Sensit CRP Rapid Test Kit

Cat No.: S048-02

In-vitro Diagnostics

INTENDED USE

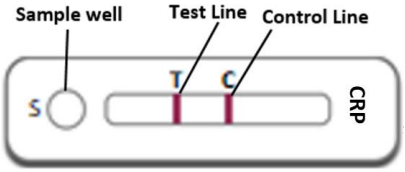
Sensit CRP Rapid Test is a lateral flow immunoassay for the detection of C-Reactive protein in whole blood. This test is intended to be used as a screening test and as an aid in the diagnosis of inflammation in the body. Sensit CRP Rapid Test is intended for initial screening only and all reactive samples should be confirmed by supplemental assay.

SUMMARY & TEST DESCRIPTION

CRP is an acute phase protein that develops in a wide range of acute and chronic inflammatory conditions like bacterial, viral, or fungal infections; rheumatic and other inflammatory diseases; malignancy; and tissue injury or necrosis. The term "acute phase" refers to local and systemic events that accompany inflammation. Local responses include vasodilation, platelet aggregation, neutrophil chemotaxis, and the release of lysosomal enzymes. Systemic responses include fever, leukocytosis, and a change in the hepatic synthesis of acute phase proteins (a) hepatic protein, which by definition, increases or decreases in serum concentration by at least 25%). Stimuli to the acute phase include many different forms of tissue injury, such as infection, immuno/allergic reaction, thermal injury, hypoxic injury, trauma, surgery, and malignancy. The clinical use of acute phase protein is an aid to diagnosis. Because the acute phase response is relatively non-specific, the value of measuring acute phase protein concentrations is to assess the extent of inflammation reflecting momentary disease activity. Similar to tumor markers, acute phase proteins may monitor the course of disease in response to therapeutic intervention. In healthy people, CRP levels are very low (80 mg/L). Levels return to normal once the inflammation has resolved. Sensit CRP Rapid Test Kit qualitatively detects the presence of C-reactive Protein.

TEST DESCRIPTION & PRINCIPLE

Sensit CRP Rapid Test works on chromatographic immunoassay. Basic components of the test strip include a) a Conjugate pad, which contains a detection molecule, colloidal gold conjugated; b) a nitrocellulose membrane strip containing two lines T: anti-CRP Ab and C: Goat Anti-Mouse antibody.



Test sample that is added to the sample well, with an adequate amount of buffer migrates from the sample pad along the conjugate pad where CRP present in the sample will bind to the colloidal gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zone where the complex will bind to the immobilized anti CRP Ab (on test line) producing a visible line on the membrane. If the CRP is not present in the sample, no reaction occurs in the capture zone and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

MATERIALS PROVIDED

1. Each test pouch contains:
   a. One test card and dropper
   b. Desiccant
2. Assay Diluent in dropper bottle
3. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTION & WARNING

1) Use within 10 minutes after opening pouch.
2) Do not touch result window.
3) Do not reuse test kit.
4) Do not use test kit beyond expiry date.
5) Use only for in-vitro diagnostic purpose.

SAMPLE COLLECTION AND PREPARATION

Whole Blood:

- Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.

Note:

- *If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.*
- *For storage period longer than 5 days, freezing is recommended. Store at -20^{0}C*
- *The specimen should be brought to room temperature prior to use.*

Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 10 µl of the specimen to the Sample well "S". (To take 10 µl, aspirate only up to the bubble point in the dropper provided Refer Diagram .1.)

Diagram 1. 10µl sample

Aspirate to the bubble to obtain a 10µl sample

3. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample well.
4. Wait for 10 minutes and interpret the result. The result is considered invalid after 15 minutes.

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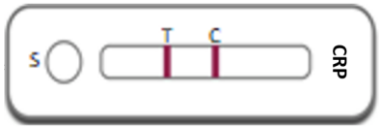
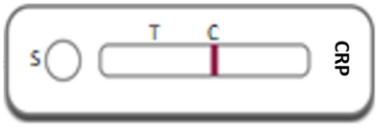
INTERPRETATION OF TEST RESULT

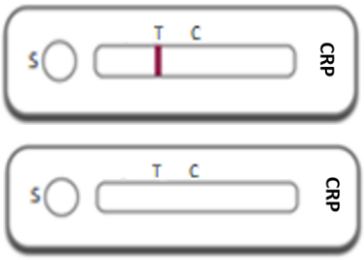
Positive: A clear pink control band ("C") and a detectable test band ("T") appear, indicating the presence of CRP in the sample.



Negative: A pink colored band appears only at control region ("C") indicating the absence of CRP in the sample.



Invalid: If the control line fails to appear within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested.



References

1. Cui, N., Zhang, H., Chen, Z., & Yu, Z. (2019). Prognostic significance of PCT and CRP evaluation for adult ICU patients with sepsis and septic shock: retrospective analysis of 59 cases. *The Journal of international medical research*, *47*(4), 1573–1579.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in CRP Rapid Test for single-step detection of CRP are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
X	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use

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ubio Biotechnology Systems Pvt Ltd
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UBD/QA/IFU/S048-02
Rev. No: A1.1/22-11-2021