



GIMA S.p.A.
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Code 24527 Semi Quantitative hsCRP Test Disk
For Serum, Plasma or Whole Blood Specimen

Explanation of the Test

A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in whole blood. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues. For professional use only.

The Semi Quantitative CRP test is a highly sensitive test used to detect CRP in whole blood. The sensitivity of the test is 1 mg/L CRP.

Materials Provided

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

1. CRP test device.
2. Buffer.
3. Instructions.
4. Disposable sample dropper.

Precautions

The CRP test kit should be stored at room temperature or 4-30°C (40- 86°F). 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 disk from the foil pouch, and place it on a flat, dry surface.
2. Collect fingertip blood if necessary (or venous blood/serum/plasma) as shown in Figure 1.
3. Holding the sample dropper above the test disk and add 2 hanging drops of whole blood or 1 hanging drop of serum/plasma into the Sample Well. (Figure 2).
4. Open the buffer bottle and hold it upside down. Make sure holding the bottle vertically (note: drops may contain 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. (Figure 3)
5. As the test begins to work, you will see purple color dyes move across the Result Window in the center of the test disk.
6. Interpret test results at 5 minutes. Do not interpret test results after 7 minutes.

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

Interpretation of the Test (Figure 4):

1. A color band will appear at the left section of the Result Window to show that the test is working properly. This band is the Control Band (“C” band).
2. The middle section of the Result Window indicates the Reference Band (“R” band).
3. The right section of the Result Window indicates the Test Band (“T” band).

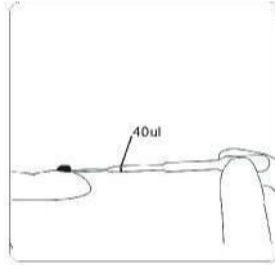


Figure 1

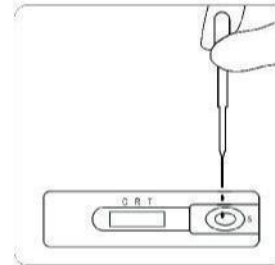


Figure 2

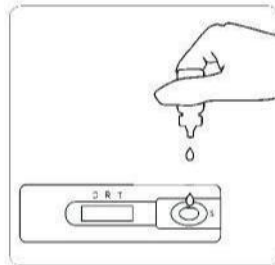


Figure 3

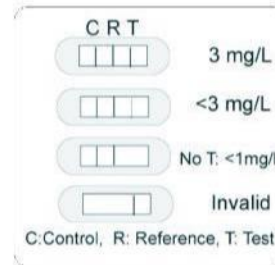


Figure 4

CRP concentration of less than 1 mg/L: there is no visible test line (T).

CRP concentration of 1 mg/L or less than 3 mg/L: the intensity of the test line (T) is weaker than reference line (R) indicating that CRP level is 1 mg/L to less than 3 mg/L.

CRP concentration of 3 mg/L: the intensity of the test line (T) is similar to the reference line (R) indicating that CRP level is 3 mg/L

CRP concentration higher than 3 mg/L: the intensity of the test line (T) is darker than the reference line (R) indicating that CRP level is higher than 3 mg/L.

Note: Generally, the higher the CRP level in the specimen, the stronger the “T” band color will be. Very higher CRP level specimens can cause reduced “T” line color intensity (Hook Effect).

Invalid: if after performing the test, no color band for the reference band or the control band 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 7 minutes. Interpreting test results after 7 minutes, the sensitivity of the test will be higher than 1 mg/L. Some specimens with a high rheumatoid factor concentration may yield a nonspecific 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

1. 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.
2. Decontaminate and dispose of all specimens, reaction kits, lancet needles and potentially contaminated materials, as if they were infectious wastes, in a biohazard container.
3. Do not use the kit after the expiration date.
4. For professional in vitro diagnostic use only.

REF 24527 / SQ182-116















 Ameritech Diagnostic Reagent Co., Ltd
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Tongxiang, ZJ, China
MADE IN CHINA

EC REP CEpartner4U BV,
ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS



IVD FOR PROFESSIONAL USE

Index of Symbols

	Read instructions carefully
	For in vitro diagnostic use only
	Store between 4° and 30°C
	Contains sufficient for “n” tests
	Expiration date (see box / package)
	Lot number (see box / package)
	Authorized representative in the European community
	Disposable device, do not re-use
	Product code
	Keep away from sunlight
	Keep in a cool, dry place
	Read instructions carefully
	Product complies with European Directive no. 98/79/EC on In Vitro diagnostic devices
	Manufacturer