

IMMUNOQUICK® HIV



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. For professional *in vitro* diagnostic use only.

INTENDED USE

The IMMUNOQUICK® HIV Rapid Test Cassette (Whole Blood/Serum/Plasma) 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

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. The IMMUNOQUICK® HIV Rapid Test Cassette (Whole Blood/Serum/Plasma) 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.

TEST PRINCIPLE

The IMMUNOQUICK® HIV Rapid Test Cassette (Whole Blood/Serum/Plasma) 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 pre-coated with recombinant HIV antigens in the test line regions, T1 and T2. The T1 test line is pre-coated 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

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.

MATERIAL PROVIDED

- Test cassettes
- Droppers
- Buffer
- Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
- Centrifuge
- Timer

STORAGE AND STABILITY

Store as packaged in the sealed pouch either 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 after the expiration date.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.

- Do not eat, drink or smoke in the area where the specimens or test cassettes are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION AND STORAGE

The IMMUNOQUICK® HIV Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

- 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 2 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.
 - Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
 - 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 3 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 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
 - 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.
 - If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

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.

BIOSYNEX



BIOSYNEX
12, rue Eitoré Bugatti – CS28006
67038 STRASBOURG Cedex – France

Tél. : +33 3 88 77 57 00
Fax : +33 3 59 81 21 74

info@biosynex.com
www.biosynex.com