TruQuick™ Rubella IgM 40T

A rapid test for the qualitative detection of IgM antibodies to Rubella in serum or plasma.

REF **TQ1140** IVD **Rx Only**

INTENDED USE
TruQuick Rubella IgM is a lateral flow chromatographic immunoassay for the qualitative detection of IgM antibodies to Rubella in serum or plasma to aid in the diagnosis of Rubella infection. Results of this test are used in conjunction with the results of other tests and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST
Rubella virus is a member of the Togaviridae family, found mainly in human populations. Generally rubella is considered a mild adolescence disease. However a maternal infection could be transmitted through the placenta to the fetus, causing congenital rubella. Primary rubella infection contracted during early pregnancy, may have severe consequences as severe fetal damage, stillbirth or abortion. Children born asymptomatic may develop these abnormalities later in life.[1, 2] Widespread vaccination has significantly reduced the incidence of rubella in all age groups. However, 10 to 20% of young adults still appear susceptible to the virus. To reduce the risk of severe complications, accurate serological methods must be performed to determine the serologic status of childbearing-aged women. TruQuick Rubella IgM is a rapid chromatographic immunoassay for the qualitative detection of IgM antibodies to rubella virus in serum or plasma specimens.

BIOLOGICAL PRINCIPLES
TruQuick Rubella IgM is a qualitative, lateral flow immunoassay for the detection of IgM antibodies to Rubella in serum or plasma specimens. In this test, Rubella Antigen iscoated in the test line region of the test. During testing, the serum or plasma specimen reacts with goat anti-human IgM-coated particles in the test strip. The mixture then migrates forward on the membrane by capillary action and reacts with the Rubella- Antigen on the membrane in the test line region respectively. The presence of a colored line in the test line region indicates a positive result for Rubella infection, while its absence indicates a negative result for that infection. To serve as a procedural control, a colored line will always appear in the control line region of the strip 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 contains goat anti-human IgM and Rubella antigen. A Streptavidin-rabbit IgG is employed in the control line system. 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

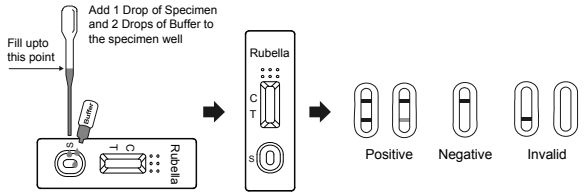
PRECAUTIONS
1. For in vitro diagnostic use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
4. Humidity and temperature can adversely affect results.
5. The used test should be discarded according to local regulations.

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 in the sealed pouch 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 Rubella IgM can be performed using either serum or plasma specimens. Collect serum and plasma samples according to standard laboratory methods.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, nonhemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8 C for up to three days. For long-term storage, specimens should be kept below -20 C.
4. 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.
5. If specimens are to be shipped, they should be packed in compliance with local regulations for the transportation of etiologic agents.

TEST PROCEDURE
Allow the test, specimen, Buffer and/or controls to reach room temperature (15-30 C) prior to testing.
1. Remove the Test Cassette from the sealed pouch and use it within one hour. Best results will be obtained if the assay is performed immediately after opening foil pouch.
2. Place the Test Cassette on a clean and level surface. Hold the dropper vertically, draw the specimen about **1 cm above** the upper end of the nozzle as shown in the illustration below.. Transfer 1 full drop (**approx. 20 µL**) of specimen to each specimen well, then add 2 drops of Buffer (approximately 80 µL) to the sample well and start the timer. See the illustration below.
3. Wait for the colored line(s) to appear. The result should be read at 15 minutes. Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the test line region.
***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of Rubella antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.
NEGATIVE: **One colored line appears in the control line region (C)**. No line appears in the test line regions.
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 individually for both two sections. Two colored lines appearing in the control region (C) for both two sections is the internal 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 Rubella IgM has been compared with leading commercial EIA Rubella tests, demonstrating an overall accuracy of 98.3%.

LIMITATIONS OF THE PROCEDURE
1. TruQuick Rubella IgM is for in vitro diagnostic use only. This test should be used for detection of IgM antibodies to Rubella in serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgM antibodies to Rubella can be determined by this qualitative test.
2. TruQuick Rubella IgM will only indicate the presence of IgM antibodies to Rubella in the specimen and should not be used as the sole criteria for the diagnosis of Rubella infections.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Rubella infection.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
TruQuick Rubella IgM was compared with leading commercial EIA Rubella tests; the results show that TruQuick Rubella IgM has a high sensitivity and specificity.

Method		Rubella EIA (IgM)		Total Results
TruQuick Rubella IgM	Results	Positive	Negative	
	Positive	33	3	36
	Negative	2	262	264
Total Results		35	265	300

Sensitivity: 94.3% (95% CI*: 80.8%-99.3%) *Confidence Interval
Specificity: 98.9% (95% CI*: 96.7%-99.8%)
Correlation: 98.3% (95% CI*: 96.2%-99.5%)

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 10 replicates of three specimens: a negative, a low positive and a high positive. Samples were correctly identified > 99% of the time.

Inter-Assay Precision
Between-run precision was determined by 10 independent assays on the same three specimens: a negative, a low positive and a high positive. Three different lots of the TruQuick Rubella IgM were tested. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY
TruQuick Rubella IgM were tested with samples from patients diagnosed with HAV, HBV, HCV, HIV, RF, Syphilis, *H. pylori*, CMV, Toxoplasmosis and HSV 1/2. The results showed no crossreactivity.

TESTS FOR INTERFERING SUBSTANCES
TruQuick Rubella IgM has been tested and no interference was observed in specimens containing the following compounds.

Acetaminophen 20 mg/dL	Caffeine 20 mg/dL	EDTA 20 mg/dL
Acetylsalicylic Acid 20 mg/dL	Gentisic Acid 20 mg/dL	Ethanol 10%
Ascorbic Acid 2 g/dL	Phenylpropanolamine 20 mg/dL	Glucose 20 mg/dL
Bilirubin 1 g/dL	Salicylic Acid 20 mg/dL	Phenothiazine 20 mg/dL

REFERENCES

1. Mellinger AK, Cragan ID. Atkinson WL et al. High incidence of congenital rubella syndrome after a rubella ourbreak. Ped Infect Dis J. 1995;14:573-5.
2. Herrman KL. Rubella virus In: Lennette EH, Balows AC, Hausler WJ, Shadomy HJ. editors. Manual of Clinical Microbiology, ASM, Washington, DC. 1985;Ch. 6.779-754.

SNTQ1140 **REV. 05/17**

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

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.