TruQuick™ Procalcitonin 10T

A rapid test for the qualitative detection of *Procalcitonin* in whole blood, serum or plasma.

REF **TQ4010** IVD **Rx Only**

INTENDED USE
TruQuick Procalcitonin is a rapid chromatographic immunoassay for the qualitative detection of *Procalcitonin* in whole blood, serum or plasma.

SUMMARY AND EXPLANATION OF THE TEST
Procalcitonin (PCT) is a small protein that comprises 116 amino acid residues with a molecular weight of approximately 13 kDa which was first described by Moullec et al. in 1984.[1] PCT is produced normally in C-cells of the thyroid glands. In 1993, the elevated level of PCT in patients with a system infection of bacterial origin was reported and PCT is now considered to be the main marker of disorders accompanied by systemic inflammation and sepsis. The diagnostic value of PCT is important due to the close correlation between PCT concentration and the severity of inflammation. It was shown that "inflammatory" PCT is not produced in C-cells. Cells of neuroendocrine origin are presumably the source of PCT during inflammation.

BIOLOGICAL PRINCIPLES
TruQuick Procalcitonin is a qualitative, lateral flow immunoassay for the detection of PCT in whole blood, serum or plasma. The membrane is precoated with anti-PCT antibody on the test line region of the strip. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-PCT antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-PCT antibody on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that 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 device contains mouse anti-PCT antibody-coated particles and mouse anti-PCT antibody coated on the membrane.
- Buffer: A buffered solution containing Proclin 300 as a preservative. The Buffer is supplied ready to use in dropper vials.
- Droppers
- Package insert

MATERIALS NOT PROVIDED
- Specimen collection containers
- Centrifuge
- Timer

PRECAUTIONS
Please read all the information in this package insert before performing the test.
1. For in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimen or kits are handled.
3. Handle all the specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Humidity and temperature can adversely affect results.

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

SHELF LIFE AND STORAGE
Store as packaged at room temperature or refrigerated (2-30 C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

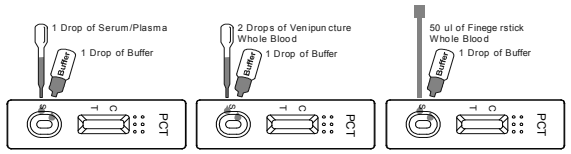
SPECIMEN COLLECTION AND PREPARATION
1. TruQuick Procalcitonin can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
2. To collect **Venipuncture Whole Blood specimens**: Collect anti-coagulated blood specimen) following standard laboratory procedures.
   To collect **Fingerstick Whole Blood specimens**:
   - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
   - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
   - 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.

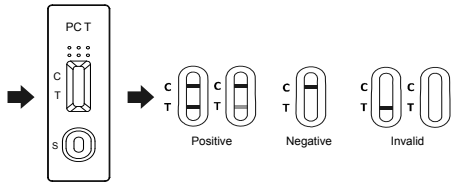
   Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
   - Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
   - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (S) of the Test Cassette.
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, nonhemolyzed specimens.
4. 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 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 run within two days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. 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.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents

TEST PROCEDURE
Allow test cassette, specimen, Buffer and/or controls to equilibrate to room temperature (15-30 C) prior to testing.
1. Remove the Test Cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the Test Cassette on a clean and level surface.
   For **Serum or Plasma** specimens:
   - Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen well (S) of the Test Cassette, and **add 1 drop of Buffer** (approximately 40 µL), then start the timer. See illustration below.

   For **Venipuncture Whole Blood** specimens:
   - Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the Test Cassette, and **add 1 drop of Buffer** (approximately 40 µL), then start the timer. See illustration below.

   For **Fingerstick Whole Blood** specimens:
   - To use a capillary tube: Fill the capillary tube and **transfer approximately 50 µL of fingerstick whole blood specimen** to the specimen well (S) of the Test Cassette, then **add 1 drop of Buffer** (approximately 40 µL) and start the timer. See illustration below.
3. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.





INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).
***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of PCT antigen present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test 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 Cassette. 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.

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. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit; however, 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 Procalcitonin has been compared with a leading commercial PCT EIA test. The correlation between these two systems is over 98.8%.

LIMITATIONS OF THE PROCEDURE
1. TruQuick Procalcitonin is for in vitro diagnostic use only. This test should be used for the detection of PCT in whole blood, serum or plasma specimen.
2. TruQuick Procalcitonin cannot detect less than 1 ng/mL of PCT in specimens.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. In some instances elevated Procalcitonin levels, due to noninfectious reasons, can be observed:
   - During the first days after trauma or surgical intervention burns, release of proinflammatoric cytokines, lung cancer (oat cell carcinoma), Medullary Thyroid Carcinoma (C-Cell Carcinoma)
   - New born children, < 48hours
   - Severe cardiogenic shock

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity
TruQuick Procalcitonin correctly identified a panel of specimens when compared to a leading commercial PCT EIA test using clinical specimens. The results show that the sensitivity of TruQuick Procalcitonin is 98.7%, and the specificity is 98.9%.

Method		EIA		Total Results
TruQuick Procalcitonin	Results	Positive	Negative	
	Positive	231	3	234
	Negative	3	280	283
Total Results		234	283	517

Sensitivity: 98.7% (95% CI*: 96.3%-99.7%)
Specificity: 98.9% (95% CI*: 96.9%-99.8%)
Correlation: 98.8% (95% CI*: 97.8%-99.7%) *Confidence Intervals

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 15 replicates of three specimens: negative, low positive and high positive. The negative and positive values were correctly identified 99% of the time.
Inter-Assay Precision
Between-run precision was determined by using the same three specimens of negative, low positive and high positive of PCT in 15 independent assays. Three different lots of TruQuick Procalcitonin were tested. The specimens were correctly identified 99% of the time.

CROSSREACTIVITY
TruQuick Procalcitonin was tested with samples confirmed to contain the following: HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, *H. pylori*, Mononucleosis, CMV, Rubella and Toxoplasmosis positive specimens. The samples showed no crossreactivity

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

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

No interference was observed at the concentrations tested.

REFERENCES

1. Le Moullec JM, et al. The complete sequence of human procalcitonin. FEBS Letters 1984;167(1), 93-97.
2. Assicot M, et al. High serum procalcitonin concentrations in patients with sepsis and infection. Lancet 1993;341(8844), 515-518.
3. Meisner M, Reinhart K. Is procalcitonin really a marker of sepsis? Int J Intensive Care 2001;8(1), 15-25.
4. Sponholz C, et al. Diagnostic value and prognostic implications of serum procalcitonin after cardiac surgery: a systematic review of the literature. Critical Care 2006;10, R145.
5. Meisner M. Pathobiochemistry and clinical use of procalcitonin. Clin Chim Acta 2002;323, 17-29.

CE

SNTQ4010 **REV. 09/17**

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.