline. EP9-A2, NCCLS, 2002.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on SAA Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged
REF	Catalogue number		

Thank you for purchasing SAA Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

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