



hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay)

Instructions for Use

INTENDED USE

hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of C-reactive protein (CRP) in human serum, plasma, whole blood or fingertip blood samples. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury and inflammatory disorders. Measurement of high sensitivity CRP (hs-CRP), when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes (ACS), may be useful as an independent marker of prognosis for recurrent events in patients with stable coronary disease or ACS. For professional and laboratory use only.

SUMMARY

C-reactive protein is an acute-phase reactant that precipitated with Pneumococcal C-polysaccharide, and is a non-specific immune response component. CRP has wide distribution in our body, and is an acute phase protein produced in the liver in response to microbial infection or tissue injury, it measures general levels of inflammation in the body, and the hs-CRP can be used to detect lower concentrations of CRP in serum or plasma. Studies revealed hs-CRP levels seem to be correlated with Atherosclerosis and Acute Myocardial Infarction. And the hs-CRP is an inflammation "marker" for ACS patient and is helpful for primary prevention and risk assessment of cardiovascular disease. Its combination with the ratio of total cholesterol to HDL-C is more accurate than other risk factors in predicting cardiovascular disease. The American Heart Association and US Centers for Disease Control and Prevention have advocated hs-CRP as a predictor of cardiovascular disease (CVD) to define risk groups: less than 1.0 mg/L indicates low risk, 1.0 to 3.0 mg/L means moderate risk, and the amount above 3.0 mg/L (lower than 10 mg/L) strongly suggests a high risk of CVD. Moreover, higher CRP levels are found in late pregnant women, mild inflammation and viral infections (10–40 mg/L), active inflammation, bacterial infection (40–200 mg/L), severe bacterial infections and burns

(>200 mg/L).

PRINCIPLE

hs-CRP+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 CRP antibody specifically binds to target 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 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 CRP concentration in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the CRP 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
hs-CRP+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

* hs-CRP+CRP test card

A test card consists of: Fluorescently labeled CRP antibody, CRP 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

temperature (15–30°C), 7 days at 2–8°C, and 6 months at -20°C.

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

APPLICABLE DEVICE

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

Realtime 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 the 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 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 **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: **3 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 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 (**3 minutes**) and automatically test

the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 208:

- (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 draw 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.

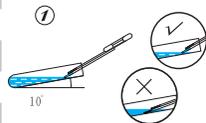
2. Place the sample diluent at the correct position in Getein 1200/Getein 1600.

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:

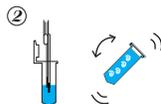
1. It is required to perform "SD card" calibration when using a new batch of kits for Getein 1100/Getein 1160/Getein 1180.
2. The directions for using disposable pipet are as follows:

Directions to use disposable pipet

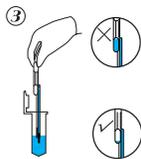


Insert the disposable pipet into the sample tube, gently touch the liquid surface with the capillary tip, and draw the sample.

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 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 hs-CRP+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. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	10 g/L	10 g/L	0.2 g/L

EXPECTED VALUE

hs-CRP: The expected normal value for hs-CRP was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for hs-CRP is 3.0 mg/L. (The probability that hs-CRP value of a normal person below 3.0 mg/L is 95%.)

CRP: The expected normal value for CRP was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for CRP is 10.0 mg/L. (The probability that CRP 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	0.5~200.0 mg/L
Limit of Detection	≤0.5 mg/L
Within-Run Precision	≤10%
Between-Lot Precision	≤15%

REFERENCES

1. Danesh J, Whincup P, Wskler M, et al. Low grade inflammation and coronary heart disease: prospective study and updated meta-analysis. *BJM* 2000; 321:199~204.
2. Rifai N, Ridker PM. Proposed cardiovascular risk assessment algorithm using high-sensitivity C-reactive protein and lipid screening. *Clin Chem* 2001; 47:28~30.
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on hs-CRP+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 15223-1:2021.

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

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

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Catalogue number	Applicable analyzer	Package specification
IF1003-10T	Getein 1100	10 T/kit
IF1003	Getein 1100	25 T/kit
IF5003-10T	Getein 1160	10 T/kit
IF5003	Getein 1160	25 T/kit
IF3003-10T	Getein 1180	10 T/kit
IF3003	Getein 1180	25 T/kit
IF4003	Getein 1200	2*24 T/kit
IF4003-96T	Getein 1200	2*48 T/kit
IF2003	Getein 1600	2*24 T/kit
IF2003-96T	Getein 1600	2*48 T/kit
IF6003-10T	Getein 208	10 T/kit
IF6003	Getein 208	25 T/kit