TruQuick™ HIV 1,2,O 40T

A rapid test for the diagnosis of Human Immunodeficiency Virus to detect antibodies to HIV type 1, type 2 and Subtype O qualitatively in whole blood, serum or plasma.

REF **TQ5740** IVD **Rx Only**

INTENDED USE

TruQuick HIV 1,2,O is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) type 1, type 2 and subtype O in whole blood, serum or plasma to aid in the diagnosis of HIV infection

SUMMARY AND EXPLNATION OF THE TEST

HIV (Human Immunodeficiency Virus) is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from the host cell membrane. Several viral glycoproteins are on the envelope. Each virus contains two copies of positive-sense genomic RNAs. HIV-1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy people with high potential risk for developing AIDS.[1] HIV-1 consists of Subtype M and Subtype O. Highly divergent strains of HIV-1 were first recognized in 1990 and grouped provisionally as Subtype O as this variation has similar glycoprotein markers to HIV-1 but a slight variation to the protein marker. Although rarely compared to HIV-1 and HIV-2, infections caused by Subtype O have so far been identified in Africa (Cameroon), France and Germany. HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals.[2] HIV-1, HIV-2, and Subtype O all elicit immune responses.[3] Detection of HIV antibodies in serum, plasma or whole blood is the most efficient and common way to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV.[4] Despite the differences in their biological characters, serological activities and genome sequences, HIV-1, HIV-2, and Subtype O show strong antigenic cross-reactivity.[5, 6] Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.

TruQuick HIV 1,2,O is a rapid test to qualitatively detect the presence of antibodies to HIV type 1, type 2, and/or Subtype O in whole blood, serum or plasma specimen.

BIOLOGICAL PRINCIPLES

TruQuick HIV 1,2,O is a qualitative, membrane based immunoassay for the detection of antibodies to HIV-1, HIV-2, and Subtype O in whole blood, serum or plasma. The membrane is precoated with recombinant HIV antigens in the test line regions, T1 and T2. The T1 test line is precoated with HIV-1 and Subtype O antigen and the T2 test line is pre-coated with HIV-2 antigen. During testing, the whole blood, serum or plasma specimen reacts with HIV antigen coated particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with recombinant HIV antigen on the membrane in the test line region. If the specimen contains antibodies to HIV-1 and/or Subtype O, or HIV-2, one colored line will appear in the test line region; if the specimen contains antibodies to HIV-1 and/or Subtype O, and HIV-2, two colored lines will appear in the test line region. Both indicate a positive result. If the specimen does not contain HIV-1, Subtype O, and/or HIV-2 antibodies, no colored line will appear in the test line region indicating a negative result. To serve as a procedural control, a colored line will always appear in 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 contains HIV type 1, type 2, and Subtype O recombinant antigens coated particles and HIV type 1, type 2, and Subtype O recombinant antigens coated on the membrane.
- 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
- Lancets (for fingerstick whole blood only)
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

PRECAUTIONS

1. For in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. The used test should be discarded according to local regulations.
7. 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

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 HIV 1,2,O can be performed using whole blood (from venipuncture or fingerstick) serum or plasma.
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.

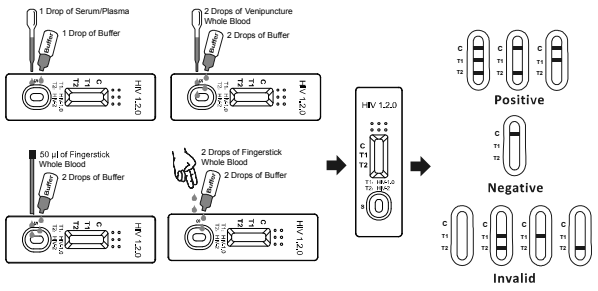
   Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
   - Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
   - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood 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 serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
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 local 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.
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 1 drop of Buffer** (approximately 40 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 drop of Buffer** (approximately 80 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above.)

POSITIVE:* Two or three distinct colored lines appear. One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).

***NOTE:** The intensity of the color in the test line region (T1 and T2) will vary depending on the concentration of HIV antibodies present in the specimen. Therefore, any shade of color in the test line region (T1 and/or T2) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and T2).

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 device. If the problem persists, discontinue using the test kit immediately and contact Meridian's Technical Service 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 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 HIV 1,2,O was compared with a leading commercial HIV EIA test. The correlation between these two systems is 99.9%.

LIMITATIONS OF THE PROCEDURE

1. TruQuick HIV 1,2,O is for in vitro diagnostic use only. The test should be used for the detection of HIV antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in HIV antibodies can be determined by this qualitative test.
2. TruQuick HIV 1,2,O will only indicate the presence of HIV antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HIV infection.
3. As with all rapid test cassettes, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of HIV infection.

SPECIFIC PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

TruQuick HIV 1,2,O has correctly identified specimens of seroconversion panel and has been compared to a leading commercial ELISA HIV test using clinical specimens. The results show that the sensitivity of the TruQuick HIV 1,2,O is >99.9% and the specificity is 99.9%.

Method		ELISA		Total Result
TruQuick HIV 1,2,O	Results	Positive	Negative	
	Positive	148	2	150
	Negative	0	1728	1728
Total Result		148	1730	1878

Sensitivity: > 99.9% (98.0%-100%)*
Specificity: 99.9% (99.6%-100%)*
Correlation: 99.9% (99.6%-100%) *

*95% Confidence Intervals

REPRODUCIBILITY

Intra-Assay Precision

Within-run precision was determined by using 10 replicates of eight specimens: a negative, a HIV-1 low positive, a HIV-1 medium positive and a HIV-2 low positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assay Precision

Between-run precision was determined by 10 independent assays on the same eight specimens: a negative, a HIV-1 low positive, a HIV-1 medium positive and a HIV-2 low positive. Three different lots of TruQuick HIV 1,2,O were tested over a three day period using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY

TruQuick HIV 1,2,O was tested by RF, HBsAg, HBsAb, HbeAg, HBeAb, HBcAb, anti-Syphilis, anti-HCV, anti-*H. pylori*, HAMA, Mononucleosis, EBV IgM, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no crossreactivity.

TESTS FOR INTERFERING SUBSTANCES

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

Acetaminophen 20 mg/dL	Caffeine 20 mg/dL
Acetylsalicylic Acid 20 mg/dL	Gentistic Acid 20 mg/dL
Ascorbic Acid 20 mg/mL	Albumin 2 g/dL
Creatine 200 mg/dL	Hemoglobin 1.1 g/dL
Bilirubin 1 g/dL	Oxalic Acid 600mg/dL

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

REFERENCES

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2. Arya SK, Beaver B, Jagodzinski L, Ensoli B, Kanki PJ, Albert J, et al. New human and simian HIV-related retroviruses possess functional transactivator (tat) gene. Nature 1987;328:548-550.
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4. Janssen RS, Satten GA, Stramer SL, Rawal BD, O'Brien TR, Weiblen BJ, et al. New testing strategy to detect early HIV-1 infection for use in incidence estimates and for clinical and prevention purposes. JAMA 1998;280(1): 42-48.
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6. Greenberg AE, Wiktor SZ, DeCock KM, Smith P, Jaffe HW, Dondero TJ, Jr. HIV-2 and natural protection against HIV-1 infection. Science 1996;272:1959-1960.

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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.