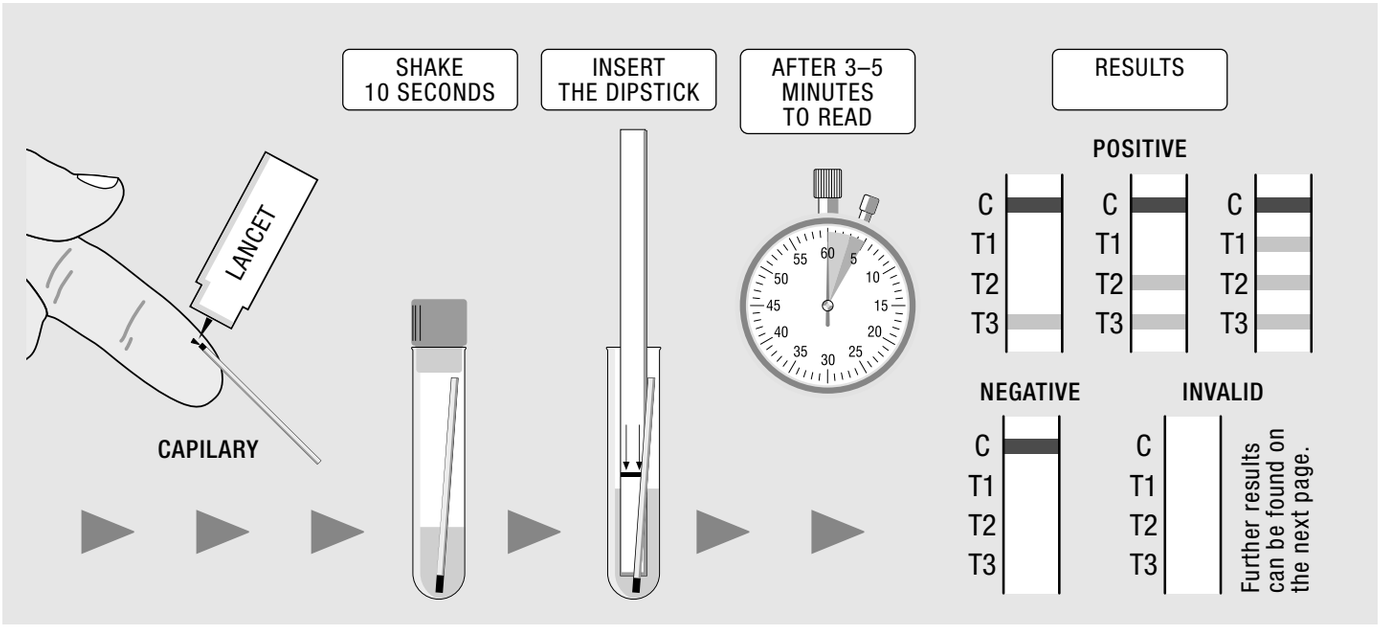
CLEARTEST® DIAGNOSTIK

CRP 10-40-80

CRP Semi-Quantitative Rapid Test Dipstick (Whole Blood /Serum/Plasma)

FOR PROFESSIONAL USE ONLY

IVD



PACKAGE INSERT
A rapid test for the diagnosis of myocardial infarction (MI) by detecting CRP Semi-quantitatively in whole blood, serum or plasma. For professional in vitro diagnostic use only.

INTENDED USE
The CrP Rapid Test Dipstick (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the Semi-quantitative detection of human CrP in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI). The cutoff of the test is 10 µg/ml.

SUMMARY
C-reactive Protein (CrP) in patient's sera has been found in association with acute infections, necrotic conditions and a variety of inflammatory disorders. There is a strong correlation between serum levels of CrP and the onset of the inflammatory process. Monitoring the levels of CrP in patient's sera indicates the effectiveness of treatment and the assessment of patient recovery. It is used in particular to differentiate bacterial infections from virus infections.

PRINCIPLE
The CrP Rapid Test Dipstick (Whole Blood/Serum/Plasma) detects C-reactive Protein through visual interpretation of color development on the internal strip. The sample now moves through the test strip from bottom to top. If the test sample contains CrP, it attaches to the first anti-CrP antibody which is conjugated with a red gold colloidal for color marking. The red CrP-antibody-gold complex, together with the sample liquid, diffuses through the membrane that is pre-dispensed with lines of different amounts of the second anti-antibody. The CrP-antibody-gold complex is immobilized by the second antibodies leading to the formation of red lines. The number of lines depends on the concentration in the sample. The more CrP is contained in the sample, the more red lines become visible.
A red line should always appear in the control (C) line area. It serves as a procedural control, confirming that sufficient specimen volume was used and indicates an adequate membrane wicking and proper procedural technique.

REAGENTS
The test strips include anti-CrP antibody coated particles and CrP antibodies coated on the membrane.

PRECAUTIONS
- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to any testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2–30 °C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND PREPARATION

Preparation

Before performing the test, please make sure that all components are brought to room temperature (15–30 °C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

1. Take a tube with buffer solution out of the kit. Document patients name or ID on it. Open the screw cap. **Blood Sample Taking**
2. Collect the specimen according to standard procedures.
   - Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2–8 °C for up to 3 days. For long term storage, specimens should be kept below –20 °C. Whole blood collected by venipuncture should be stored at 2–8 °C if the test is to be used within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
   - Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
   - EDTA-, citrate- or heparin blood can be used as well. Before performing the test, it has to be diluted accordingly with the supplied buffer. **Sample Dilution / Sample Stability**
3. Administer the blood-filled end-to-end capillary into the plastic tube with dilution buffer. Alternatively, the 10 µL of specimen can be added directly with the micro pipette into the buffer
4. Close the tube and shake the sample by hand forcefully for approximately 10 seconds so sample and dilution buffer mix well.
5. Let the diluted sample rest for approximately 1 minute.
6. The sample can then be used immediately or stored for up to 8 hours.

