TruQuick™ Chagas 40T

A rapid test for the qualitative detection of IgG anti-*Trypanosoma cruzi* (*T. cruzi*) in whole blood, serum or plasma.

REF **TQ2540** IVD **R_x Only**

INTENDED USE
TruQuick Chagas is a lateral flow chromatographic immunoassay for the qualitative detection of IgG anti-*T. cruzi* in serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with *T. cruzi*. Any positive reaction with TruQuick Chagas should be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST
Chagas disease is an insect-borne, zoonotic infection by the protozoan *T. cruzi*, which causes a systemic infection of humans with acute manifestations and long term sequelae. It is estimated that 16-18 million individuals are infected worldwide, and roughly 50,000 people die each year from chronic Chagas disease (World Health Organization).[1]

Buffy coat examination and xenodiagnosis used to be the most commonly used methods[2, 3] in the diagnosis of acute *T. cruzi* infection. However, both methods are either time consuming or lack of sensitivity. Recently, serological testing has become the mainstay in the diagnosis of Chagas's disease. In particular recombinant antigen-based tests eliminate false-positive reactions which are commonly seen in the native antigen tests.[4-5]

TruQuick Chagas is a rapid antibody test which detects IgG antibodies to *T. cruzi* within 15 minutes without any instrument requirements. By utilizing *T. cruzi*-specific recombinant antigen, the test is highly sensitive and specific.

BIOLOGICAL PRINCIPLES
TruQuick Chagas is a qualitative, membrane based immunoassay for the detection of IgG anti-*T. cruzi* in whole blood, serum or plasma. The membrane is precoated with recombinant mouse anti-human IgG on the test line region of the cassette. During testing, the whole blood, serum or plasma specimen reacts with recombinant Chagas antigen conjugated to colloidal gold. The mixture migrates along the membrane by capillary action to react with mouse anti-human IgG on the membrane and generate a colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear at 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: TruQuick Chagas contains recombinant Chagas antigen-conjugated to colloidal gold and mouse anti-human IgG coated on the membrane. Each cassette is packaged in a foil pouch.
- Buffer: A buffered solution containing Proclin as a preservative. The Buffer is supplied in a dropper vial ready for use.
- Droppers
- Package Insert

MATERIALS NOT PROVIDED
- Specimen collection containers
- Centrifuge (for plasma only)
- Timer
- Lancets (for fingerstick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

PRECAUTIONS
1. All reagents are for in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure 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 assayed.
5. Humidity and temperature can adversely affect results.

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

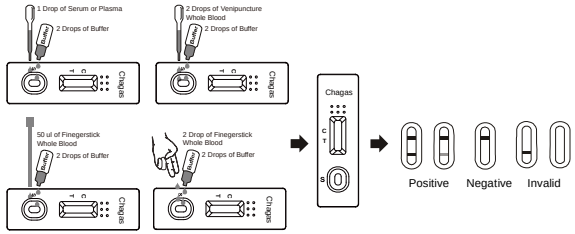
SHELF LIFE AND STORAGE
The kit can be stored at room temperature or refrigerated (2-30 C). The Test Cassette is stable through the expiration date printed on the sealed pouch. The Test Cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. TruQuick Chagas can be performed using whole blood (from venipuncture or fingerstick), serum or plasma. Collect and prepare whole blood, serum and plasma using standard laboratory methods.
2. 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 area of the Test Cassette.

   Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
   - Position the patient's finger so that the drop of blood is just above the specimen area of the Test Cassette.
   - Allow two hanging drops of fingerstick whole blood to fall into the center of the specimen area on the Test Cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
3. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
4. Testing should be performed immediately after the specimens have been collected. 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 federal regulations for transportation of etiologic agents.

TEST PROCEDURE
Allow Test Cassette, Buffer, specimen, and/or controls to equilibrate to room temperature (15-30 C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the Test Cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the cassette on a clean and level surface.
   For **Serum or Plasma** specimen: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen area, then **add 2 drops of Buffer** (approximately 80 µL) and start the timer. See illustration below.
   For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen area, then **add 2 drops of Buffer** (approximately 80 µL) and start the timer. See illustration below.
   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube **and transfer approximately 50 µL of fingerstick whole blood specimen** to the specimen area of Test Cassette, then **add 2 drops of Buffer** (approximately 80 µL) and start the timer. See illustration below.
   - To use hanging drops: Allow **2 hanging drops of fingerstick whole blood specimen** (approximately 50 µL) to fall into the specimen area of Test Cassette, then **add 2 drops of Buffer** (approximately 80 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. The test 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 Chagas antibodies present in the specimen. Therefore, any shade of red in the test region should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No apparent red or pink line appears in the test region.
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 positive 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 plese contact Meridian's Technical Services Departmet at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES
TruQuick Chagas has been compared with a leading commercial Chagas EIA test. The correlation between these two systems is 98.1%.

LIMITATIONS OF THE PROCEDURE
1. The TEST PROCEDURE and the INTERPREATION OF RESULTS sections must be followed closely when testing the presence of anti-*T. cruzi* antibody in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. TruQuick Chagas is limited to the qualitative detection of anti-*T. cruzi* antibody in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-*T. cruzi* antibody. However, a negative test result does not preclude the possibility of exposure to or infection with *T. cruzi*.
4. A negative result can occur if the quantity of the anti-*T. cruzi* antibody present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
A total of 264 samples from susceptible subjects were tested by TruQuick Chagas and by a commercial Chagas EIA kit. Comparison for all subjects is shown in the following table.

Method		EIA		Total Result
TruQuick Chagas	Results	Positive	Negative	
	Positive	13	4	17
	Negative	1	246	247
Total Result		14	250	264

Sensitivity: 92.9% (95% CI*: 66.1%-99.8%)
Specificity: 98.4% (95% CI*: 96.0%-99.6%)
Correlation: 98.1% (95% CI*: 95.6%-99.4%) *Confidence Intervals

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 10 replicates of serum and plasma for four specimens: a negative, a low positive, a medium positive and a high positive. The replicates produced the correct result > 99% of the time.
Inter-Assay Precision
Between-run precision was determined by 10 independent assays on serum and plasma for the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the TruQuick Chagas were tested. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY
TruQuick Chagas was tested with samples from patients diagnosed with HAMA, RF, HAV, HBV, HCV, HEV, Syphilis, HIV, Mononucleosis, CMV, Rubella and Toxoplasmosis. The results showed no crossreactivity.

TESTS FOR INTERFERING SUBSTANCES
Interfering Substances
The following potentially interfering substances were added to TruQuick Chagas 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/mL	Albumin 2 g/dL
Creatine 200 mg/dL	Hemoglobin 1000 mg/dL
Bilirubin 1 g/dL	Oxalic Acid 60 mg/dL

None of the substances interfered in the assay at the concentration tested.

REFERENCES

1. WHO. Control of Chagas disease: report of a WHO expert committee. 1991.
2. Frasch ACC, Reyes MB, Sanchez DO. Diagnosis of Chagas disease: present and future. In: Chagas disease and the nervous system. Washington, DC: pan AHO. 1994:47-53.
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4. Lorca M, Gonzalez A, Reyes V, Veloso C, Vergara U, Frasch C. The diagnosis of chronic Chagas disease using recombinant antigens of *Trypanosoma cruzi*. Rev Med Chil. 1993;121(4):363-8.
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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

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.