CE
IVD

C-reactive protein Rapid Test Kit (Colloidal Gold)

PRODUCT NAME
C-reactive protein (CRP) Rapid Test Kit (Colloidal Gold)

SPECIFICATION
25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE
The C-reactive protein (CRP) Rapid Test is used for semi-quantitative determination and monitoring of CRP concentrations in whole blood/serum/plasma specimens.
The C-reactive protein (CRP) Rapid Test is an immunochromatographic test, based on two specific antibodies against human CRP. The concentration-dependent formation of test lines allows a rapid semi-quantitative determination of CRP in whole blood samples, plasma and serum.

PRINCIPLE
The diluted sample is added into the sample well of the device. 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-CRP antibody. The CRP-antibody-gold complex is immobilized by the antibodies coated on the membrane leading to the formation of red lines. The number of lines depends on the CRP concentration in the sample. The more CRP is contained in the sample, the more red lines become visible.
The control line serves as a procedural control and indicates that sufficient volume of specimen has been added and membrane wicking has occurred.
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.
The C-reactive protein (CRP) Rapid Test is a rapid test that semi-qualitatively detects the presence of CRP in whole blood, plasma or serum specimens at the sensitivity of 10ng/mL, 30ng/mL and 60ng/mL. The test utilizes a combination of monoclonal antibodies to selectively detect elevated levels of CRP in whole blood, plasma or serum. At the level of claimed sensitivity, the C-reactive protein (CRP) Rapid Test shows no cross-reactivity interference from the related CRP or others at high physiological levels.

COMPOSITION
The test contains anti-CRP particles and anti-CRP coated on the membrane.

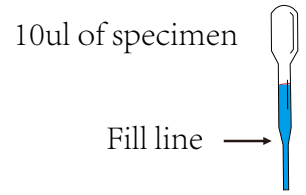
Individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents precoated at the corresponding regions
Disposable pipettes	For adding specimens
Buffer in the dilute tubes	Phosphate buffered saline with Tween 20 and preservative
Package insert	For operating instructions
Specimen collection container	For specimen collection
Timer	For timing use
Centrifuge	For preparing serum/plasma specimens

Materials required but not provided: Specimen collection container, Timer, Centrifuge.

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.

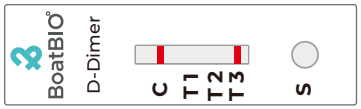
WARNINGS AND PRECAUTIONS
- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary 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.
- The C-reactive protein (CRP) Rapid Test is for professional in vitro diagnostic use, and should only be used for the semi-quantitative detection of C - reactive protein.
- The C-reactive protein (CRP) Rapid Test 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 only be made by a physician after all clinical and laboratory findings have been evaluated.
- 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.

SPECIMEN COLLECTION AND PREPARATION
- Specimens should be collected by standard protocol.
- The C-reactive protein (CRP) Rapid Test can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect Fingerstick Whole Blood specimens:
- Wash the patient's hand then allow to dry. Massage the hand without touching the puncture. Puncture the skin with a sterile lancet. Wipe away the first sign of blood. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site. Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube or hanging drops.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the 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 run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- Use a disposable pipette to transfer 10 L of the specimens and add to the dilution tube with buffer.
- Bottom up and down the tube for several time to mix the specimens well.
- The diluted sample can be kept at room temperature for at least 8 hours. EDTA, citrate or heparin blood can also be used as a sample.

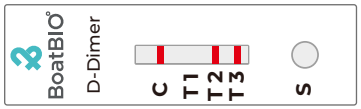


TEST PROCEDURE
Bring tests, buffer, specimens and/or controls to room temperature (15-30°C) prior to testing.
Bring tests, specimens, buffer, and/or controls to room temperature (15-30°C) before use.
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. Add 3 drops of diluted specimen above to the specimen well and start the timer.
3. Wait for the colored bands to appear. The result should be read at 5 minutes. Do not interpret the result after 8 minutes.

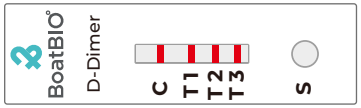
INTERPRETATION OF TEST RESULTS
Positive result
A Control band (C) and a test band (T3) appears indicates a CRP level 10 mg/L at least.



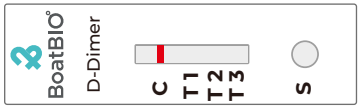
A Control band (C) and two test bands (T3 and T2) appear indicates a CRP level 30 mg/L at least.



A Control band (C) and three test bands (T1, T2 and T3) appears indicates a CRP level 60 mg/L at least.



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



Invalid result
No Control band appears. Results from any test which has not produced Control band 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 band failure.

QUALITY CONTROL

• Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms 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.

EXPECTIED VALUES

The C-reactive protein (CRP) Rapid Test has been compared with a leading commercial CRP EIA test, demonstrating an overall accuracy of 98.9%.

PERFORMANCE

Sensitivity and Specificity
The C-reactive protein (CRP) Rapid Test has been evaluated with a leading commercial CRP EIA test using clinical specimens. The results show that the sensitivity of the C-reactive protein (CRP) Rapid Test is 98.1% and the specificity is 99.2% relative to the leading EIA test.
Procalcitonin Semi-Quantitative Rapid Test Cassette vs. EIA

Method		EIA Test		Total Results
Semi-Quantitative Rapid Test Cassette	Results	Positive	Negative	
	Positive	104	2	106
	Negative	2	256	258
Total Results		106	258	364

Relative Sensitivity: 98.1%(93.3%-99.8%)*
Relative Specificity: 99.2%(97.3%-99.9%)*
Accuracy: 98.9%(97.2%-99.7%)* *95% Confidence Interval

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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