



SAA Fast Test Kit (Immunofluorescence Assay)

Instructions for Use

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. For professional and laboratory use only.

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 response 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, like 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

SAA Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescently labeled SAA monoclonal antibody specifically binds to target SAA molecules in the sample, forming a labeled antigen-antibody complex. The

complex through capillary action to the detection zone, where it is captured by another SAA monoclonal antibody coated on the detection area of nitrocellulose membrane, ultimately forming a fluorescent double-antibody sandwich complex. The test line fluorescence intensity demonstrates proportional correlation with SAA concentration in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the SAA in sample be detected quantitatively.

CONTENTS

| Materials provided | Getein 1100/ Getein 1160/ Getein 1180/ Getein 208 | | Getein 1200/ Getein 1600 | |
|----------------------|--|----------|---|---|
| | 10 T/kit | 25 T/kit | 2*24 T/kit | 2*48 T/kit |
| SAA test card* | 10 pcs | 25 pcs | 24 test cards in 1 cartridge, and 2 cartridges in 1 box | 48 test cards in 1 cartridge, and 2 cartridges in 1 box |
| Disposable pipet | 10 pcs | 25 pcs | / | / |
| Sample diluent** | 10 tubes | 25 tubes | 1 box | 1 box |
| Instructions for use | 1 pc | 1 pc | 1 pc | 1 pc |
| SD card | 1 pc | 1 pc | 1 pc in each cartridge | 1 pc in each cartridge |

* SAA test card

A test card consists of: Fluorescently labeled SAA monoclonal antibody, SAA monoclonal antibody and polyclonal IgG antibody.

** Sample diluent

(1) Sample diluent for Getein 1100/ Getein 1160/ Getein 1180/ Getein 208 in each tube mainly consists of: phosphate buffer (20 mmol/L), Na₂S (<0.1%).

(2) Sample diluent for Getein 1200/ Getein 1600 is an independent packing box mainly consists of:

-Phosphate buffer (20 mmol/L), Na₂S (<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),

-Box with pipette tips (96 tips/box),

-Mixing plate (1 piece/box).

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".

2. Do not mix or interchange different batches of kits.

APPLICABLE DEVICES

Getein 1100 Immunofluorescence Quantitative Analyzer

Getein 1160 Immunofluorescence Quantitative Analyzer

Getein 1180 Immunofluorescence Quantitative Analyzer

Getein 1200 Immunofluorescence Quantitative Analyzer

Getein 1600 Immunofluorescence Quantitative Analyzer

Getein 208 Hand-held Integrated System

STORAGE AND STABILITY

Storage stability:

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

-For the test card of Getein 1100/Getein 1160/Getein 1180/Getein 208: Use the test card within 1 hour once the foil pouch is opened.

-For test card of Getein 1200/Getein 1600: 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.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional and laboratory use only, not for near-patient test and self-testing.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches until performing the test.
5. Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
6. It is recommended that operators take necessary self-protection measures (work clothes, goggles and disposable gloves, etc) when touching kits or samples.

SPECIMEN COLLECTION AND PREPARATION

1. Serum, plasma, whole blood and fingertip blood can be used as samples in the assay.
2. Heparin, sodium citrate and EDTA can be used as the anticoagulant for plasma and whole blood. EDTA can be used as the anticoagulant for fingertip blood. Do not use hemolysis specimens.
3. Serum and plasma are stable for 4 hours at room temperature (15~30°C), 7 days at 2~8°C, and 6 months at -20°C.
4. Whole blood and fingertip blood are stable for 4 hours at room temperature (15~30°C), 3 days at 2~8°C and avoid cryopreservation.
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. **SAMPLE VOLUME (for Getein 1100/Getein 1160/Getein 1180/ Getein 208): 10 μ L.**

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature

before testing.

For Getein1100:

- (1) Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- (2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- (3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- (4) Using disposable pipet or pipette, deliver **10 μ L** of sample into one tube of sample diluent, mix thoroughly. Then drop **100 μ L** of sample mixture into the sample well on the test card.
- (5) Reaction time: **5 minutes**. After reaction time is elapsed, insert the test card into Getein1100 and press "ENT" button (click on "Start" icon for Android Getein1100). The result will be shown on the screen and printed automatically.

