HIV Rapid Test Device

(Whole Blood /Serum/Plasma)

Dia Sure

REF: HIV-W23

INTENDED USE

The HIV Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative, presumptive detection of antibodies to HIV-1/HIV-2 in human whole blood, serum or plasma specimens. This kit is intended for use as an aid in the diagnosis of HIV infection. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

INTRODUCTION

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from 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. HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals. Both HIV-1 and HIV-2 elicit immune response. 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.

PRINCIPLE

The HIV Rapid Test Device (Whole Blood/Serum/Plasma) detects antibodies to HIV-1/HIV-2 through visual interpretation of color development on the internal strip. Recombinant HIV-1/2 antigens are immobilized on the test region of the membrane.

During testing, the specimen reacts with Recombinant HIV-1/2 antigens conjugated to colored particles and precoated onto the conjugate pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there are sufficient HIV-1/HIV-2 antibodies in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result.

The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Individually packed test devices
- Droppers
- Package insert
- Buffer

Materials Required but Not provided

- Specimen collection container
- Centrifuge
- Timer
- Sterile lancets (for finger stick whole blood only)

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure 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.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The HIV Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using human whole blood, serum or plasma specimens.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave 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 3 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen serum or plasma specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of serum or plasma specimens.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

TEST PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

1.Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within an hour.

2a.For serum/plasma specimens:

Using the provided dropper, carefully transfer 1 drop (25 μL) of serum or plasma to the sample well (S), and then add 1 drop of buffer to the sample well (S).

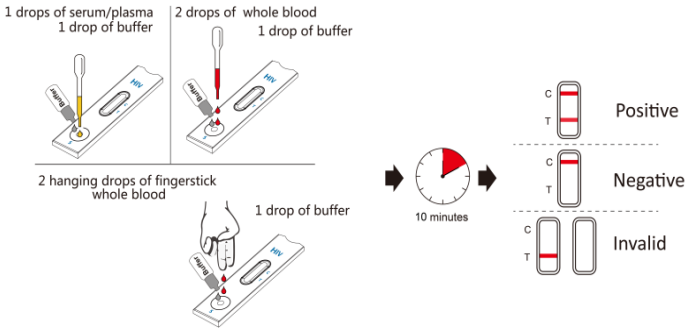
2b.For whole blood specimens:

Using the provided dropper, carefully transfer 2 drops (50 μL) of whole blood to the sample well (S), and then add 1 drop of buffer to the sample well (S).

2c.For finger stick whole blood specimens:

Dispense 2 drops of finger stick whole blood onto the sample well (S) of the test device, then add 1 drop of buffer and start the timer. Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.

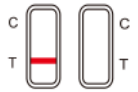
3.Read the result at 10 minutes. Do not interpret the result after 20 minutes.



RESULT INTERPRETATION

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The HIV Rapid Test Device (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should be only used for the qualitative detection of antibodies to HIV-1/HIV-2.
2. The HIV Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of HIV-1/HIV-2 antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HIV viral infection.

3. 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 rule out the presence of HIV-1/HIV-2 antibodies in blood, as antibodies may be present below the minimum detection level of the test.
4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Diagnostic Sensitivity

A total of 602 HIV positive specimens were tested using the HIV Rapid Test Device (Whole Blood/Serum/Plasma) and comparison with commercially available tests (Table 1). The diagnostic sensitivity of the test is >99% (95% CI: 99.4% ~ 100.0%).

Table 1: Summary of HIV Antibody positive specimens

	HIV Rapid Test Device (Whole Blood/Serum/Plasma)			Commercially Available Test	
	Sample type	Negative	Positive	Negative	Positive
Anti-HIV-1 positive	Serum	0	200	0	200
	Plasma	0	108	0	108
Anti-HIV-1 positive, different subtypes	Plasma	0	94	0	94
Anti-HIV-2 positive	Serum	0	1	0	1
	Plasma	0	99	0	99
Anti-HIV positive	Whole blood (finger stick)	0	100	0	100
Total		**0**	**602**	**0**	**602**

Diagnostic Sensitivity calculated per sample type:
Diagnostic Sensitivity of serum: >99% (201/201) (98.1% ~100.0%)*
Diagnostic Sensitivity of plasma: >99% (301/301) (98.7% ~ 100.0%)*
Diagnostic Sensitivity of capillary (finger stick) whole blood: >99% (100/100) (96.3% ~ 100.0%)*
Overall Agreement: >99% (602/602) (99.4% ~ 100.0%)*
*95% Confidence Interval

Diagnostic Specificity

A total of 2000 HIV negative specimens were tested using the HIV Rapid Test Device (Whole Blood/Serum/Plasma) and comparison with commercially available tests (Table 2). The diagnostic specificity of the test is >99% (95% CI: 99.8% ~ 100.0%).

