CRP ALL IN®
Rapid Test for Semi-Quantitative Detection of CRP in Blood

CE

Ref.: TR-CRP-001
Instructions for use

INDICATION FOR USE

CRP ALL IN® is a rapid test for the semi-quantitative detection of C-reactive protein (CRP) in the blood.
CRP ALL IN® is a rapid test for professional use to assess the cause of an inflammatory condition.

INTRODUCTION

CRP ALL IN® allows you to carry out a rapid examination that can point to the viral or bacterial origin of an infection.
C-reactive protein (CRP) is detectable in the blood in greater or lesser quantities during inflammatory reactions (viral infection, bacterial infection, various inflammatory disorders). CRP is an early biological marker of the inflammatory response, and proportional to its intensity. In particular, it is used to differentiate between bacterial and viral infections and thus help in the decision to start antibiotic treatment.

TEST PRINCIPLE

CRP ALL IN® enables semi-quantitative detection of CRP concentration by visual interpretation of the color intensity of the test strip.
Anti-CRP antibodies are immobilized on the test area of the nitrocellulose membrane. Anti-CRP antibodies conjugated to colloidal gold-labeled particles are used as a lyophilized conjugate.
During the test, the whole blood sample collected by the user is dragged along the buffer and then migrates along the nitrocellulose membrane. If the sample under test contains CRP, it binds with the stained conjugate. The complex thus formed migrates over the membrane to the test line (T) where it will be captured by the anti-CRP antibody attached to the membrane.
A colored test line will appear in the results window (T). The intensity of the T-line depends on the concentration of CRP in the sample. The absence of a test line (T) indicates a normal CRP level (less than 10mg/L). A lower intensity of the test line (T) than that of the reference line (R) indicates that the level of CRP in the sample is between 10 and 40 mg/L. A test line intensity (T) higher than that of the reference line (R) and lower than that of the control line (C) indicates that the CRP level in the sample is between 40 and 100 mg/L. A higher intensity of the test line (T) than that of the control line (C) indicates that the CRP level in the sample is greater than 100 mg/L.
The appearance of a colored band at the control line (C) serves as a procedural check, indicating that the correct volume of sample has been added and that the membrane has been wicked.

EQUIPMENT PROVIDED

- 10 sealed pouches containing an individual CRP test
- 10 single-use lancets
- 10 alcohol swabs
- 1 instruction manual for professional use

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). Do not freeze the kit. The kit is stable until the expiry date indicated on the bag. REMOVE THE KIT FROM THE SEALED POUCH ONLY JUST BEFORE PERFORMING THE TEST.

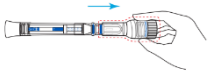
WARNINGS AND PRECAUTIONS

- Do not use the kit after the expiry date, do not use the kit with holes or damage in the bag.
- Erroneous results can be obtained if the kit is improperly stored.
- The kit is for single use only. It should only be taken out of the bag just before the test is carried out (to avoid cross-contamination).
- If the pad comes into contact with skin or eyes, rinse thoroughly with water.
- Keep the bin clean. Do not touch the bin and make sure it does not touch any surface before use.

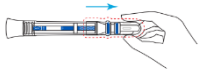
PROCEDURE

Make sure the CRP ALL IN® kit <u>is at room temperature (15-30°C)</u> before testing.
Humidity and temperature can affect results

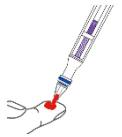
1. Remove the test from its pouch (the test must be taken within an hour).
2. Then place the test on a clean, flat surface.
3. Clean the fingertip (preferably one finger of the non-dominant hand) with an alcohol swab.
4. Remove the cap from the lancet and prick on the side with your fingertip.
5. Squeeze your finger until a large drop of blood appears on your fingertip.
6. Remove the extraction tube from the test.



7. Remove the protective cap.



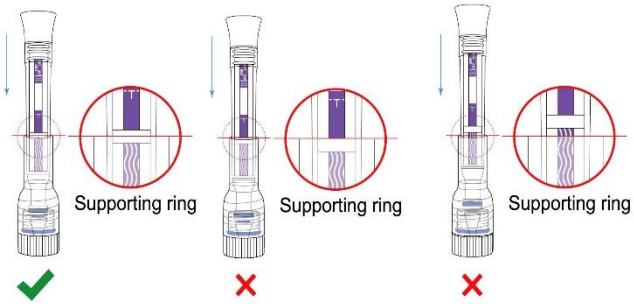
8. Bring the sample collector into direct contact with the drop of blood. The blood is sucked up automatically. Suction stops when the capillary is completely filled.



NOTE: If the capillary is not completely filled, squeeze the finger again to form a new drop of blood and repeat step 8.

