CRP Semi-Quantitative Rapid Test Package Insert

REF VICR-402	English

INTENDED USE

The VivaDiag™ CRP Semi-Quantitative Rapid Test is a rapid chromatographic immunoassay for the Semi-quantitative detection of human C-Reactive Protein (CRP) in whole blood, serum or plasma. It is intended to be used as an aid in the diagnosis of inflammatory condition. The cutoff of the test is 10 mg/L. For *in vitro* diagnostic use only.

SUMMARY

C-reactive protein (CRP) is detected in patient specimens in conjunction with acute infections, necrosis and various inflammatory disorders. CRP values do not increase to the same extent in viral infections as in bacterial ones, which is why this parameter can contribute to their differentiation. CRP is a protein which is predominantly formed by the liver during an acute inflammatory process. A positive test result indicates the presence, not the cause, of an acute inflammatory reaction. CRP synthesis is stimulated by antigen-immune complexes, bacteria, fungi or trauma. Monitoring of CRP levels in patients can provide information on the effectiveness of treatment and facilitate the assessment of patient recovery.

The inter-individual variation of CRP values is relatively high. Age, overweight, diabetes mellitus type 2, smoking, intake of gestagen (progestin)/estrogen medication or atherosclerotic/ cardiovascular diseases, among others, may contribute to elevated values. In general, values of >10mg/L can be regarded as elevated for the majority of patients.

- Disease severity can be classified on the basis of the CRP concentration into:
- Mild inflammation (>10-40mg/L). Possible causes: local abscess, mild operative or accident trauma, heart attack, deep vein thrombosis, inactive rheumatic diseases, metastasised malignant tumor and isolated viral infections.
- Moderate inflammation (>40-100mg/L). Possible causes: severe inflammatory processes like purulent cystitis, bronchitis, dental suppuration, urinary tract infections and genital infections.
- High-grade inflammation (>100mg/L). Possible causes: acute generalised bacterial or fungal infections (sepsis) and severe tissue injury following polytrauma or major surgical procedures.

PRINCIPLE

The CRP Semi-Quantitative Rapid Test is a lateral flow chromatographic immunoassay. The test consists of: 1) a burgundy colored conjugate pad containing CRP-antibody conjugated with colloidal gold 2) a nitrocellulose membrane strip containing three test lines (T1, T2 and T3 lines) and a control line (C line). The T1, T2 and T3 lines are pre-coated with ant-CRP-antibodies and the C line is pre-coated with a control line antibody.

After the specimen is added to the specimen well (S) of the test device, it reacts with anti-CRP antibodies which are conjugated to coloured particles and pre-coated onto the conjugate pad of the internal test strip. The mixture then migrates along the membrane chromatographically by capillary action and reacts with further anti-CRP antibodies immobilised in the test line regions: T3, T2 and T1 of the membrane. The presence of a coloured line in the test line region(s) T3 and/or T2, and/or T1indicates a positive result. The absence of a coloured line in the test line region(s) T3 and/or T2, and/orT1 indicates a negative result. The number of lines depends on the CRP concentration in the specimen. The higher the CRP concentration in the specimen, the more coloured lines become visible.The formation of a coloured line in the control line region C serves as aprocedural control, indicating that the proper volume of specimen has beenadded and membrane wicking has occurred.

COMPOSITION

Materials provided and available for purchase

1. Test device in foil pouch
2. 10μL Dropper
3. Buffer
4. Alcohol pad
5. Safety lancet
6. Package insert

Materials required but not provided:

1. Specimen collection container
2. Centrifuge (for serum/plasma samples)
3. Timer
4. Personal protective equipment, such as protective gloves, medical masks, lab coats, etc.
5. Appropriate biohazardous waste containers and disinfectants.

WARNINGS AND PRECAUTIONS

- For professional *In vitro* diagnostic use only.
- Do not use after the expiration date.
- The test result is invalid over 8 minutes.
- The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.
- All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.
- Do not use other kinds of the sample dilution to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

STORAGE AND STABILITY

- Store the test kit in a cool, dry place between 2-30°C. Keep away from light. Exposure to temperature and / or humidity outside the specified conditions may cause inaccurate results.
- Use the test kit at temperatures between 15-30°C. Do not freeze the kit or expose the kit over 30°C.
- Use the test kit between 10-90% humidity.
- Do not use the test kit beyond the expiration date (printed on the foil pouch and box).

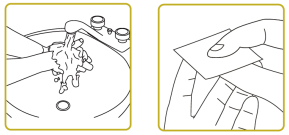
Note: *All expiration dates are printed in Year-Month-Day format. 2022-06-18 indicates June18, 2022.*

SPECIMEN COLLECTION AND HANDLING

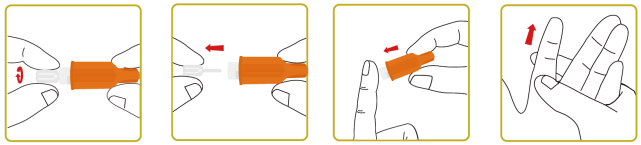
The VivaDiag™ CRP Semi-Quantitative Rapid Test can be performed using whole blood, serum or plasma.

