TruQuick™ CRP 10T

A semiquantitative rapid test to detect CRP in whole blood, serum or plasma.

REF **TQ4210** IVD **Rx Only**

INTENDED USE
TruQuick CRP is a rapid chromatographic immunoassay for the semiquantitative detection of human CRP in whole blood, serum or plasma as an aid in the diagnosis of inflammatory conditions.

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 viral infections.

BIOLOGICAL PRINCIPLES
TruQuick CRP detects C-reactive Protein through visual interpretation of color development on the internal strip. Anti-CRP antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-CRP antibodies conjugated to colored particles and precoated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If the intensity of the test band is weaker than reference band (R), it indicates that the CRP level in the specimen is between 10-30 mg/L. If the intensity of the test band (T) is stronger than the reference band (R), it indicates that the CRP level is above 30 mg/L. The appearance of control line serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

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

MATERIALS NOT PROVIDED
- Specimen collection tubes
- 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 (eg. 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.

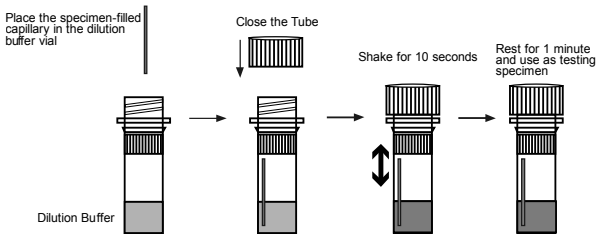
HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

SHELF LIFE AND STORAGE
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.

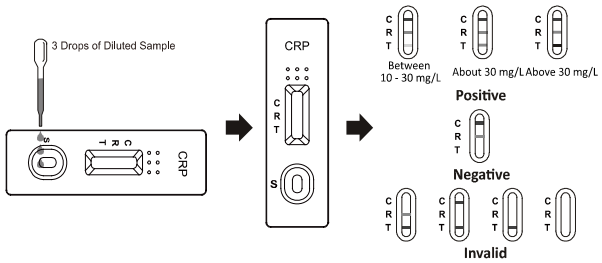
SPECIMEN COLLECTION AND PREPARATION
Preparation
1. Before performing the test, please make sure that all components are brought to room temperature (15-30 C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a single Dilution Buffer Vial out of the kit. Label it with patient's ID. Open the screw cap.

Blood Sample Collection
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 for 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 fingerstick should be tested immediately.
2. 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.
3. EDTA-, citrate- or heparin-anticoagulated blood can be used. Before performing the test, the sample has to be diluted accordingly with the supplied buffer.

Specimen Dilution / Stability
1. With the capillary tube, aspirate 10 µL blood. It is important that the capillary is filled end to end to ensure 10 µL blood.
2. Place the end-to-end blood-filled capillary into the dilution buffer vial. Alternatively, the 10 µL of specimen can be added directly with the micropipette into the sample Dilution Buffer Vial.
3. Close the vial and shake the sample vigorously for approximately 10 seconds so that sample and dilution buffer mix well. (See Figure-1)
4. Let the diluted sample rest for approximately 1 minute.
5. The diluted specimen 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 the 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. Open the tube containing specimen. Transfer 3 drops of the specimen to the 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 result after 10 minutes.



INTERPRETATION OF RESULTS
POSITIVE: Three colored bands appear on the membrane. One band appears in Control region (C) and one band in the Reference region (R). Another band should appear in the test region (T).
- A test band (T) signal which is weaker than the R indicates a CRP level **between 10 and 30 mg/L**.
- A test band (T) signal which is close to R indicates a CRP level **about 30mg/L**.
- A test band (T) signal which is stronger than the R indicates a CRP level **above 30 mg/L**.

NEGATIVE: Colored lines appear in both the control (C) and reference (R) regions. No colored line appears in the test line region (T). It indicates a CRP level less than 10 mg/L.
INVALID: Control band or Reference band fail to appear. Results from any test unit, which has not produced Control band or Reference 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 Meridian's Technical Services Department at 800-343-3858 or your local distributor.
NOTE:
1. The color intensity in the test region (T) may vary depending on the concentration of CRP 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 CRP in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band 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 brand and reference band appearing in the reference regions are considered internal procedural controls, 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
TruQuick CRP has been evaluated with a leading commercial CRP EIA and correlates well.

LIMITATIONS OF THE PROCEDURE
1. TruQuick CRP is for in vitro diagnostic use, and should only be used for the semiquantitative detection of C - reactive protein.
2. TruQuick CRP will only indicate the semiquantitative 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. CRP values near the cut-off level (10 mg/L) and reference line (R: 30 mg/L) should be reported with caution as with all semiquantitative assays there exists some level of variation. Therefore, a T line with slightly higher intensity than R can also represent a value slightly below 30 mg/L. A repeat test or further quantitative test is recommended in such cases.
5. 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 2,000 mg/L of CRP.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
TruQuick CRP has been evaluated with a leading commercial CRP EIA test using clinical specimens. The results show that the sensitivity of TruQuick CRP is 98.8% and the specificity is 98.7% relative to the leading EIA test.

Method		EIA		Total Result
TruQuick CRP	Results	Positive	Negative	
	Positive	79	4	83
	Negative	1	296	297
Total Result		80	300	380

Sensitivity: 79/80 = 98.8% (95% CI*: 95.6%~100%);
Specificity: 296/300 = 98.7% (95% CI*: 96.6%~99.6%);
Correlation: (79+296)/(79+1+4+296) = 98.7%(95% CI*: 97.0%~99.6%). *Confidence Intervals

REPRODUCIBILITY
Inter-Assay Precision
Negative, CRP low positive, CRP middle positive and CRP high positive samples were run in 10 replciates individually on 10 separate days using the same lot of TruQuick CRP. The expected results were obtained with all replicates in serum and plasma.
Intra-Assay Precision
Negative, CRP low positive, CRP middle positive and CRP high positive samples were run in replicates of 10 in three separate lots of product. The expected results were obtained with all replicates in serum and plasma.

CROSSREACTIVITY
TruQuick CRP was tested with HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-HIV, Syphilis, HAMA, RF, Mononucleosis, anti-CMV, anti-Rubella, anti-Toxoplasmosis, anti-*H. pylori* positive specimens. The samples showed no crossreactivity.

TESTS FOR 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
Creatine 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 interfered in the assay at the concentration 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.

Manufactured By

Meridian Bioscience, Inc.
Corporate Office
3471 River Hills Drive
Cincinnati, Ohio 45244 USA
Telephone: 513.271.3700
Orders/Customer Service:
800.543.1980
Technical Support Center:
800.343.3858
Information Fax: 513.272.5432
Ordering Fax: 513.271.0124

EC REP
Authorized Representative

Meridian Bioscience Europe S. r. L
Via dell' Industria, 7
20020 Villa Cortese, Milano
ITALY
Tel: +39 0331 43 36 36
Fax: +39 0331 43 36 16
Email: info@meridianbioscience.eu
WEB: www.meridianbioscience.eu

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.