TruQuick™ HSV 1,2 IgM 40T

A rapid test for the qualitative detection of IgM antibody to HSV 1/2 in whole blood, serum or plasma.

REF **TQ2040** IVD **Rx Only**

INTENDED USE
TruQuick HSV 1,2 IgM is a lateral flow chromatographic immunoassay for the detection of IgM anti-HSV 1/2 in whole blood, serum or plasma. This kit is intended to be used as an aid in the diagnosis of infection with HSV 1/2.

SUMMARY AND EXPLANATION OF THE TEST
Herpes simplex virus 1 and 2 (HSV-1 and HSV-2), also known as human herpesvirus 1 and 2 (HHV-1 and HHV-2), are two members of the herpesvirus family, Herpesviridae, that infect humans.[1] Both HSV-1 (which produces most cold sores) and HSV-2 (which produces most genital herpes) are ubiquitous and contagious. They can be spread when an infected person is producing and shedding the virus. According to the World Health Organization, 67% of the world population under the age of 50 have HSV-1.

Symptoms of herpes simplex virus infection include watery blisters in the skin or mucous membranes of the mouth, lips, nose or genitals.[2] Lesions heal with a scab characteristic of herpetic disease. Sometimes, the viruses cause very mild or atypical symptoms during outbreaks. However, they can also cause more troublesome forms of herpes simples. As neurotropic and neuroinvasive viruses, HSV-1 and HSV-2 persist in the body by becoming latent and hiding from the immune system in the cell bodies of neurons. After the initial or primary infection some infected people experience sporadic episodes of viral reactivation or outbreaks. In an outbreak, the virus in a nerve cell becomes active and is transported via the neuron's axon to the skin, where virus replication and shedding occur and cause new sores.[2] It is one of the most common sexually transmitted infections.[3]

The detection of anti-HSV 1/2 IgM antibody enables effective diagnosis of acute or recent HSV 1/2 infection. TruQuick HSV 1/2 IgM is a rapid chromatographic immunoassay for the qualitative detection of IgM antibody to HSV 1/2 in whole blood, serum or plasma specimens.

BIOLOGICAL PRINCIPLES
In this test, HSV 1/2 antigen is coated in the test line region of the test. During testing, the whole blood, 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 HSV 1/2 antigen on the membrane in the test line region. The presence of a colored line in the test line region indicates a positive result for HSV 1/2 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 HSV 1/2 antigen. A Streptavidin-rabbit IgM 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 contain
- Centrifuge
- Timer

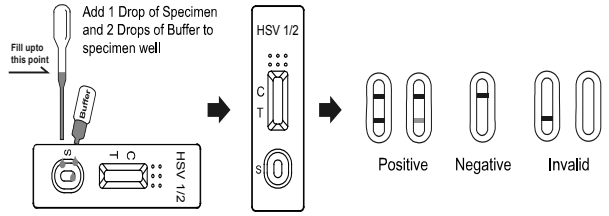
PRECAUTIONS
1. For in vitro diagnostic use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Dispose of all specimens and materials used to perform the test as biohazardous waste.
4. This package insert must be read completely before performing the test.
5. Bring all reagents to room temperature (15-30 C) before use.

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 HSV 1,2 IgM can be performed using whole blood, serum or plasma. Collect whole blood, serum or plasma using standard laboratory methods.
2. Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
3. 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.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8 C if the test is to be run within two days of collection. For long term storage, specimens should be kept below -20 C. 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 for more than three times.
6. If specimens are to be shipped, they should be packed in compliance with federal regulations covering 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 each sample well, then add 2 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 lines appear. One colored line should always appear in the control line region (C) and another colored line(s) 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 HSV antibody 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 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. 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 HSV 1,2 IgM was compared with a leading commercial HSV IgM ELISA test. The correlation between these two systems is 97.9%

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

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
TruQuick HSV 1,2 IgM was compared with a leading commercial EIA HSV 1/2 test using specimens obtained from symptomatic and asymptomatic individuals. The results show that TruQuick HSV 1,2 IgM has a high sensitivity and specificity.

Table: Clinical Study Results

Method		HSV 1/2 IgM EIA		Total Results
TruQuick HSV 1,2 IgM	Results	Positive	Negative	
	Positive	32	4	36
	Negative	3	301	304
Total Result		35	305	340

Sensitivity: 91.4% (95% CI*: 76.9%-98.2%) *Confidence Interval
Specificity: 98.7% (95% CI*: 96.7%-99.6%)
Correlation: 97.9% (95% CI*: 95.8%-99.2%)

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 10 replicates of serum and plasma for three specimens: a negative, a low positive, and a high positive. The negative, low positive, and high positive samples were correctly identified > 99% of the time.
Inter-Assay Precision
Between-run precision was determined by 10 independent assays for serum and plasma using the same three specimen types: a negative, a low positive, and a high positive. Three different lots of TruQuick HSV 1,2 IgM were tested. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY
TruQuick HSV 1,2 IgM was tested with samples from patients diagnosed with HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV, HIV, Syphilis, *H. pylori*, Toxoplasmosis, CMV and Rubella. The samples showed no crossreactivity.

TESTS FOR INTERFERING SUBSTANCES
The following compounds were tested using TruQuick HSV 1,2 IgM and no interference was observed.

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. Ryan KJ, Ray CG, eds. Sherris Medical Microbiology 4th ed. McGraw Hill. 2004;p. 555-62.
2. Herpes simplex. DermNet NZ. New Zealand Dermatological Society. 2006 Sep 16.
3. Straface G, Selmin A, Zanardo V, De Santis M, Ercoli, A, Scambia G. Herpes simplex virus infection in pregnancy. Inf Dis in Ob and Gyn. 2012;p. 1-6.

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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.