TruQuick™ CMV IgM 40T

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

REF **TQ1040** IVD **Rx Only**

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

SUMMARY AND EXPLANATION OF THE TEST
Cytomegalovirus is a herpes virus. It is a leading etiological agent for congenital abnormalities and complications among those who receive massive blood transfusions and immunosuppressive therapy. About half of pregnant women who contract a primary infection spread the disease to their fetus.[1-3] Infection during pregnancy may cause mental retardation, blindness, and/or deafness of the neonate. The detection of anti-CMV IgM antibodies enables effective diagnosis of acute or recent CMV infection. TruQuick CMV IgM is a rapid chromatographic immunoassay for the qualitative detection of IgM antibodies to CMV in serum or plasma specimens.

BIOLOGICAL PRINCIPLES
In this test, antigens of CMV are coated in the test line regions of the Test Cassette. 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 CMV-specific antigens on the membrane in the test line region. The presence of a colored line in the test line region indicates a positive result for CMV 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: Test Cassettes carry goat anti-human IgM, and CMV antigen. A streptavidin-IgG is employed in the control line system. Each cassette is packaged in a foil pouch.
- Buffer: A Buffered solution containing ProClin 300 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

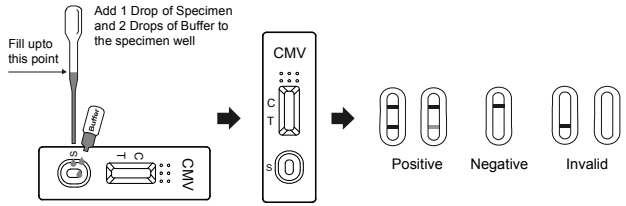
PRECAUTIONS
1. For in vitro diagnostic use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
4. Humidity 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 CMV IgM can be performed using either serum or plasma specimens. Collect serum or plasma using standard laboratory methods.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed 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 3 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. 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 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 illustration below. Transfer 1 full drop **(approx. 20 µL)** of specimen to the sample well, then add two drops of Buffer (approximately 80 µL) 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 region may vary depending on the concentration of CMV 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. 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
TruQuick CMV IgM has been compared with leading commercial EIA CMV tests, demonstrating an overall accuracy of 98.9%.

LIMITATIONS OF THE PROCEDURE
1. TruQuick CMV IgM is for in vitro diagnostic use only. This test should be used for detection of IgM antibodies to CMV in serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgM antibodies to CMV can be determined by this qualitative test.
2. TruQuick CMV IgM will only indicate the presence of IgM antibodies to CMV in the specimen and should not be used as the sole criteria for the diagnosis of CMV 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 CMV infection.

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

Method		CMV EIA (IgM)		Total Results
	Results	Positive	Negative	
TruQuick CMV IgM	Positive	28	4	32
	Negative	2	266	268
Total Results		30	270	300

Sensitivity: 93.3% (95% CI*: 77.9%-99.2%)
Specificity: 98.5% (95% CI*: 96.3%-99.69%)
Correlation: 98.0% (95% CI*: 95.7%-99.3%)
*Confidence Interval

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. The 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 TruQuick CMV IgM were tested. The specimens were correctly identified > 99% of the time.

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

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

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

REFERENCES

1. Starr SE, Friedman HM. Human CMV. Chapter 65. In Manual of Clin. Microbiol., 4th ed., Lennett EH, et al. ed. Am. Soc. Microbiol. 1985;pp. 771-719.
2. Jor MC. Latent infection and the elusive cytomegalovirus. Rev. Infect. Dis. 1983;5:205-215.
3. Starr SE. Cytomegalovirus. Ped. Clin. N. Am. 1979;26:282-293.

SNTQ1040 **REV. 06/17**

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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
	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.