图纸名称	外贸荧光SAA/CRP说明书	图纸编号	WIF51-S-04	尺　寸	210*140MM	设　计	梁安琪

基蛋生物 GeteinBiotech

适用范围：外贸荧光SAA/CRP

变更内容：1. 升级
2. 增加1160和1200机型

技术要求：
1. 图案样式大小参照图纸，以样品为准
2. 材质：60g双胶纸，纸质厚度均一
3. 图案清晰、完整、色彩均一，无明显色差、外观整洁
4. 文字内容正确，无重影、模糊不清，排版正确，字体不易刮花

颜色色值：C M Y K100

140mm

SAA/CRP
Fast Test Kit
(Immunofluorescence Assay)

User Manual

REF IF1090 for Getein1100
IF5090 for Getein1160
IF2090 for Getein1600
IF4090 for Getein1200

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.

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

The test uses mixed anti-human SAA monoclonal antibody Ⅰand CRP monoclonal antibody Ⅰconjugated with fluorescence latex coated on the nitrocellulose membrane and another set of anti-human SAA monoclonal antibody Ⅱ and CRP monoclonal antibody Ⅱ coated on different test lines, respectively. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human SAA and CRP monoclonal antibodies will bind with the SAA and CRP in sample respectively and form marked antigen-antibody complexes. These complexes move to the test detection zone by capillary action. Then marked antigen-antibody complexes will be captured on different test lines by SAA monoclonal antibody Ⅱ and CRP monoclonal antibody Ⅱ, respectively. The fluorescence intensity of test line increases in proportion to the amount of SAA and CRP in sample.

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

CONTENTS

1. A kit for Getein1100/Getein1160 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein SAA/CRP test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
3) User manual: 1 piece/box
4) SD card: 1 piece/box
2. A kit for Getein1600/Getein1200 contains:
Package specifications: 2×24 tests/box, 2×48 tests/box
Sealed cartridge with 24/48 Getein SAA/CRP test cards
User manual: 1 piece/box
Materials required for Getein1600/Getein1200:
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, protein stabilizer, surfactant.
4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (the conjunction of sample pad and nitrocellulose membrane is coated with fluorescence latex-labelled anti-human SAA monoclonal antibody Ⅰand CRP monoclonal antibody Ⅰ), nitrocellulose membrane (test lines are coated with another anti-human SAA monoclonal antibody Ⅱ and CRP monoclonal antibody Ⅱ, respectively. 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 DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months.
Use the test card for Getein1100/Getein1160 within 1 hour once the foil pouch is opened.
For test card of Getein1600/Getein1200: 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°C with a valid period of 24 months.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch is damaged.
5. Do not open pouches until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. 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 peripheral blood samples***.
2. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma.
3. Suggest using serum and plasma samples for better results.
4. The test should be performed within 4 hours after blood collection. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing (whole blood sample and peripheral blood may be stored up to 3 days at 2-8°C).
5. Refrigerated or frozen sample (only serum or plasma) should be reached to room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples or hemolysis samples.
7. SAMPLE VOLUME (for Getein1100/Getein1160): ***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/Getein1160:

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/Getein1160.
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. For disposable capillary pipette using, please refer to the direction in the package.
8. Reaction time: ***5 minutes***. Insert the test card into Getein1100/Getein1160 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600/Getein1200:

9. Each cartridge for Getein1600/Getein1200 contains a specific RFID card which can calibrate automatically.
10. Place the sample diluent at the correct position in Getein1600/Getein1200.
11. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600/Getein1200 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 kit for Getein1100/Getein1160.
2. It is suggested to calibrate once for one batch of kits for Getein 1100/Getein1160.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1600/Getein1200 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/Getein1600/Getein1200.
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.

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

1.Measuring Range
SAA: 5.0~200.0 mg/L　　CRP: 0.5~200.0 mg/L
2.Lower Detection Limit
SAA: ≤5.0 mg/L　　CRP: ≤0.5 mg/L
3.Within-run Precision　　≤10%
4.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	Triglyceride	Bilirubin
Concentration (Max)	25 g/L	0.1 g/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/CRP 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 15223-1:2016.

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
Σ	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/CRP Fast Test Kit (Immunofluorescence Assay).
Please read this user manual carefully before operating to ensure proper use.

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