and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME: ***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.
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “QC (SD)” calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, press "ENT" button to enter testing interface.
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 ***120 µl*** of sample mixture (or 4 drops of sample mixture when using disposable pipet) into the sample port on the test card.
8. ***Reaction time: 90 seconds.*** Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:
1. It is required to perform “QC (SD)” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Valid: When a purplish-red band appears at the control area (C), use FIA8000 to analyze the test card and get the result.
Invalid: If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

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 mg/L. (The probability that hs-CRP value of a normal person below 3 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 mg/L. (The probability that CRP value of a normal person below 10 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 mg/L
Lower Detection Limit	≤0.5 mg/L
Within-Run Precision (n=10)	≤10%
Between-Run Precision	≤15%
Recovery:	
CRP	101% (mean)
hs-CRP	103% (mean)

Method Comparison:
The assay was compared with HITACHI 7600/OLYMPUS AU5400 and its matching hs-CRP test kits with 200 serum samples (61 positive samples and 139 negative samples). The correlation coefficient (r) for hs-CRP+CRP is 0.941.

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the results 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 interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

REFERENCES

1. Danesh J, Whincup P, Wslker 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 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for hs-CRP+CRP (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

Thank you for purchasing One Step Test for hs-CRP+CRP (Colloidal Gold). Please read this user manual carefully before operating to ensure proper use.

Version: WCG07-DL-S-01

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CE IVD

One Step Test for hs-CRP+CRP

(Colloidal Gold)

User Manual Cat.# CG1003

INTENDED USE

One Step Test for hs-CRP+CRP (Colloidal Gold) is intended for in vitro quantitative determination of C-reactive protein (CRP) in serum, plasma, whole blood or fingertip blood. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury and inflammatory disorders. Measurement of high sensitivity CRP (hs-CPR), 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.

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 microbic 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 factor 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

The test uses an anti-human CRP monoclonal antibody conjugated with colloidal gold and another anti-human CRP monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the gold-labelled anti-human CRP monoclonal antibody binds with the CRP in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human CRP monoclonal antibody resulting in a purplish red streak appears on the test line. The color intensity of the test line increases in proportion to the amount of CRP in sample.

Then insert test card into FIA8000 Quantitative Immunoassay Analyzer (hereinafter referred to as FIA8000), the concentration of CRP in sample will be measured and displayed on the screen. The value will be stored in FIA8000 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

A kit contains:

1. Getein hs-CRP+CRP test card in a sealed pouch with desiccant 25
2. Disposable pipet 25
3. User manual 1
4. SD card 1
5. Sample diluent 25

A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, a colloidal gold pad (coated with a gold-labelled anti-human CRP monoclonal antibody), nitrocellulose membrane (the test line is coated with another anti-human CRP monoclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Sample diluent composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

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

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

Store the sample diluent at 2~8℃ for better results.

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 fingertip blood samples. Heparin, sodium citrate and EDTA*** can be used as the anticoagulant for plasma, whole blood and fingertip blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. If testing will be 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 should reach room temperature