SureScreen Diagnostics

CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

A rapid test for the semi-quantitative detection of C-reactive protein in whole blood, serum or plasma.

For professional in vitro diagnostic use only.

【INTENDED USE】

The CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the semi-quantitative detection of C-reactive protein in whole blood, serum or plasma.

【SUMMARY】

C - reactive protein (CRP) in patient's sera has been found in association with acute infections, necrotic conditions and a variety of inflammatory disorders. There is a strong correlation between serum levels of CRP and the onset of the inflammatory process. Monitoring the levels of CRP in patient's sera indicates the effectiveness of treatment and the assessment of patient recovery. It is used in particular to differentiate bacterial infections from virus infections.

【PRINCIPLE】

The CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is a semi-quantitative, membrane based immunoassay for the detection of C-reactive protein in whole blood, serum or plasma. During testing, the specimen is dropped into the specimen well and reacts with the particle conjugated with CRP antibody, and the mixture migrates upward on the membrane chromatographically by capillary action to react with anti-CRP antibody pre-located on the membrane and generate a purple line. The number of lines depends on the CRP concentration in the sample. The more CRP is contained in the sample, the more color lines become visible. The control line serves as a procedural control and indicates that sufficient volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test cassette contains CRP antibody conjugated colloid gold and CRP antibody coated on the membrane and buffer with 0.03%Proclin 300.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Don't use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Don't use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Collect the Fingerstick Whole Blood specimen using a capillary tube.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below 20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

【MATERIALS】

Materials provided

Test cassettes Droppers Buffer Package insert

Materials required but not provided

Specimen collection containers Centrifuge (for plasma only)
Timer Lancets (for fingerstick whole blood only)
Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

【DIRECTIONS FOR USE】

Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

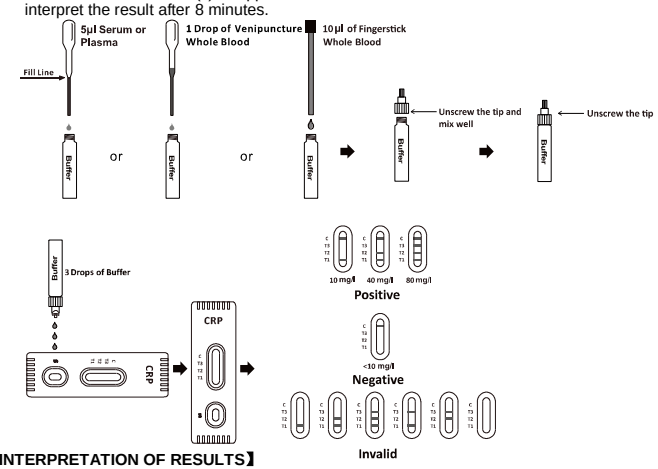
1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the cassette on a clean and level surface.

For Serum or Plasma or venipuncture Whole Blood specimen:

- Use a disposable pipette to transfer 5 μL of the serum or plasma specimens or 1 drop of whole blood (approximately 10μl) and add to the dilution tube with buffer.
- Bottom up and down the tube for several time to mix the specimens well.
- Add 3 drops of diluted specimen above to the specimen well and start the timer.
- Wait for the colored line(s) to appear. The test result should be read at 5 minutes. Do not interpret the result after 8 minutes.

For Fingerstick Whole Blood specimen:

- Fill the capillary tube and transfer approximately 10μL of fingerstick whole blood specimen to the dilution tube with buffer.
- Bottom up and down the tube for several time to mix the specimens well.
- Add 3 drops of diluted specimen above to the specimen well and start the timer.
- Wait for the colored line(s) to appear. The test result should be read at 5 minutes. Do not interpret the result after 8 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

Positive(+)：One color line appears in the control region (C). One color line appears in the test region (T) least.

Test line(T)	Semi quantitative result
Only T1 appears	CRP level is 10mg/L at least
Only T1 and T2 appear	CRP level is 40mg/L at least
T1,T2 and T3 appear	CRP level is above 80 mg/L

Negative(-)：One color line appears in the control region (C). No apparent purple line appears in the test region (T).Negative result showed: There was not CRP in the sample, or the content of CRP below the detectable range.

