TruQuick™ CHIK IgG/IgM 40T

A rapid test for the qualitative detection of IgG and IgM antibodies to Chikungunya in whole blood, serum or plasma.

REF **TQ2140** IVD **Rx Only**

INTENDED USE

TruQuick CHIK IgG/IgM is a rapid immunoassay for the qualitative detection of IgG and IgM antibodies to Chikungunya in whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Chikungunya. Any positive reactions with TruQuick CHIK IgG/IgM should be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

Chikungunya is a rare viral infection transmitted by the bite of infected mosquitoes, predominantly *Aedes aegypti* mosquito. It is characterized by a rash, fever, and severe joint pain (arthralgia) that usually lasts for three to seven days. The name is derived from the Makonde word meaning 'that which bends up' in reference to the stooped posture developed as a result of the arthritic symptoms of the disease. It occurs during the rainy season in tropical areas of the world, primarily in Africa, South-East Asia, southern India and Pakistan.[1, 2]

The symptoms are most often clinically indistinguishable from those observed in dengue fever. Indeed, dual infection of dengue and chikungunya has been reported in India.[3] Unlike dengue, hemorrhagic manifestations are relatively rare and most often the disease is a self limiting febrile illness. Therefore it is very important to clinically distinguish dengue from Chikungunya infection.

Chikungunya is diagnosed based on serological analysis and viral isolation in mice or tissue culture. An IgM immunoassay is the most practical lab test method.[4]

BIOLOGICAL PRINCIPLES

TruQuick CHIK IgG/IgM is a qualitative, membrane-based immunoassay for the detection of IgG and IgM antibodies to Chikungunya in whole blood, serum or plasma. The membrane is precoated with mouse anti-human IgG and mouse anti-human IgM at the test line region of the cassette. During testing, the whole blood, serum or plasma specimen reacts with recombinant Chikungunya antigen conjugated to colloidal gold. The mixture migrates along the membrane by capillary action to react with mouse anti-human IgG or/and mouse anti-human IgM 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: The Test Cassette contains recombinant Chikungunya antigen conjugated to colloidal gold, mouse anti-human IgG and mouse anti-human IgM 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
- Lancets (for fingerstick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
- Centrifuge (for plasma only)
- Timer

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 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. TruQuick CHIK IgG/IgM can be performed using whole blood (from venipuncture or fingerstick), serum or plasma. Collect and prepare whole blood, serum or plasma according to 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.

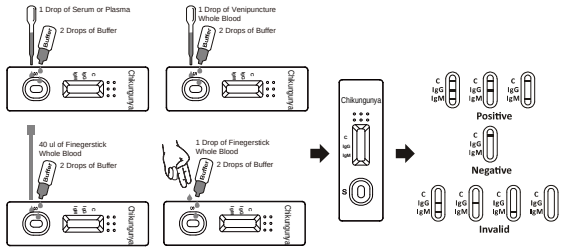
   Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:
   - Touch the end of the capillary tube to the blood until filled to approximately 40 µL. Avoid air bubbles.
   - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to 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 one hanging drop 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 40 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 1 drop of whole blood** (approximately 40 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 40 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 **1 hanging drop of fingerstick whole blood specimen** (approximately 40 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. Read the result at 15 minutes, do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above.)

IgG POSITIVE: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the IgG region.

IgM POSITIVE: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the IgM region.

IgG and IgM POSITIVE: Three distinct colored lines appear. One colored line should be in the control region (C) and another two colored lines should be in the IgG and IgM regions.

NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of Chikungunya 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 IgG and IgM 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 please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES

Chikungunya virus infection occurs in people who live in or travel to areas with active mosquito populations including countries of Africa, Asia, Europe and Indian and Pacific Oceans. TruQuick CHIK IgG/IgM correlates closely with other commercially available IgM/IgG assays with samples from patients from these areas (correlation 92.5%).

LIMITATIONS OF THE PROCEDURE

1. The TEST PROCEDURE and the INTERPRETATION OF RESULTS sections must be followed closely when testing for the presence of antibodies to Chikungunya in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. TruQuick CHIK IgG/IgM is limited to the qualitative detection of antibodies to Chikungunya in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable Chikungunya antibodies. However, a negative test result does not preclude the possibility of exposure to Chikungunya.
4. A negative result can occur if the quantity of Chikungunya antibodies 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. 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 93 samples from susceptible subjects were tested by TruQuick CHIK IgG/IgM and by a commercial Chikungunya IgM EIA kit. Comparison for all subjects is shown in the following table.

