Intended Use:
One Step Test for hs-CRP (Colloidal Gold) applies colloidal gold immunochromatography to detect high-sensitivity C-reactive protein (hs-CRP) in serum, plasma and whole blood samples semi-quantitatively or quantitatively. This test supports the detection of mild or early forms of cardiovascular disease.

Principle of the Procedure:
Two kinds of high specific and sensitive anti-human hs-CRP monoclonal antibodies are used for the test strips. One is gold-labelled and coated on the polyester film, and the other is fixed on the test line of the product. The antibodies form sandwich complexes with any hs-CRP in the blood sample. The sample passes through the detection zone, in which the hs-CRP sandwich complexes gather along a line, appearing as a purplish red streak (the test or signal line). Excess gold-labelled antibodies gather along the control line, signaling visually that the test is valid. The intensity of the test line increases in proportion to the hs-CRP concentration.

Reagents and Materials provided:
The Test Strips contain: Sample pad, colloidal gold pad (sprayed by colloidal gold-labelled hs-CRP monoclonal antibody), chromatography membrane (T-line coated with hs-CRP monoclonal antibody, C-line coated with IgG), absorbent paper and lining.

Kit contains:
1. Foil Bag contains one test card, one pipette and one desiccant 10 or 25
2. Manual 1
3. Standard colorimetric card 1
4. Sample dilution buffer 10 or 25

Matching Equipment:
FIA8000 Series Quantitative Immunoassay Analyzer

Storage Requirements:
1. Store the strip at 4~30°C within 12 months.
2. Use the test card within 1 hour once the foil bag is opened.

Sample Material and Volume:
Serum/plasma/whole blood 10 μl

Specimen Collection and Preparation:
1. A serum, plasma or whole blood specimen is required for testing by this product.
2. The plasma specimen is suggested to use heparin as anticoagulant.
3. Transport specimens at room temperature or chilledly and avoid extreme temperatures.
4. It is recommended to avoid using severely hemolyzed specimens whenever possible. If a specimen appears to be severely hemolyzed, another specimen should be obtained and tested.
5. The serum or plasma specimen (2~8°C) should be tested within 7 days. If the testing can’t be completed within 7 days, the serum or plasma specimen should be stored at -20°C (half a year at most) until testing. The whole blood specimen (2~8°C) is suggested to be tested within 3 days.
6. The blood specimens must be restored to room temperature before testing.
Test Procedure:
1. Restore the test card and the blood specimen to room temperature (20~25°C better).
2. Open the pouch and label the strip with the patient specimen number.
3. Drop 10 μl whole blood (serum or plasma) to the sample dilution buffer in the tube, and mix gently and thoroughly.
4. Drop 120 μl mixed solution to the sample port of the test card.
5. Referring to the standard colorimetric card, get the semi-quantitative result by eye after 5~10 mins, or read the quantitative result with the matching equipment.

Results:
Positive (+): There are two purplish red streaks. One is located on the test line 2 (T2), the other is located on the control line (C). There are three purplish red streaks. One is located in the QC area (C), the other two are in the test zone (T) (purplish red streaks appear on the test line 1 and 2 at the same time). If the color intensity of the test line 1 (T1) is poorer than “++”, refer to the result of test line 2 (T2).

Negative (-): Only one purplish red streak appears, just located on the control line (C). Negative results mean there is no hs-CRP in the samples, or the concentration of hs-CRP is below the detectable range.

Invalid: There is no purplish red streak on the control line (C). This means that some performances must be wrong or the test strip has already been invalid. At this time, please read the manual carefully again, and try a new one. If as before, stop using the kits and contact with the manufacturer.

Measurable Ranges:
hs-CRP 0.5-100 mg/L

Limitations of the Procedure:
1. The results of the strip should not be used as absolute evidence of diagnosis and should be evaluated according to all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.
2. Factors such as high temperature or high humidity, as well as additional substances in blood specimens may interfere with the test and cause erroneous results.

Warnings and Precautions:
1. Use for in vitro diagnostics.
2. Use by healthcare professionals.
3. The best testing temperature is 15~30°C, and the best humidity is 40~60%.
4. Do not use the strip beyond the expiration date printed on the outside of the box.
5. The strip must be used within 1 hour once its foil pouch has been opened.
6. The transfer pipette should be used for one specimen only. Discard it after used.
7. Patient specimens, used strip and transfer pipettes may be potentially infectious. Proper handling and disposal methods should be established by the laboratory direction in accordance with local regulations.
8. Proper laboratory safety techniques should be followed at all times when working with potentially infectious blood specimens.