9. Insert the point-down test into its holder on a table.
10. Press **hard** on the test to pierce the lid of the diluent pod and insert the test **to the bottom of the holder.**

NOTE: When the test is placed vertically in the extraction tube, the edge of the extraction tube should reach the middle of the support ring. If this is not the case, the test migration will not start and the result will be invalid.



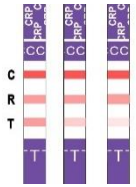
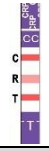
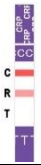
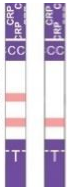
11. Read the results in **5 minutes**. Do not read after 10 minutes.

INTERPRETATION OF RESULTS

The results should be interpreted according to the intensity of the color of the lines.
These lines are of 3 types:

- Control line (C): validates the correct performance of the test procedure and allows the CRP concentration to be estimated
- Reference Line (R): Used to estimate the concentration of CRP
- Test Line (T): Gives the result of the test

The intensity of the color of the test line (T) will thus vary depending on the concentration of CRP present in the sample. Concentration ranges were confirmed by comparison with a quantitative reference test.
However, this is a semi-quantitative test, which cannot determine the exact concentration of CRP in the sample.

Result	Test Line Intensity (T)	Possible Interpretation of CRP Rates
POSITIVE	**Three distinct red lines appear.**	
	The intensity of the test line (T) is lower than or close to that of the reference line (R). Intensity (T) ≤ (R)	CRP concentration ≤ 40 mg/L
	The intensity of the test line (T) is darker than that of the reference line (R) but lower than that of the control line (C). Intensity (R) < (T) < (C)	CRP concentration between 40 mg/L and 100 mg/L
	The intensity of the test line (T) is close to or darker than that of the control line (C). Intensity (T) ≥ (R)	CRP concentration ≥ 100 mg/L
NEGATIVE	**Two red lines appear in areas C and R, and no lines appear in the test area (T).**	
	No test line (T)	Normal CRP concentration (< 10 mg/L)
INVALID		
	The control line (C) and/or reference line (R) do not appear: - The test was not inserted into the bottom of the extraction tube. - An insufficient sample volume or the procedure for carrying out the sample was not carried out correctly. - Read the leaflet again and repeat the test with a new device.	

QUALITY CONTROL

In-house quality control

Internal quality control is included in the test. The appearance of a control red line (C) confirms that a sufficient sample volume has been used and that the test procedure has been correctly followed.

BOUNDS

- The CRP ALL IN® test is intended for professional in vitro diagnostic use, and should only be used for the semi-quantitative detection of C-reactive protein present in whole blood samples collected with a fingertip.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should be made by the physician after evaluation of all clinical and laboratory findings.
- Failure to follow the test procedure may adversely affect the performance of the test and/or invalidate the test result.
- The results obtained with this test, especially in the case of weak and difficult-to-interpret test lines (T), should be used in conjunction with other clinical information available to the physician.

PERFORMANCE

Crochet effect

No hook effects were detected up to a concentration of 1000 mg/L CRP. At this concentration, the test showed results >100 mg/L.

Test Performance

The CRP ALL IN® assay was evaluated against the turbidimetric inhibition immunoassay technique. A total of 68 positive and 82 negative samples were collected. The sensitivity and specificity results obtained are summarized in the following tables

		Turbidimetric inhibition immunoassay		Total
		Positive	Negative	
CRP ALL IN®	Positive	66	0	66
	Negative	2	82	84
Total		68	82	150

Relative sensitivity: 97.1% (89.9% ~ 99.2%)*
Relative specificity: 100% (95.5% ~ 100.0%)*
Overall agreement: 98.7% (95.3% ~ 99.6%)*
*95% confidence interval

The performance of the CRP ALL IN® test was also evaluated in a prospective clinical study, compared to a reference technique routinely used in a French hospital expert center. A total of 9 positive and 22 negative samples were collected. The study showed 100% agreement between the reference technique and the test.

Limit of detection

The minimum detection concentration for C-reactive protein is 10mg/L.

Interference

The following substances were assessed at the concentrations listed below.
The results showed no interference.

Substance	Concentration
Ascorbic acid	20mg/dl
Haemoglobin	1000mg/dl
Gentisic acid	20mg/dl
Paracetamol	20mg/dl
Aspirin	20mg/dl
Caffeine	20mg/dl
Oxalic acid	60mg/dl
Uric acid	20mg/dl
Bilirubin	1000mg/dl
Triglycerides	3g/dl

BIBLIOGRAPHICAL REFERENCES

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. Blinking. Chem. 43, 52-58.

SYMBOL LEGEND

	Read the user manual	Σ	Number of tests per kit		Manufacturer
IVD	For in vitro *diagnostic use* only		Expiry date		Do not reuse
2°C 30°C	Store between 2 and 30°C	LOT	Batch number	REF	Reference
CE	CE marking				

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