TruQuick™ CRP 10T

A rapid test for the diagnosis of inflammatory condition by detecting CRP qualitatively in whole blood, serum or plasma.

REF **TQ3210** IVD **Rx Only**

INTENDED USE
TruQuick CRP 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 OF THE TEST
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.

BIOLOGICAL PRINCIPLES
TruQuick CRP 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.

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: The Test Cassettes includes anti-CRP antibody-coated particles and CRP antibodies coated on the membrane.
- Plastic tubes with Buffer: A buffered solution containing ProClin 300 as a preservative. The Buffer is supplied ready to use.
- Capillaries
- Droppers
- Workstation
- Package Insert

MATERIALS NOT PROVIDED
Timer
Centrifuge

PRECAUTIONS
1. For 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 tests.
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.

HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

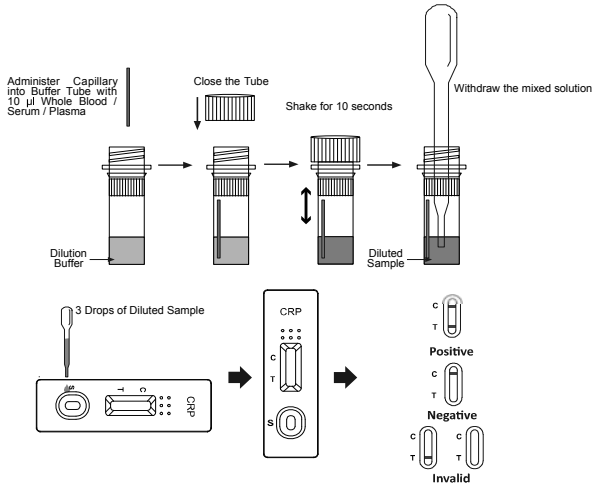
SHELF LIFE AND STORAGE
1. The kit should be stored at 2-30 C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence 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
1. 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 three 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 two 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-anticoagulated blood can be used as well. Before performing the test, the sample has to be diluted accordingly with the supplied buffer.

Sample Dilution / Sample Stability
1. 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 micropipette into the Buffer
2. Close the tube and shake the sample by hand forcefully for approximately 10 seconds so sample and dilution buffer mix well.
3. Let the diluted sample rest for approximately one minute.
4. The sample can then be used immediately or stored for up to eight hours.

TEST PROCEDURE
Bring tests, specimens, Buffer, and/or controls to room temperature (15-30 C) before use.
1. Remove the Test Cassette 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.



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another 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 Meridian's Technical Services Department at 800-343-3858 or 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
This test should be performed per applicable local, state, or federal regulations or accrediting agencies.
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 external controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES
CRP plasma levels increase within six to eight hours after occurrence of an acute event, 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 eg. in bacterial sepsis or major surgical procedures.

LIMITATIONS OF THE PROCEDURE
1. TruQuick CRP is for in vitro diagnostic use, and should only be used for the qualitative detection of C-reactive protein.
2. TruQuick CRP 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.

SPECIFIC PERFORMANCE CHARACTERISTICS
TruQuick CRP has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. ELISA served as the reference method for TruQuick CRP. The specimen was considered positive if ELISA results were positive. The specimen was also considered negative if the ELISA results were negative.

Method		ELISA		Total Results
TruQuick CRP	Results	Positive	Negative	
	Positive	29	3	32
	Negative	1	197	198
Total results		30	200	230

Sensitivity: 96.7% (95% CI:*82.8%-99.9%)
Specificity: 98.5% (95% CI:*95.7%-99.7%)
Correlation: 98.3% (95% CI:*95.6%-99.5%) *Confidence Intervals

REPRODUCIBILITY
Inter-Assay Precision
Negative, low positive, middle positive and high positive samples were run in 10 replicates on 10 separate days using the same lot of TruQuick CRP. The correct results were obtained with each replicate.
Intra-Assay Precision
Negative, low positive, middle positive and high positive samples were run in replicates of 10 with three separate lots of product. The results were consistent between the lots.

CROSSREACTIVITY
HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HIV, Syphilis, HAMA, RF, Mononucleosis, CMV, Rubella, Toxoplasmosis, and *H. pylori* positive specimens, as confirmed by ELISA and clinical diagnosis, were tested with TruQuick CRP. No crossreactivity was observed.

TESTS FOR INTERFERING SUBSTANCES
Potentially interfering substances were spiked into negative and positive plasma and serum specimens (ELISA confirmed) at the concentrations listed.

Ascorbic acid 2 g/dL	Acetylsalicylic acid 20 mg/dL
Hemoglobin 1 g/dL	Acetaminophen 20 mg/d:
Gentisic acid 20 mg/dL	Creatine 200 mg/dL
Oxalic acid 60 mg/dL	Albumin 2 g/dL
Bilirubin 1 g/dL	Caffeine 20 mg/dL

There was no interference with the test at the concentrations tested..

REFERENCES

1. Morley JJ, Kushner. 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. 1982;389:406-417.
2. Peltola HO. C-reactive protein for rapid monitoring of infections of the central nervous system. Lancet. 1982;980-983.
3. Macy EM, Hayes TE, Tracy RP. Variability in the measurement of C-reactive protein in healthy subjects: implications for reference intervals and epidemiological applications. Clin. Chem. 1997;43,52-58.

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SYMBOL USAGE
You may see one or more of these symbols on the labeling/packaging of this product:
Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	BUF RXN	Reaction Buffer
	Manufacturer		For IVD Performance Evaluation Only
Σ	Contains sufficient for <n> tests	SOLN STOP	Stopping Solution
	Temperature limitation	CONJ ENZ	Enzyme Conjugate
SN	Serial number	CONTROL	Assay Control
TEST	Test Device	REAG	Reagent
	Date of manufacture	BUF WASH	Wash Buffer
BUF	Buffer		Warning
CONJ	Conjugate	DIL SPE	Specimen Diluent (or Sample Diluent)
SUBS	Substrate	BUF WASH 20X	Wash Buffer Concentration: 20X
RUO	Research Use Only	DET REAG	Detection Reagent
IUO	Investigational Use Only	Rx Only	Prescription Use Only
	Do not use if package is damaged		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.