IgM Results

Method		EIA		Total Result
TruQuick CHIK IgG/IgM	Results	Positive	Negative	
	Positive	65	0	65
	Negative	7	21	28
Total Result		72	21	93

Sensitivity: 90.3% (95% CI: *81.0%-96.0%)
Specificity: > 99.9% (95% CI: *86.7%-100%)
Correlation: 92.5% (95% CI: *85.1%-96.9%)
*Confidence Intervals

A total of 68 samples from susceptible subjects were tested by TruQuick CHIK IgG/IgM and by a commercial Chikungunya IgG EIA kit. Comparison for all subjects is shown in the following table.

IgG Results

Method		EIA		Total Result
TruQuick CHIK IgG/IgM	Results	Positive	Negative	
	Positive	33	1	34
	Negative	2	32	34
Total Result		35	33	68

Sensitivity: 94.3% (95% CI: *80.8%-99.3%)
Specificity: 97.0% (95% CI: *84.2%-99.9%)
Correlation: 95.6% (95% CI: *87.6%-99.1%)
*Confidence Intervals

REPRODUCIBILITY

Intra-Assay Precision

Within-run precision was determined by using 10 replicates of serum and plasma for five specimens: a negative, a Chikungunya IgM middle titer positive, a Chikungunya IgM high titer positive, a Chikungunya IgG middle titer positive and a Chikungunya IgG high titer positive. The samples were correctly identified 100% of the time.

Inter-Assay Precision

Between-run precision was determined by 10 independent assays on serum and plasma for the same five specimens: a negative, a Chikungunya IgM middle titer positive, a Chikungunya IgM high titer positive, a Chikungunya IgG middle titer positive and a Chikungunya IgG high titer positive. Three different lots of the TruQuick CHIK IgG/IgM were tested over a 10 day period. The specimens were correctly identified 100% of the time.

CROSSREACTIVITY

TruQuick CHIK IgG/IgM has been tested with samples from patients with HAMA, RF, HAV, HBV, HEV, HCV, Syphilis, HIV, Mononucleosis, CMV, Rubella and Toxoplasmosis. The samples showed no crossreactivity.

TESTS FOR INTERFERING SUBSTANCES

The following potentially interfering substances were added to Chikungunya negative and positive specimens.

Acetaminophen 20 mg/dL	Caffeine 20 mg/dL
Acetylsalicylic Acid 20 mg/dL	Gentisic Acid 20 mg/dL
Ascorbic 20 mg/mL	Albumin 2 g/dL
Creatine 200 mg/dL	Hemoglobin 1000 mg/dL
Bilirubin 1 g/dL	Oxalic Acid 60 mg/dL
Uric acid 20 mg/dL	Methanol 10%

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

REFERENCES

1. Shah KV, Gibbs CJ Jr, Banerjee G. Virological investigation of the epidemic of haemorrhagic fever in Calcutta: isolation of three strains of Chikungunya virus. Indian J Med Res. 1964;52 676-83.
2. Powers AM, Brault AC, Tesh RB, Weaver SC. Re-emergence of Chikungunya and O'nyong-nyong viruses: evidence for distinct geographical lineages and distant evolutionary relationships. J Gen Virol. 2000;81:471-9.
3. Myers RM, Carey DE. Concurrent isolation from patient of two arboviruses, Chikungunya and dengue type 2. Science. 1967;157:1307-8.
4. Thein S, La Linn M, Aaskov J, Aung MM, Aye M, Zaw A, Myint A. Development of a simple indirect enzyme-linked immunosorbent assay for the detection of immunoglobulin M antibody in serum from patients following an outbreak of chikungunya virus infection in Yangon, Myanmar. Trans R Soc Trop Med Hyg. 1992 86:438-42.
5. Yamamoto K, Hashimoto K, Simizu B, Ogata T. Structural proteins of Chikungunya virus. J Virol. 1984 Jul;51(1):254-8.

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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.