# HHSS --CrP--Test (cassette test)

## INTENDED USE

The MHS C-reactive protein immunological test System is a device that consists of reagents used to measure C-reactive protein in whole blood, serum or plasma by immunochemical techniques. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues or in identification of bacterial infections. It is especially useful for cardiac risk assessment. For Professional use only. The Semi Quantitative CRP test is a highly sensitive test used to detect CRP in whole blood, serum or plasma. The sensitivity of the test is 1 g/ml CRP.

## MATERIALS PROVIDED

The CRP test kit contains the following items to perform the test:

- CRP test cassette with pipette in foil pouch (20 per kit box)
- Instructions (1 per kit box)
- Buffer (2 bottles per kit box)

## MATERIALS REQUIRED, BUT NOT PROVIDED

- Stop watch
- Utensils for sample collection

## PRECAUTIONS

The CRP test kit should be stored at room temperature or 4-30 C. If test kit is refrigerated, it should be brought to room temperature before use. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

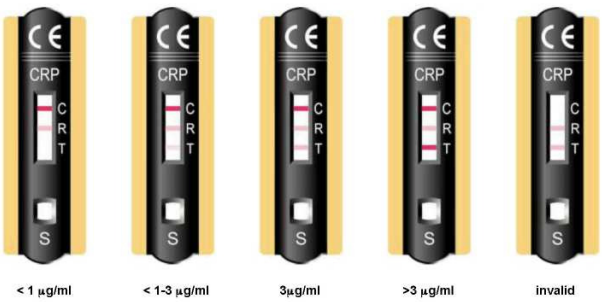
## PROCEDURE OF THE TEST

1. Remove the test cassette from the foil pouch, and place it on a flat, dry and clean surface. Hold the sample dropper above the test cassette and add 40 l (2 drops) of whole blood or 15 l serum/plasma (1 drop) into the sample well (S).
2. Open the buffer bottle and hold it upside down. Make sure holding the bottle vertically (Note: drops may contains air-bubbles if not holding the buffer bottle vertically), slowly add 3 to 4 hanging drops of buffer into the sample well. Note: add the next drop after the previous drop is absorbed into the sample well.
3. As the test begins to work, you will see a purple coloured front moving across the result window in the centre of the test cassette.
4. Interpret test results at 5 minutes. Do not interpret test results after more than 7 minutes.

**CAUTION:** The above Interpretation time is based on reading the test results at room temperature of 15 to 30 C. If your room temperature is significantly lower than 15 C, then the Interpretation time should be properly increased.

## INTERPRETATION OF THE TEST

- A coloured line will appear at the section of the result window distant from the sample well to show that the test is working properly. This line is the control line ("C" line).
- The middle section of the result window indicates the reference line ("R" line).
- The section of the result window dose to the sample well indicates the test line ("T" line).




**CRP concentration of less than 1 µg/ml:** there is no visible test line (T). According to the American Heart Association, this means low risk of cardiac problems.

**CRP concentration of 1 µg/ml or less than 3 µg/ml:** The intensity of the test line (T) is weaker than reference line (R) indicating that CRP level is 1 g/ml to less than 3 g/ml. According to the American Heart Association, this means average risk of cardiac problems.

**CRP concentration of 3 µg/ml:** The intensity of the test line (T) is similar to the reference line (R) indicating that CRP level is 3 g/ml. According to the American Heart Association, this means average risk of cardiac problems.

**CRP concentration higher than 3 µg/ml:** The intensity of the test line (T) is darker than the reference line (R) indicating that CRP level is higher than 3 g/ml. According to the American Heart Association, this means high risk of cardiac problems.

**Note:** Generally, the higher the CRP level in the specimen, the stronger the "T" line colour will be. Very high CRP level specimens (more than 500 g/ml) can cause reduced "T" line colour intensity (Hook Effect).

**Invalid:** If after performing the test, no colour line for the reference line or the control line is visible within the Result window, the result is considered invalid. Some causes of invalid results are not following the directions correctly, such as insufficient amount of sample or buffer added or the test may have deteriorated beyond the expiration date.

**Note:** A positive result will not change once it has been established at 7 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after more than 7 minutes. Interpreting test results after 7 minutes, the sensitivity of the test will be higher than 1 g/ml . Some specimens with a high rheumatoid factor concentration may yield a non-specific positive result.

## LIMITATIONS OF THE TEST

Although the CRP Test is very accurate in detecting CRP, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained.

As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a Single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

## WARNINGS

- The same lancet needle should be used for one person only and should not be shared with another person, because the used needle is a biohazard.
- Decontaminate and dispose of all specimens, reaction kits, lancet needles and potentially contaminated materials, as if they were infectious wastes, in a biohazard Container.
- Do not use the kit after the expiration date.
- Do not use if pouch is torn or damaged.
- For in vitro diagnostic use only

## SYMBOLS

| | | | |
|---|---|---|---|
| IVD | For in-vitro diagnostic use only | 2 | For single use only |
| Cont. | Content | | Expiry date |
| LOT | Lot number | | Store at room temperature |

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