CE

RHELAX-CRP®

SLIDE TEST FOR C-REACTIVE PROTEIN

SUMMARY

C-reactive protein (CRP) is a serum protein, which is synthesized in the liver. Its rate of synthesis and secretion increases within hours of an acute injury or the onset of inflammation and may reach as high as 20 times the normal levels.
Elevated serum concentration of CRP is an unequivocal evidence of an active tissue damage process and CRP measurement thus provides a simple screening test for organic disorders. Apart from indicating inflammatory disorders, CRP measurement helps in differential diagnosis, in the management of neonatal septicaemia and meningitis where standard microbiological investigations are difficult.
Its use in postoperative surveillance is of great importance. CRP levels invariably rise after major surgery but fall to normal within 7-10 days. Absence of this fall is indicative of possible septic or inflammatory post operative complications.
Serum CRP measurement also provides useful information in patients with myocardial infarction there being an excellent correlation between peak levels of CRP and Creatine phosphokinase (CPK).

PRESENTATION

REF		10420005	10420025	104200035	10420050	104200070	10420100
Latex/ Tests		5 ml	25 Tests	35 Tests	50 Tests	70 Tests	100 Tests
Control	+	-	0.4 ml	0.4 ml	0.4 ml	0.4 ml	0.4 ml
Control	-	-	0.4 ml	0.4 ml	0.4 ml	0.4 ml	0.4 ml
Six circle black plastic slide		-	1	1	1	1	1
Sample droppers		-	25	35	50	70	100
Mixing stick ladder		-	1	2	2	3	4
Rubber teat		-	1	1	1	2	2
Pack insert		1	1	1	1	1	1

REAGENTS

1. RHELAX®-CRP reagent: A uniform suspension of polystyrene latex particles coated with agglutinating sera for CRP. The reagent is standardized to detect CRP concentrations greater than 0.6 mg/dl. The standardization of detection limit of RHELAX®-CRP is traceable to the W.H.O., International reference Standard (85/506) for Human C-reactive protein.
2. Positive control, reactive with RHELAX®-CRP reagent.
3. Negative control, non-reactive with RHELAX®-CRP reagent.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY

1. Store the reagent at 2-8^{0}C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label. Do not use reagents after the expiry date.

PRINCIPLE

RHELAX®-CRP slide test for detection of CRP is based on the principle of agglutination. The test specimen (serum) is mixed with RHELAX®-CRP latex reagent and allowed to react. If CRP concentration is greater than 0.6 mg/dl a visible agglutination is observed. If CRP concentration is less than 0.6 mg/dl, then no agglutination is observed.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The reagents that are derived from human source have been tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
3. The reagents contain 0.1% Sodium Azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive and negative controls provided with the kit.
5. Shake the latex reagent well before use to disperse the latex particles uniformly and improve test readability.
6. Only a clean and dry slide must be used. Clean the slide with distilled water and wipe dry.
7. Accessories provided with the kit only must be used for optimum results.
8. Do not use damaged or leaking reagents.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is required prior to specimen collection by approved techniques.
Only serum must be used for testing. Should a delay in testing occur, store the sample at 2-8^{0}C. Samples can be stored for up to a week. Do not use hemolysed serum.

MATERIAL PROVIDED WITH THE KIT

Reagent

RHELAX®-CRP latex reagent, Positive control, Negative control.

Accessories

Slide with six reaction circles, Sample dispensing pipettes, Mixing sticks, Rubber teat.

ADDITIONAL MATERIAL REQUIRED

Stop watch, Test tubes, A high intensity direct light source, Isotonic saline.

TEST PROCEDURE

1. Bring reagent and test specimen (serum) to room temperature before use.
2. Tighten the cap of each; Latex reagent bottle, positive control and negative control bottles respectively in the clockwise direction to pierce the bottle nozzle.

