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CE IVD

SAA/CRP
Fast Test Kit
(Immunofluorescence Assay)

Instructions for Use

INTENDED USE

SAA/CRP Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of serum amyloid A (SAA) and C-reactive protein (CRP) in serum, plasma, whole blood and fingertip blood samples. This test can be used as a sensitive index in the diagnosis of infection and inflammation. For professional and laboratory use only.

SUMMARY

Serum amyloid A (SAA) is an acute time-limited protein, belonging to a heterogeneous protein in the apolipoprotein family, with a relative molecular weight of about 12 kDa. In the acute time-limited response, stimulated by interleukin-6 (IL-6) and interleukin-1 (IL-1), liver cells synthesize and secrete a large amount of SAA into the blood, which rapidly rises by about 1000 times within 5-6 hours. The half-life of SAA is about 50 minutes. SAA can quickly decrease to normal level when infection sources are cleared. It can be used as a sensitive indicator reflecting the control of infection and inflammation in the body.

C-reactive protein is synthesized by hepatocytes, produced during fetal lactation, and transmitted by the non-maternal placenta. When the body is infected or the tissue is damaged, macrophages and other white blood cells are activated to produce interleukin-6 (IL-6), interleukin-1 (IL-1), and other cytokines and other mediators. These cytokines and mediators stimulate hepatocytes and epithelial cells to produce CRP after reaching the liver.

At present, elevated serum SAA has been detected in various diseases such as bacteria, virus infection, atherosclerosis, coronary heart disease, and acute transplant rejection. SAA provides a clinical auxiliary diagnosis for certain diseases, such as viral infection, transplant rejection, coronary heart disease, etc. The combined detection of SAA and CRP is helpful for the early diagnosis of neonatal sepsis and the identification of bacterial infections from viral infections. The sensitivity of SAA during viral infection is significantly higher than that of CRP, while SAA and CRP are both elevated in patients with a bacterial infection.

PRINCIPLE

SAA/CRP 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 antibody/ CRP antibody specifically binds to target SAA/CRP 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/CRP 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/CRP concentration in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the SAA/CRP in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
SAA/CRP 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/CRP test card

A test card consists of: Fluorescently labeled SAA antibody, SAA antibody, fluorescently labeled CRP antibody, CRP antibody, polyclonal IgG antibody.

** Sample diluent

(1)Sample diluent for Getein 1100/ Getein 1160/ Getein 1180 in each tube mainly consists of: Phosphate buffer (20 mmol/L), NaN_3 (<0.1%).

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

-Phosphate buffer (20 mmol/L), NaN_3 (<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.

STORAGE AND STABILITY

Realtime stability:
Store the kit at 4~30℃ 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: 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): 10 μL.***

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 Getein 1100:

(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 ***10μL*** of sample into one tube of sample diluent, mix thoroughly. Then drop ***100 μL*** 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 Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

(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 μL*** of sample into one tube of sample diluent, mix thoroughly. Then drop ***100 μL*** 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.

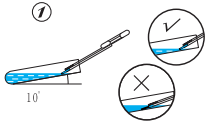
For Getein 1200/Getein 1600:

(1) Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.
(2) Place the sample diluent at the correct position in Getein 1200/Getein 1600.
(3) 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:

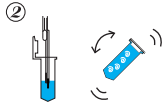
1. It is required to perform "SD card" calibration when using a new batch of kits for Getein 1100/Getein 1160/Getein 1180.
2. The directions for using disposable pipet are as follows:

Directions to use disposable pipet

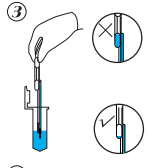


Insert the disposable pipet into the sample tube, gently touch the liquid surface with the capillary tip, and draw the sample.

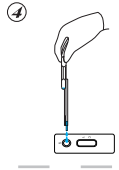
Note: Do not immerse the exhaust pipe below the liquid level.



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.

RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1600/Getein 1200 can scan the test card automatically and display the result on the screen. For additional information, please refer to the instructions for use of Getein 1100/Getein 1160/Getein 1180/ Getein 1600/ Getein 1200.
Others: Measuring range of the SAA is 5.0 mg/L~200.0 mg/L and CRP is 0.5 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 4 times.

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. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Triglyceride	25 g/L
Bilirubin	0.1 g/L

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 10.0 mg/L calculated by using normal distribution methods (95% confidence interval).
The expected normal value for CRP and was determined by testing samples from 399 apparently healthy individuals. The reference range of CRP is 10.0 mg/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
SAA: 5.0~200.0 mg/L CRP: 0.5~200.0 mg/L
Limit of Detection
SAA: ≤5.0 mg/L CRP: ≤0.5 mg/L
Within-Run Precision ≤10%
Between-Lot Precision ≤15%

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/CRP 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 15223-1:2021.

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*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
Σ	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/ European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		Caution

Thank you for purchasing SAA/CRP Fast Test Kit (Immunofluorescence Assay).
Please read this instructions for use carefully before operating to ensure proper use.

Version: WIF51-S-06

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Catalogue number	Applicable analyzer	Package specification
IF1090-10T	Getein 1100	10 T/kit
IF1090	Getein 1100	25 T/kit
IF5090-10T	Getein 1160	10 T/kit
IF5090	Getein 1160	25 T/kit
IF3090-10T	Getein 1180	10 T/kit
IF3090	Getein 1180	25 T/kit
IF4090	Getein 1200	2*24 T/kit
IF4090-96T	Getein 1200	2*48 T/kit
IF2090	Getein 1600	2*24 T/kit
IF2090-96T	Getein 1600	2*48 T/kit