ACCUCARE®

ONE STEP HIV 1/2 3-LINE RAPID TEST

(Whole Blood/Serum/Plasma)

One step rapid Card Test for detection and subtyping of antibody to human immunodeficiency Virus-1 and/or Virus-2 in Whole Blood/Serum/Plasma

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	HIVC 01
10 Tests	HIVC 10
25 Tests	HIVC 25
50 Tests	HIVC 50

CLINICAL SIGNIFICANCE

HIV is the etiologic agent of Acquired immunodeficiency Syndrome (AIDS). The virion is surrounded by a lipid 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 a high potential of risk for developing AIDS. HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals. Both HIV-1 and -2 elicit an immune response.

Detection of HIV antibodies in serum or plasma 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.

Despite the differences in their biological characteristics, serological activities and genome sequences of HIV-1 and -2 show strong antigenic cross-reactivity. Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.

The HIV 1/2 3-line Test device (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence and subtype of antibody to HIV-1 and/or -2 in Whole Blood/Serum/Plasma specimen. The test utilizes a combination of multiple recombinant HIV proteins coated particles and multiple recombinant HIV proteins to selectively detect antibody to the HIV-1 and HIV-2 in Whole Blood/Serum/Plasma.

PRINCIPLE

The HIV 1/2 3-line Test Device (Whole Blood/serum/plasma) is a qualitative, membrane based immunoassay for the detection of antibody HIV in serum or plasma. The membrane coated with recombinant HIV antigens on the test line region. When a specimen is applied at one end of the membrane, it reacts with recombinant HIV antigen coated particle that has already been applied to the specimen pad at the same end. The mixture then migrates chromatographically towards the other end of the membrane and reacts with the recombinant HIV antigens on the membrane in the test line region. If the specimen contains antibodies to HIV-1 or HIV-2, a colored line will appear in the test line regions for either HIV-1 and/or HIV-2, showing a positive result. The absence of the colored line indicates that the specimen does not contain the anti-HIV antibodies, showing a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

CONTENTS

Test Device
Assay Buffer
Instruction for Use (IFU)
Disposable (Dropper) 10 µl sampling device
Desiccant

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Humidity and temperature can adversely affect results.

LIMITATIONS

1. The One Step HIV 1/2 3-line test device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of antibodies to HIV in Serum or Plasma.
2. The One Step HIV 1/2 3-line test device (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HIV in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1 and/or HIV-2 infections.
3. For confirmation, further analysis of the specimens should be performed, such as ELISA and/or western blot analysis. As with all diagnostic tests, 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 follow-up tests using other clinical methods are recommended. A negative result at any time does not preclude the possibility of HIV-1 and/or -2 infections.

SPECIMEN COLLECTION & PREPARATION

1. The HIV 1/2 3-line Test Device (Whole Blood/serum/plasma) can be performed using either Whole Blood or serum or plasma.
2. If you do not want to use whole blood than separate the serum or plasma from whole 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, it should be packed in compliance with federal regulations for transportation of etiologic agents.

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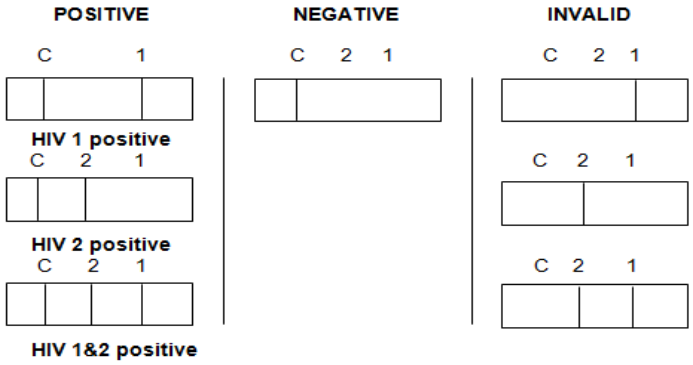
ONE STEP HIV 1/2 3-LINE RAPID TEST

(Whole Blood/Serum/Plasma)

PROCEDURE

1. Allow test device, Assay buffer and specimen equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and flat surface. Carefully dispense 1 drop (10 µl) of Whole Blood/Serum/Plasma into the sample well (S) using the sample dropper provided.
4. Add 2 drops (70 µl) of buffer from the dropper bottle to the sample well (S) of the device and start the timer. Avoid trapping air bubbles in the sample well (S).
5. Read the results at 15 minutes. Do not interpret the results after 15 minutes.

INTERPRETATION OF RESULTS



1. POSITIVE

- If two color bands appears, one at control line 'C' and other at test line HIV-1 '1', the specimen is positive for HIV-1.
- If two color bands appears, one at control line 'C' and other at test line HIV-2 '2', the specimen is positive for HIV-2.
- If Three color bands appears, one at control line 'C', one at test line HIV-1 '1' and second at test line HIV-2 '2', the specimen is positive for both HIV-1 & HIV-2.

2. NEGATIVE

If only one color band appear at control line 'C' as the specimen is Negative for HIV-1 & HIV-2.

3. INVALID

If no color band appear, at control line 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device/Strip.

NOTE: The intensity of the color band in the test line region will vary depending on the concentration of anti-HIV 1/2 antibodies present in the specimen. However, neither the quantitative value nor the rate of increase in anti-HIV 1/2 antibodies can be determined by this qualitative test.

INTERFERING SUBSTANCES

No interference in the ACCUCARE® ONE STEP HIV 1/2 3-Line Rapid Test was evident when the following substances were tested:

Sample Type	Number of Samples Tested	Positive	Negative
Clinical Specimens	100	02	98
Pregnant women	100	00	100
Other disease Samples*	100	00	100

*Other disease Samples: These are the samples that potentially interfere with anti-HIV immunoassays. Details of the samples are as below:

Sample Type	No. of Sample Tested
Anti-HCV Positive	20
HBsAg Positive	20
Anti-HBsAg	15
Anti-HAV Positive	15
Rubella Positive	15
Anti-HTLV Positive	15
Total	**100**

PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP HIV 1/2 3-Line Rapid Test has been evaluated with positive and negative samples confirmed by ELISA examination.

Specimen	Positive	Negative	Sensitivity
HIV-1	180	00	100 %
HIV-2	20	00	100 %

Specimen	Positive	Negative	Specificity
Negative	00	1400	100 %

BIBLIOGRAPHY

1. Chang, SY, Bowman, BH, Weiss, JB, Garcia, RE and white, TJ. The origin of HIV-1 isolates HTLV-IIIB, Nature.
2. Arya, SK, Beaver, B, Jagodzinski, L, ensoli B, kanki, PJ, Albert, J, Fenyo, EM, Biberfeld, G, Zagury. JF and Laure, F. New human and simian HIV-related retroviruses possess functional transactivator (tat) gene. Nature (1987).

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For *in vitro* Diagnostic use only		Keep Dry
Σ	Tests per Kit		Do Not Use if Damaged

ISO 13485:2016

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