Test line (T)	Semi quantitative result
No line	CRP level is lower than 10mg/L

INVALID: C line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A color line appearing in the control region (C) is internal positive procedural control. It confirms adequate membrane wicking .

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of C-reactive protein in whole blood, serum or plasma specimen.
2. The CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the semi-quantitative level of CRP in the specimen and should not be used as the sole criteria for evaluating inflammatory disorders risks.
3. This test is only used for detecting whole blood / serum / plasma samples of C reaction protein, not as the unique standard for diagnosis. Even if the result is positive, the comprehensive analysis of the clinical symptoms and other detection methods should be considered either.
4. The presence of some rheumatoid factors clinical positive sample will probably interfere the test result.
5. There is a slight possibility that some whole blood specimens with a very high viscosity or stored more than 2 days may not run properly on the test device. Repeat the rest with a serum or plasma specimen from the same patient using a new test device.
6. The elevated results of CRP in oral contraceptive (OC) users should be reported with caution as The American Physiological Society has recommended further studies on impact of OC use on CRP and inflammatory parameters.
7. High concentrations of CRP may produce a dose hook effect, resulting in false negative results. High dose hook effect has not been observed with this test up to 2000mg/L of CRP.

【EXPECTED VALUES】

CRP is a non-specific marker for acute infections, necrotic conditions and a variety of inflammatory disorders. For ruling out bacterial infections risks, its expected value is less than 10 mg/L as per AHA.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and specificity

The CRP Semi-Quantitative Rapid Test Cassette (Whole blood/Serum/Plasma) has been tested in comparison with a leading commercial CRP EIA test using clinical specimens.

Method		EIA				Total
		Negative	Positive			
CRP Semi-Quantitative Rapid Test Cassette	Result	0-10 mg/l	10-40 mg/l	40-80 mg/l	≥80 mg/l	
	0-10mg/l	99	1	0	0	100
	10-40mg/l	3	52	1	0	56
	40-80mg/l	0	3	25	5	33
	≥80mg/l	0	0	3	79	82
Total		102	56	29	84	271
% Relative Accuracy		97.1%	92.9%	86.2%	94.0%	98.5%
			99.4%			

Relative sensitivity: 168/169=99.4% (CI*: 96.7%~100%)
Relative specificity: 99/ (99+3) =97.1 % (CI*: 93.9%~98.1%)
Relative Accuracy: (99+168)/ (99+3+169) =98.5 % (CI*: 91.6%~99.4%)
*95% Confidence Interval

Precision

Intra-Assay

Assays were carried out to determine assay reproducibility using replicates of 10 tests in three different runs for each of three lots using CRP specimen levels at 0 mg/l, 10 mg/l, 40 mg/l, 80 mg/l and 200 mg/l. The specimens were correctly identified >99.9% of the time.

Inter-Assay

Between-run precision has been determined by using the five CRP specimen levels at 0mg/l, 10mg/l, 40mg/l, 80mg/l and 200mg/l of CRP in 3 independent assays. Three different lots of the CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99.9%of the time.

Interfering Substances

The following substances do not interfere with the test results at the indicated concentrations: Human Albumin at 20mg/ml, Bilirubin at 10mg/ml, Hemachrome at 10mg/ml, acetoaminophen at 20mg/dl and Creatine at 200mg/dl.

【BIBLIOGRAPHY】

1. Morley JJ, Kushner (1982) Serum C-reactive protein levels in disease. In: Kushner I, Volanakis JE, Gewurz H,eds. C-reactive protein and the plasma protein response to tissue injury. Ann. NY Acad. Sci. 389: 406-417.
2. Peltola HO (1982) C-reactive protein for rapid monitoring of infections of the central nervous system. Lancet: 980-983.
3. Macy EM, Hayes TE and Tracy RP (1997) Variability in the measurement of C-reactive protein in healthy subjects: implications for reference intervals and epidemiological applications. Clin. Chem. 43, 52-58.

Index of Symbols

	Consult instructions for use	Σ	Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #

Manufacturer
SureScreen Diagnostics Ltd
1 Prime Parkway
Prime Enterprise Park
Derby. DE1 3QB
United Kingdom

CE

Number: RP5225001
Effective date:2017-06-26