Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

OneStep C-Reactive Protein (CRP) Serum/ Whole Blood/ Plasma RapiCard™ InstaTest

REF 166800-1-44

IVD See external Label 2 -30°C ∑= 10 Tests

INTENDED USE

The Cortez C-Reactive Protein (CRP) Serum/ Whole Blood/ Plasma RapiCard™ is a rapid chromatographic immunoassay for the qualitative detection of human CRP in whole blood, serum or plasma as an aid in the diagnosis of inflammatory condition. The cutoff of the test is 10 µg/ml.

SUMMARY AND EXPLANATION

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.

TEST PRINCIPLE

The Cortez C-Reactive Protein (CRP) Serum/ Whole Blood/ Plasma RapiCard™ detects C-reactive Protein through visual interpretation of color development on the internal cassette. The sample now moves through the test cassette from bottom to top. If the test sample contains CRP, it attaches to the anti-CRP antibody which is conjugated with a red gold colloidal for color marking. 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.

MATERIALS AND COMPONENTS

The RapiCard™ tests include anti-CRP antibody coated particles and CRP antibodies coated on the membrane.

Material provided with the kit

- Cortez CRP Whole Blood/Serum/Plasma RapiCard™
- Plastic tubes with buffer
- Capillaries
- Package insert
- Droppers
- Workstation

Materials required but not provided

- Timer
- Centrifuge

PRECAUTION

1. For professional *in vitro* diagnostic use only.
2. 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 inserts.
3. 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).
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. Read the entire procedure carefully prior to any testing.
6. 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.
7. Do not interchange or mix reagents from different lots.
8. Humidity and temperature can adversely affect results.
9. 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 & PREPARATION

Preparation

Before performing the test, please make sure that all components are brought to room temperature (15-30℃). 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

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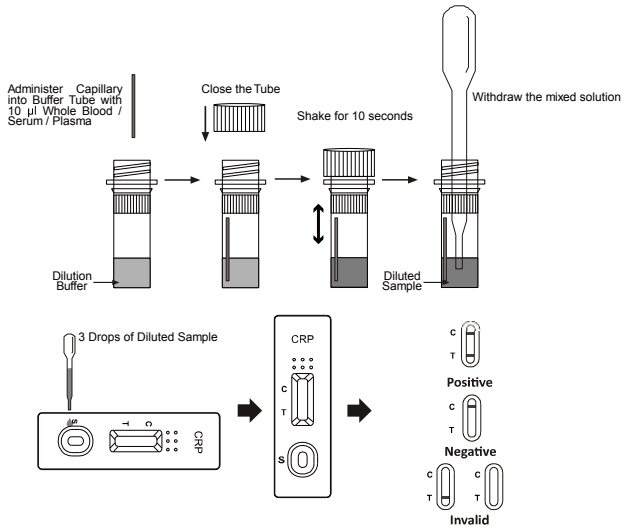
4. Close the tube and shake the sample by hand forcefully for approximately 10 seconds so sample and dilution buffer mix well.
5. Let the diluted sample rest for approximately 1 minute.
6. The sample can then be used immediately or stored for up to 8 hours.

ASSAY PROCEDURE

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

1. Remove the CRP RapiCard 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 .Transfer 3 drops of mixed specimens to sample well. Start the timer.
3. Wait for the colored lines to appear. The result should be read at 5 minutes. Do not interpret the results at 10 minutes.



RESULTS

(Please refer to the illustration above)

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of CRP antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test 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.

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.

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 OF PROCEDURE

1. The Cortez C-Reactive Protein (CRP) Serum/ Whole Blood/ Plasma RapiCard™ is for professional in vitro diagnostic use, and should only be used for the qualitative detection of C - reactive protein.
2. The Cortez C-Reactive Protein (CRP) Serum/ Whole Blood/ Plasma RapiCard™ will only indicate the presence of CrP antigen 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.

REFERENCES

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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.

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