For Getein160/Getein1180:

- (1) Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- (2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- (3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- (4) Using disposable pipet or pipette, deliver **10 μ L** of sample into one tube of sample diluent, mix thoroughly. Then drop **100 μ L** of sample mixture into the sample well on the test card.
- (5) Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (**5 minutes**) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein208:

- (1) Long press the Power Button to start the analyzer.
- (2) The system will enter (Test) menu.
- (3) Confirm SD card lot No. in accordance with test kit lot No..Read the relevant information in the SD card for calibration.
- (4) Insert test card according to the analyzer prompts.
- Note:** Do not move the test card after it is inserted.
- (5) Add sample according to the analyzer prompts. Then drop **10 μ L** of sample and drop it into sample diluent. Then drop **60 μ L** of sample mixture into the sample port on the test card.
- (6) After sample adding, the system starts react-time countdown automatically.
- (7) After the countdown is over, the result will be shown on the screen.

For Getein 1200/Getein 1600:

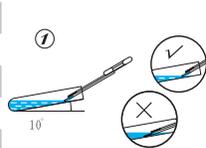
1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.

- Place the sample diluent at the correct position in Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/ Getein 1600 will do the testing and print the result automatically.

Note:

- It is required to perform "SD card" calibration when using a new batch of kits for Getein 1100/Getein 1160/Getein 1180/ Getein 208.
- The directions for using disposable pipet are as follows:

Directions to use disposable pipet

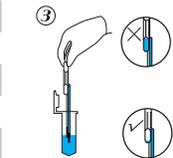


Insert the disposable pipet into the sample tube, gently touch the liquid surface with the capillary tip, and draw the sample.

Note: Do not immerse the exhaust pipe below the liquid level.



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, gently squeeze the suction bulb to perform 2-3 aspiration washing cycles, then mix the dilution manually.



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, firmly squeeze the suction bulb to aspirate the mixed sample.



Squeeze the suction bulb and drop the mixed sample vertically into the sample well on the test card.

TEST RESULTS

Getein 1100/Getein 1160/Getein 208/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen.

For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180/Getein 208/Getein 1200/ Getein 1600.

Others:

Measuring range of the SAA is 5.0 mg/L~ 200.0 mg/L. Dilute the sample which concentration is higher than the upper limit with sample diluent, and the dilution ratio should be less than 5 times.

EXPECTED VALUE

SAA: The expected normal value for SAA was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for SAA is 10.0 mg/L. (The probability that SAA value of a normal person below 10.0 mg/L is 95%.)

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
 Limit of Detection ≤5.0 mg/L
 Within-Run Precision ≤10%
 Between-Lot 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. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferents.

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

REFERENCES

- Kivity S, Danilesko I, Benzi 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.
- Clinical and Laboratory Standards Institute. Protocols for determination of limits of quantitation; approved guideline-second edition. EP17-A, CLSI, 2004.
- Clinical and Laboratory Standards Institute. Evaluation of precision performance of quantitative measurement method; approved guideline-second edition. EP17-A, CLSI, 2004.
- 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 details in the European Standard EN ISO 15223-1:2021.

| Key to symbols used | | | |
|---------------------|---|--|--|
| | Manufacturer | | Use-by date |
| | Do not re-use | | Date of manufacture |
| | Consult instructions for use or consult electronic instructions for use | | Batch code |
| | Temperature limit | | In vitro diagnostic medical device |
| | Contains sufficient for <n> tests | | Authorized representative in the European Community/European Union |
| | CE mark | | Do not use if package is damaged and consult instructions for use |
| | Catalogue number | | Caution |

| Catalogue number | Applicable analyzer | Package specification |
|------------------|---------------------|-----------------------|
| IF1044-10T | Getein 1100 | 10 T/kit |
| IF1044 | Getein 1100 | 25 T/kit |
| IF5044-10T | Getein 1160 | 10 T/kit |
| IF5044 | Getein 1160 | 25 T/kit |
| IF3044-10T | Getein 1180 | 10 T/kit |
| IF3044 | Getein 1180 | 25 T/kit |
| IF6044-10T | Getein 208 | 10 T/kit |
| IF6044 | Getein 208 | 25 T/kit |
| IF4044 | Getein 1200 | 2*24 T/kit |
| IF4044-96T | Getein 1200 | 2*48 T/kit |
| IF2044 | Getein 1600 | 2*24 T/kit |
| IF2044-96T | Getein 1600 | 2*48 T/kit |

Thank you for using SAA Fast Test Kit (Immunofluorescence Assay). Please read this Instructions for use carefully before operating to ensure proper use.

Version: WIF42-S-10

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