Labcare
...Your Partner in Laboratory Excellence

ACCUCARE™ ONE STEP HIV 1/2 3-LINE TEST (serum/plasma)

One step rapid Card Test for detection and subtyping of antibody to human immunodeficiency Virus-1 and/or-2 in serum, plasma.
Only for *In Vitro Diagnostic* Use

ORDER INFORMATION

REF	CONT
HIVC 50	50 Tests
HIVC 25	25 Tests
HIVC 10	10 Tests

CLINICAL SIGNIFICANCE

HIV is the etiologic agent of Acquired immune Deficiency 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 (serum/plasma) is a rapid test to qualitatively detect the presence and subtype of antibody to HIV-1 and/or -2 in serums or 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 serum, plasma.

PRINCIPLE

The HIV 1/2 3-line Test Device (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 of the device. When a serum or plasma 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 serum or plasma 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 serum or plasma 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.

KIT COMPONENTS

Test Device, Assay Buffer, Sample Dropper and product insert

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 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.
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.

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION & PREPARATION

1. The HIV 1/2 3-line Test Device (serum/plasma) can be performed using either serum, plasma.
2. Separate the serum or plasma from 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, they should be packed in compliance with federal regulations for transportation of etiologic agents.

DIRECTIONS FOR USE

Allow test device, buffer, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil 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 device on a clean and flat surface. Carefully dispense 1 drop (10 ul) of serum/plasma into the sample well (S) using the sample dropper provided.
3. Add 2 drops (60 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).
4. Wait for the red line(s) to appear. The test line should be read within 20 minutes. It is important that the background is clear before the result is read.

INTERPRETATION OF RESULTS

1. POSITIVE
Two or three distinct red lines appear.
The presence of a band at 'C' and bands at '1' and / or '2' within the Result Window, no matter which band appear first, indicates a positive result for HIV -1 or / and HIV -2 respectively

2. NEGATIVE
One red line appears in the control region (C). No apparent red or pink line appears in the test regions (1 or 2).

3. 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 your local distributors.

NOTE: The intensity of the red color in the test line region (T) 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.

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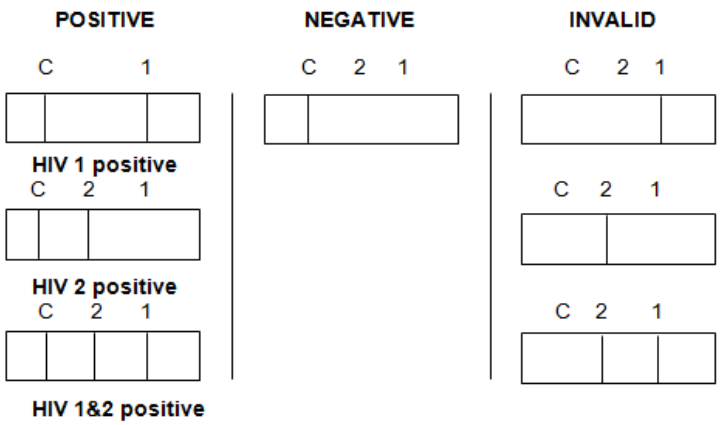

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

LIMITATIONS

1. The One-step HIV 1/2 3-line test device (serum/plasma) is for in vitro use only. The test should be used for the detection of antibodies to HIV in serum, plasma or specimens.

2. The One-step HIV 1/2 3-line test device (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 -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 infection.

BIBLIOGRAPHY

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