Table 2: Summary of HIV Antibody negative specimens

	HIV Rapid Test Device (Whole Blood/Serum/Plasma)		Commercially Available Test	
	Negative	Positive	Negative	Positive
Blood donors serum samples	500	0	500	0
Blood donors EDTA-K3 plasma samples	500	0	500	0
Blood donors EDTA-K3 whole blood samples	500	0	500	0
Hospitalized patient negative samples	200	0	200	0
Pregnant woman negative samples	200	0	200	0
HIV Ab negative capillary (finger stick) whole blood samples	100	0	100	0
Total	2000	0	2000	0

Diagnostic Specificity calculated per sample type:
Diagnostic Specificity of serum: >99% (500/500) (99.2% ~100.0%)*
Diagnostic Specificity of plasma: >99% (500/500) (99.2% ~ 100.0%)*
Diagnostic Specificity of venous whole blood: >99% (500/500) (99.2% ~ 100.0%)*
Diagnostic Specificity of hospitalized patient: >99% (200/200) (98.1% ~ 100.0%)*
Diagnostic Specificity of pregnant woman: >99% (200/200) (98.1% ~ 100.0%)*
Diagnostic Specificity of capillary (finger stick) whole blood: >99% (100/100) (96.3% ~ 100.0%)*
Overall Agreement: >99% (2000/2000) (99.8% ~ 100.0%)*
*95% Confidence Interval

Specimen type equivalence

The comparison between the 4 types of samples (serum, plasma, venous whole blood and capillary whole blood) showed perfect concordance.

Seroconversion panels

25 seroconversion panels used the 3rd generation reference assay of Genscreen HIV-1/2 v2 as control, detected 20 out of the 25 seroconversion panels. Further analysis, using comparative results of more CE marked anti-HIV assays, the HIV Rapid Test Device (whole blood/serum/plasma) did not perform worse than CE marked anti-HIV assays used in the study.

5 seroconversion panels were tested with the HIV Rapid Test Device (whole blood/serum/plasma). The performance for HIV Rapid Test Device (whole blood/serum/plasma) was equal to the commercial CE Marked Rapid anti-HIV Assays.

Cross Reactivity

Cross reactivity has been tested with below samples, no cross reactivity was found with the HIV Rapid Test Device.

Anti-HBsAg+	Influenza A Virus	Anti-E. coli
Anti-HBcAg+	Influenza B Virus	Sickle cell disease
Anti-HCV +	Influenza vaccine recipient	RF+
Anti-HTLV+	Tick born encephalitis	Anti-Toxo+
Anti-HEV+	Post immunization measles	Anti-Syphilis+
Anti-HAV+	Helicobacter pylori	Anti-HSV+
VZV+	Recipient multiple blood transfusions	

Some cross-reactivity was seen with samples positive for CMV IgM, EBV IgM and Malaria.

Interfering Substances

The following potentially interfering substances have been evaluated at the listed below, none of them affect the test performance of the HIV Rapid Test Device.

Substance	Concentration
Ascorbic Acid	20mg/dL
Hemoglobin	1000mg/dL
Bilirubin	1000mg/dL
Gentistic acid	20mg/dL
Acetoaminophen	20mg/dL
Acetosalisilyc acid	20mg/dL
Caffeine	20mg/dL
Oxalic Acid	60mg/dL
Uric acid	20mg/dL
Methonal	10%
Pregnant Women	/

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

ρ	Catalog number	ϐ	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	*In vitro* diagnostic medical device	ε	Use by
μ	Manufacturer	σ	Do not reuse
T	Contains sufficient for <n> tests	A	Authorized representative in the European Community
Y	CE marking according to IVD Medical Devices Directive 98/79/EC		

IVD

μ

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