

INTENDED USE

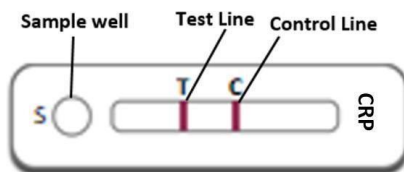
CRP A Rapid Test is a lateral flow immunoassay for the detection of C-Reactive protein in saliva. This test is intended to be used as a screening test and as an aid in the diagnosis of inflammation in the body. Sensit CRP A Rapid Test is intended for initial screening only and all reactive samples should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

SUMMARY & TEST DESCRIPTION

The CRP A Rapid Test using saliva detects C-reactive protein (CRP A), an acute phase protein that increases in response to inflammation caused by conditions such as infections (bacterial, viral, or fungal), inflammatory diseases, tissue injury, malignancy, and other acute or chronic health issues. CRP A is a key marker in the body's systemic and local inflammatory responses, which include fever, changes in liver protein production, and leukocytosis. This test helps assess the extent of inflammation, making it useful for diagnosing and monitoring conditions by reflecting disease activity. In healthy individuals, CRP A levels are typically low, but they rise during inflammation and return to normal once the underlying condition is resolved. The Sensit CRP A Rapid Test Kit provides a quick, qualitative result for CRP A detection through saliva, aiding in the evaluation and monitoring of inflammatory conditions.

TEST PRINCIPLE

Sensit CRP A 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 A 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 A 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 A Ab (on test line) producing a visible line on the membrane. If the CRP A 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
4. Sample collection bottle

STORAGE AND 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.

PRECAUTIONS AND WARNINGS

- 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

Saliva Collection by Spitting: Spit into the collection container provided. (usually a few milliliters).

Saliva Collection by Swab: Place the swab in the mouth, usually under the tongue or inside the cheek. gently rub the swab in the mouth for a specified amount of time, as directed by the test instructions.

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°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

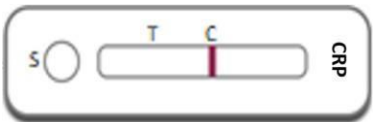
3. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample well.
4. Wait for 10 minutes and interpret the result. The result is considered invalid after 15 minutes.

INTERPRETATION OF TEST RESULT

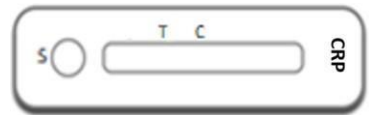
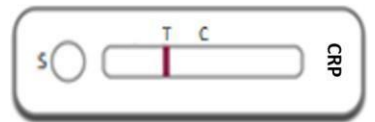
Positive: A clear pink control band (“C”) and a detectable test band (“T”) appear, indicating the presence of CRP A in the sample.



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




DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in CRP A Rapid Test for single-step detection of CRP A 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
	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

Manufactured by,

 ubio Biotechnology Systems Pvt Ltd
 Plot # 15A, Biotechnology Zone
 Kalamassery, Cochin, Kerala, India 683503
 Ph., +91-484-2970043
 e-mail: contact@ubio.co.in
<http://www.ubio.in>

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