TruQuick™ Calprotectin 10T

A rapid, one step test for the qualitative detection of Calprotectin in feces specimen.

REF **TQ6225** IVD **Rx Only**

INTENDED USE
TruQuick Calprotectin is a rapid chromatographic immunoassay for the qualitative detection of Calprotectin in feces specimens. It is to aid in the diagnosis of inflammatory gastrointestinal disorders.

SUMMARY AND EXPLANATION OF THE TEST
Calprotectin is a 24 kDa dimer of calcium-binding proteins S100A8 and S100A9.[1] The complex accounts for up to 60% of the soluble protein content of the neutrophil cytosol.[2] Calprotectin becomes available in the intestinal lumen via leukocyte shedding,[3] active secretion,[2] cell disturbance, and cell death.[3] This results in elevated fecal calprotectin levels, which can be detected in the stool.[3] Elevated fecal calprotectin levels can indicate migration of neutrophils into the intestinal mucosa, which occurs during intestinal inflammation.[4] Fecal calprotectin has been used to detect intestinal inflammation, and can serve as a marker for inflammatory bowel diseases.[5] Calprotectin is useful as a marker, as it is resistant to enzymatic degradation, and can be easily measured in feces.[6]

BIOLOGICAL PRINCIPLES
The membrane of the Test Cassette is precoated with anti-Calprotectin antibody on the test line region of the test. During testing, the specimen reacts with particles coated with anti-Calprotectin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-Calprotectin antibody on the membrane and generate a colored line. The presence of this colored line in the test line 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 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 Cassette contains anti-Calprotectin antibody-coated particles and anti-Calprotectin antibody coated on the membrane.
- Specimen Collection Tubes with Extraction Buffer: A buffered solution containing ProClin 300 as a preservative. The Tubes are supplied ready to use.
- Package insert

MATERIALS NOT PROVIDED
- Specimen collection containers
- Timer
- Droppers

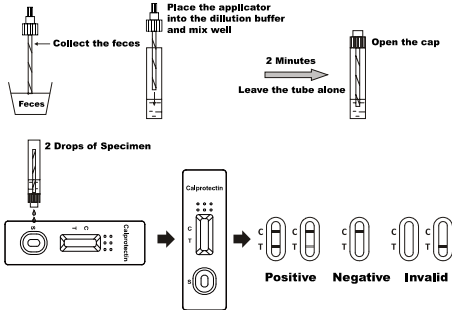
PRECAUTIONS
1. All reagents are for in vitro diagnostic use only. Do not use after expiration date.
2. The test should remain in the sealed pouch until use.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. The used test should be discarded according to local regulations.
7. 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
The kit can be stored at room temperature or refrigerated (2-30 C). The Test Cassette is stable through the expiration date printed on the sealed pouch. The Test Cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
2. Bring the necessary reagents to room temperature before use.

TEST PROCEDURE
Allow the test, specimen, Buffer and/or controls to reach room temperature (15-30 C) prior to testing.
1. To collect fecal specimens:
   Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimens may be stored for 3 days at 2-8 C if not tested within 6 hours. For long term storage, specimens should be kept below -20 C.
2. To process fecal specimens:
   - For Solid Specimens:
     Unscrew the cap of the Specimen Collection Tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
   - For Liquid Specimens:
     Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the Specimen Collection Tube containing the Extraction Buffer.
3. Tighten the cap onto the Specimen Collection Tube, then shake the tube vigorously to mix the specimen and the Extraction Buffer. Leave the tube alone for 2 minutes.
4. Bring the pouch to room temperature before opening it. Remove the Test Cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
5. Hold the Specimen Collection Tube upright and open the cap onto the Specimen Collection Tube. Invert the tube and transfer 2 full drops of the extracted specimen (approximately 80 µL) to the specimen well (S) of the Test Cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
6. Read results at 5 minutes after dispensing the specimen. Do not read results after 10 minutes.
7. **Note:** If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the Extraction Buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new Test Cassette and start afresh following the instructions mentioned above.



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 Calprotectin present in the specimen. 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.

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 Calprotectin was compared with another leading commercial rapid test. The correlation between the two systems was 98.5%

LIMITATIONS OF THE PROCEDURE
1. TruQuick Calprotectin is for in vitro diagnostic use only.
2. TruQuick Calprotectin will only indicate the presence of Calprotectin, the concentration of Calprotectin cannot be determined with the rapid test.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. Other clinically available tests are required if questionable results are obtained.

SPECIFIC PERFORMANCE CHARACTERISTICS
TruQuick Calprotectin was compared with another leading commercial rapid test using clinical specimens.

Method		Other Rapid Test		Total Result
TruQuick Calprotectin	Results	Positive	Negative	
	Positive	133	2	135
	Negative	3	198	201
Total Result		136	200	336

Sensitivity: 97.8% (95% CI*: 93.7%~99.5%);
Specificity: 99.0% (95% CI*: 96.4%~99.9%);
Correlation: 98.5% (95% CI*: 96.6%~99.5%). *Confidence Intervals

ANALYTICAL SENSITIVITY
TruQuick Calprotectin can detect levels of Calprotectin as low as 50 µg/g feces or 140 ng/mL Extraction Solution.

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 10 replicates of four specimens: 0 ng/mL, 140 ng/mL, 500 ng/mL and 10 µg/mL. The specimens were correctly identified > 99% of the time.
Inter-Assay Precision
Between-run precision was determined by 10 independent assays on the same four specimens: 0 ng./mL, 140 ng/mL, 500 ng/mL and 10 µg/mL. Three different lots of TruQuick Calprotectin were tested. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY

TESTS FOR INTERFERING SUBSTANCES
The following potentially interfering substances were tested with TruQuick Calprotectin. None of the substances interfered at the concentrations tested.

Ascorbic acid 20 mg/dL	Urea 2 g/dL
Oxalic acid 60 mg/dL	Glucose 2 g/dL
Bilirubin 100 mg/dL	Caffeine 40 mg/dL
Uric acid 60 mg/dL	Albumin 2 g/dL
Aspirin 20 mg/dL	

REFERENCES

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3. Lehmann FS, Burri E, Beglinger C. The role and utility of faecal markers in inflammatory bowel disease. Therapeutic Advances in Gastroenterology. 2014 Oct 13;8 (1): 23–36.
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5. Marshall WM, Lapsley M, Day A, Ayling R. Clinical biochemistry: Metabolic and clinical aspects (3 ed.). Elsevier Health Sciences. 2014.
6. Tibble J, Teahon K, Thjodleifsson B, Roseth A, Sigthorsson G, Bridger S, et al. A simple method for assessing intestinal inflammation in Crohn's disease. Gut. 2000;47 (4):506-13.

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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
	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
	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	R_x 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.