1) Specimen collection

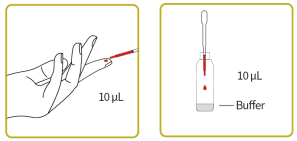
1. Wash your hands and keep your hands clean.Disinfect with alcohol pads.



2. Rotate the lid and open the safety lancet. Massage your fingers. Press the lance at the blood collection site.

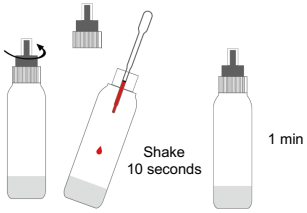


3. Use the dropper to absorb 10μL fingertip blood sample into the sample buffer tube.



2) Specimen handling

- For fingertip blood: Use the dropper to absorb 10μL blood into the sample buffer tube.
- Close the tube and slowly shake the sample for about 10 seconds to completely mix the sample and buffer.
- Rest the sample for approximately 1 minute after diluted.

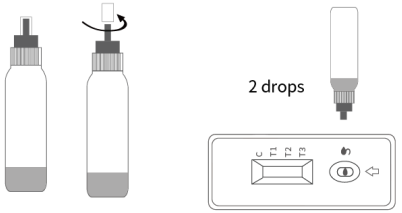


Note:
Serum, plasma and whole blood samples must be collected in a clean and dry container. EDTA, sodium citrate, heparin can be used as the anticoagulants. Recommend for detect immediately after collecting blood. If blood coagulation occurs, serum samples suggested to use.

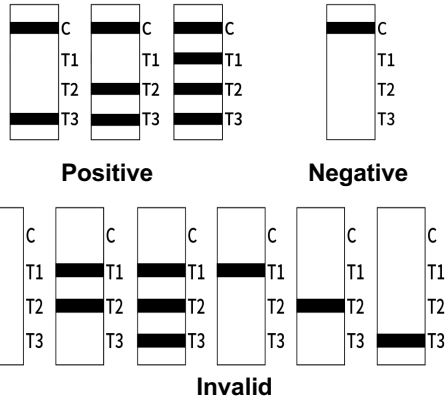
TEST PROCEDURE

Please read the instructions carefully before testing. Allow equipment and samples to equilibrate to room temperature (15°C to 30°C) prior to testing.

4. Take off the outer packing, put it onto the desk with the sample adding area up.
5. Use a dropper to take 2 drops (about 80 μL-100 μL) of the buffer sample and add to the sample adding area vertically.
6. Wait for the red line(s) to appear. Read results at **5 minutes**. Do not interpret results after 8 minutes.



INTERPRETATION OF TEST RESULTS



Positive Result:

- A Control line (C) and a test line (T3) appears indicates a CRP level of 10mg/L at least.
- A Control line (C) and two test lines (T3 and T2) appear indicates a CRP level of 40mg/L at least.
- A Control line (C) and three test lines (T1, T2 and T3) appears indicates a CRP level of 80mg/L at least.

Negative Result:

Only a Control line (C) appears and no colored line appears in the test region (T) indicates a CRP level is lower than 10mg/L.

Invalid Result:

Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not. Collect a new specimen and perform another test with a new test device/strip.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. 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

- The CRP Semi-Quantitative Rapid Test (Whole Blood /Serum/Plasma) is used for professional in vitro diagnostic, and should only be used for the semi-quantitative detection of C - reactive protein.
- The CRP Semi-Quantitative Rapid Test (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 conditions.
- Like with all diagnostic tests, a confirmed diagnosis should be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE

1. Accuracy

The CRP Semi-Quantitative Rapid Test has been evaluated with a leading commercial CRP CLIA

test using clinical samples. The results show that the sensitivity of the CRP Semi-Quantitative Rapid Test is 98.6% and the specificity is 97.9% and the accuracy is 98.0% relative to the leading CLIA test. Comparison for all subjects is showed in the following table:

VivaDiag™ CRP Semi-Quantitative Rapid Test	CLIA		
	Positive	Negative	Total
Positive	70	10	80
Negative	1	474	475
Total	71	484	555
Sensitivity	98.6% (70/71, 95%CI, 92.4%~100%)		
Specificity	97.9% (474/484, 95%CI, 97.9%~99.0%)		
Accuracy	98.0% (544/555, 95%CI, 96.5%~99.0%)		

2. Interfering Substances:
1000 μmol/L bilirubin, 6.15mmol/L triglyceride, 6.5g/L hemoglobin has no effect on the detection result.

3. Cross-Reactivity
The reagent is not affected by the rheumatoid factor, Antinuclear antibodies. The samples which was addited of PCT, RF, HCV, HBsAg, HIV, showed no cross-reactivity. RNP, dsDNA, SSA, SSB, SM, ASO, ANA and other 7 kinds of autoimmunity positive samples had no effect on the test results.

INDEX OF SYMBOLS

	Consult instructions for use		Use by	Σ	Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only	LOT	Lot number	REF	Catalog number
2°C 30°C	Storage temperature limitations		Manufacturer		Do not reuse
EC REP	Authorized Representative				

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CE
IVD

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