MATERIALS

Material Provided

- CrP test dipsticks
- Plastic tubes with buffer
- Package Insert
- Capillary Tubes

Material Required But Not Provided

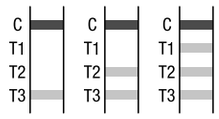
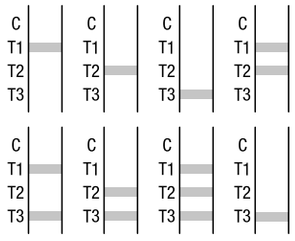
- Timer
- Centrifuge

DIRECTIONS FOR USE

Bring tests, specimens, buffer, and/or controls to room temperature (15–30 °C) before use.

1. Remove the Test Dipstick from its sealed pouch, and place it on a clean, level surface. For best results, the assay should be performed within one hour.
2. Open the tube with the diluted sample and put the test strip with the arrow pointing end into the liquid. Avoid in any case a direct wetting of the result area.
3. Leave the test for minimum 10 seconds in the diluted sample until the slightly pink-colored liquid front becomes visible in the result area.
4. Take out the test dipstick and place it on a plain and non-absorbent surface. Alternatively, the test dipstick can remain in the tube. Start the timer as the test starts to run.
5. As the test begins to run you will observe a colored liquid migrate along the membrane of the reaction area. Interpret results at 5 minutes. Please stick exactly to this timeline to ensure correct semi-quantitative results.

INTERPRETATION OF RESULTS

POSITIVE RESULTS:	
	A Control line (C) and a test line (T3) appears indicates a CrP level of 10 µg/ml at least.
	A Control line (C) and two test lines (T3 and T2) appear indicates a CrP level of 40 µg/ml at least.
	A Control line (C) and three test lines (T1, T2 and T3) appears indicates a CrP level of 80 µg/ml at least.
NEGATIVE RESULTS:	
	Only a Control line (C) appears and no colored line appears in the test region (T) indicates a CrP level is lower than 10 µg/ml.
INVALID RESULTS:	
	No Control line appears. Results from any test which has not produced Control line at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE

1. The intensity of the color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Please note that this is a semi-quantitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. Control line appearing in the control regions is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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

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

4. High concentrations of CrP may produce a dose hook effect, resulting in incorrect interpretation of CrP levels. High dose hook effect has not been observed with this test up to 2000 mg/L of CrP.

EXPECTED VALUES

CrP plasma levels increase within 6 to 8 hours after occurrence of an acute event like for example a bacterial infection or trauma and reach their peak within approximately 48 hours after the occurrence of an event. The levels fall quickly after the causing event stops, with a CrP half-life of 48 hours.

Usually, the severity of the inflammation and the inflammation activity influence the extent of the CrP increase. Values of 10 to 40 µg/ml often coincide with mild inflammation like local bacterial infections, abscess, mild trauma, malignant tumors, most viral diseases etc. Up to 100 µg/ml CrP indicate severe illness with inflammation that usually requires immediate medical treatment measures.

Values higher than 100 µg/ml are found e.g. in bacterial sepsis or major surgical procedures.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The CrP Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial CrP EIA test using clinical specimens. The results show that the sensitivity of the CrP Rapid Test Cassette (Whole Blood/Serum/Plasma) is >99.9% and the specificity is 97.5 % relative to the leading EIA test.

Method		EIA		Total Result
CrP Rapid Test Cassette (Whole Blood/ Serum/Plasma)	Results	Positive	Negative	
	Positive	67	12	79
	Negative	0	473	473
Total Result		67	485	552

Relative sensitivity: 67/67 = > 99.9 % (95 % CI*: 95.6 % ~ 100 %);
Relative specificity: 473/485 = 97.5 % (95 % CI*: 97.5 % ~ 98.7 %);
Accuracy: (67 + 473)/(67 + 12 + 473) = 97.8 %(95 % CI*: 96.2 % ~ 98.9 %).
*Confidence Intervals

PRECISION

Cross-reactivity

The CrP Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by Rheumatoid Factor, HAMA, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-H.pylori, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to CrP negative and positive specimens.

Acetaminophen:	20 mg/Dl
Caffeine:	20 mg/dL
Acetylsalicylic Acid:	20 mg/dL
Gentisic Acid:	20 mg/dL
Ascorbic Acid:	20 mg/dL
Albumin:	10,500 mg/dL
Creatin:	200 mg/dL
Hemoglobin:	1,000 mg/dL
Bilirubin:	1,000 mg/dL
Oxalic Acid:	600 mg/dL
Cholesterol:	800 mg/dL
Triglycerides:	1,600 mg/dL

None of the substances at the concentration tested interfered in the assay.

LITERATURE 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. Clin. Chem. 43, 52-58.

Index of symbols			
REF	Article number		Temperature limitation
	Observe operating instructions	LOT	Batch number
IVD	In-vitro-diagnostic		Expiry date
	Manufacturer		Content sufficient for <n> tests
	Dangerous substances		Single use
	Protect from heat and sunlight		Attention
	Protect from moisture		
	Do not use, if package is damaged		
CE	CE marked according to IVD directive 98/79/EG		

ORDERING INFORMATION

Cleartest CrP, 20 dipsticks, REF C3 4050

IVD CE

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