Qualitative Method

1. Pipette one drop of test specimen (serum) on the slide using disposable pipette provided with the kit.
2. Add one drop of RHELAX®-CRP latex reagent to the drop of test specimen (serum) on the slide by holding the latex reagent vial vertically. Do not let the dropper tip touch the liquid on the slide.
3. Using a mixing stick, mix the test specimen (serum) and RHELAX®-CRP latex reagent uniformly over the entire circle.
4. Immediately start a stopwatch. Rock the slide gently back and forth, observing for agglutination macroscopically at **two minutes**.

Semi Quantitative Method

1. Using isotonic saline prepare serial dilutions of the test specimen (serum) positive in the qualitative method 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 and so on.
2. Pipette each dilution of the test specimen (serum) onto separate reaction circles.
3. Add one drop of RHELAX®-CRP latex reagent to the drop of test specimen (serum) on the slide. Do not let the dropper tip touch the liquid on the slide.
4. Using a mixing stick, mix the test specimen (serum) and the latex reagent uniformly over the entire circle.
5. Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at **two minutes**.

INTERPRETATION OF RESULTS

Qualitative Method

Agglutination is a positive test result and indicates presence of detectable levels of CRP in the test specimen (serum).
No agglutination is a negative test result and indicates absence of detectable levels of CRP in the test specimen (serum).

Semi Quantitative Method

Agglutination in the highest test specimen (serum) dilution corresponds to the approximate amount of CRP in mg/dl present in the test specimen (serum).
Concentration of CRP can be calculated as follows:
CRP (mg/dl) = S x D
Where, S = Sensitivity of the reagent i.e. 0.6 mg/dl.
D = Highest dilution of serum showing agglutination.

REMARKS

1. Markedly lipemic, hemolysed and contaminated serum samples could produce non-specific results.
2. Use of plasma rather than serum can lead to false positive results.
3. CRP is found to be present after the first trimester of pregnancy and persists until delivery.
4. CRP levels increase in women who are on oral contraceptives.
5. CRP response is not affected by the commonly used anti-inflammatory or immunosuppressive drugs, including steroids, unless the disease activity is affected and it covers an exceptionally broad incremental range upto 3000 times.
6. Do not read results beyond indicated testing time limits.
7. Since CRP production is a non-specific response to tissue injury, it is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.
8. In cases where an increase in CRP levels is suspected, but the screening test shows negative results, semiquantitation should be done to rule out prozone effect.
9. Cap the reagent vial tightly after use to avoid spilling of reagent inside the cap.
10. Always keep the reagent vial in upright position during storage.

PERFORMANCE CHARACTERISTICS

The performance characteristics of RHELAX®-CRP were evaluated using known positive and negative serum samples. The known serum samples were validated using other commercial manufacturers latex slide test reagent having similar performance characteristics.

	Total	RHELAX®-CRP	
		+ VE	- VE
CRP + Ve samples	33	33	0
CRP - Ve samples	80	0	80
	113	33	80

Sensitivity: 100% Specificity: 100%

Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of CRP negative and CRP positive serum samples. No variations were found in the outcome of different tests.

WARRANTY

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. R.D. Eastham et.al.,C-Reactive Protein in Rheumatic Heart Disease, Am. Rheum. Dis. (1958), 17 pgs 314-318
2. Clinical Laboratory by Lothar Thomas , M.D., 1st edition, 1988, TH-Books, Verlagsgesellschaft mbH, Frankfurt, Germany, pgs 700-706.
3. Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

 Temperature limitation	 Manufacturer	 Contains sufficient for <n> tests
 Use by	 Consult Instructions for use	CONTROL + Positive control
 Date of Manufacture	REF Catalogue Number	CONTROL - Negative control
LOT Batch Number/ Lot Number	IVD *In vitro* Diagnostic Medical Device	REAGENT Description of reagent
 This side up	EC REP Authorised Representative in the European Community	

TULIP DIAGNOSTICS (P) LTD.

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EC REP

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