SPESERA HIV 1/2 Rapid Test

For professional and in vitro diagnostic use only.

Intended Use

The HIV 1/2 Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in human serum or plasma. It provides an aid in the diagnosis of infection with HIV-1 and HIV-2.

Summary

Discovered in 1983, the Human Immunodeficiency Virus is a retrovirus and identified as the etiologic agent for the Acquired Immunodeficiency Syndrome (AIDS), and AIDS related complex[1]. AIDS is characterized by changes in the population of T-cell lymphocytes that play a key role in the immune defense system. In the infected individual the virus causes a depletion of a subpopulation of T-cells, called T-helper cells, which leaves these patients susceptible to opportunistic infections and certain malignancies. The major routes of transmission are sexual contact, exposure to contaminated blood or blood products (including sharing of contaminated syringes and needles) and mother-to-newborn transmission.[2-4]
Human immunodeficiency virus type I and type II (HIV-1 and HIV-2) are enveloped single strain RNA positive virus. The causative relationship between HIV-1 and HIV-2 virus and AIDS has been established over decades. HIV-1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy individuals with a high risk for developing AIDS[5]. HIV-2 has been isolated from West African AIDS patients and from sero-positive asymptomatic individuals[6].
Both HIV-1 and HIV-2 virus can elicit strong immune responses[7], including the production of anti-virus antibodies. Presence of specific anti HIV-1 and/or HIV-2 virus antibody in blood, serum and plasma indicates the exposure of an individual to the HIV-1 and/or HIV-2 virus, being of great value for clinical diagnosis[8].
Enzyme Immunoassays (EIAs), Western Blots (WB), Nucleic Acid Amplification Test (NAT) assays and various other test systems are currently available for detection of HIV-1 and HIV-2 infection. The HIV 1/2 Rapid Test utilizes immobilized antigens for the detection of antibodies to HIV-1 and HIV-2, and is a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.

Principle

The HIV 1/2 Rapid Test is an immunoassay based on the principle of the double antigen-sandwich technique. During testing, a serum or plasma specimen migrates upward by capillary action. The antibodies to HIV-1 or HIV-2 if present in the specimen will bind to the HIV conjugates. The immune complex is then captured on the membrane by the pre-coated recombinant HIV antigens, and a visible colored line will show up in the test line region indicating a positive result. In the absence of antibodies to HIV-1 or HIV-2, a colored line will not form in the test line region indicating a negative result.
To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Warnings and Precautions

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test panel should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test panel should be discarded according to federal, state and local regulations.

Composition

The test panel contains a membrane strip coated with recombinant HIV antigens on the test line, rabbit anti-HIV antibody on the control line, and a dye pad which contains colloidal gold coupled with recombinant HIV antigens.
Each box contains test panels and package insert.

Materials required but not provided: Specimen collection container, Timer.

Storage and Stability

- Store as packaged in the sealed pouch at room temperature (4-30°C or 40-86 °F).The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.

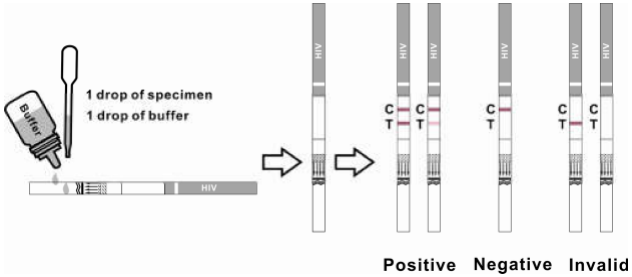
Specimen

- The test can be used to test serum or plasma specimens.
- Collect blood specimen (containing EDTA, citrate or heparin) by vein puncture following standard laboratory procedures.
- Separate the serum or plasma as soon as possible by centrifugation after collecting.
- Store specimens at 2-8°C(36-46°F) if not tested immediately. Store specimens at 2-8°Cup to 7 days. The specimens should be frozen at -20°C(-4°F) for longer storage.
- Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.
- Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

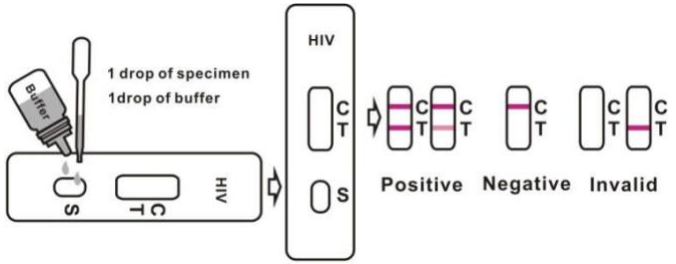
Test Procedure

Allow the test device and specimens to equilibrate to room temperature (15-30°Cor 59-86°F) prior to testing.

[For Strip]
1. Remove the test strip from the sealed pouch and use it as soon as possible.
2. Hold the dropper vertically and transfer 1 drop of specimen (approximately 35 μl) to the specimen pad of the test strip, then add 1 drop of buffer (approximately 35 μl) and start the timer. See illustration below.
3. Wait for colored lines to appear. Interpret the test results in 15 minutes. Do not read results after 20 minutes.



[For Cassette]
1. Remove the test cassette from the sealed pouch.
2. Hold the dropper vertically and transfer 1 drop of specimen (approximately 35 μl) to the specimen well(S) of the test device, then add 1 drop of buffer (approximately 35 μl) and start the timer. See the illustration below.
3. Wait for colored lines to appear. Interpret the test results in 15 minutes. Do not read results after 20 minutes.



Interpretation of Results

Positive:*Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (T). This positive result indicates the presence of antibodies to HIV-1 and/or HIV-2.
Negative: One red line appears in the control region (C). No line appears in the test region (T). This negative result indicates the absence of antibodies to HIV-1 and HIV-2.

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 using a new test panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

Quality Control

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations

- The HIV 1/2 Rapid Test is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the antibody in the blood.
- The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- A negative test result indicates that antibodies to HIV 1/2 are either not present or at levels undetectable by the test.

Performance Characteristics

Accuracy

Agreement with Commercial HIV Rapid Test

A side-by-side comparison was conducted using the SPESRA® HIV 1/2 Rapid Test and commercially available HIV 1/2 rapid tests. 1052 clinical serum or plasma specimens from three hospitals were evaluated with the SPESERA® Test and the commercial kit. The discrepant specimens were checked with a commercially available ELISA to confirm the presence of HIV antibody in the specimens. The following results are tabulated from these clinical studies:

		Commercial HIV Rapid Test		Total
		Positive	Negative	
SPESERA	Positive	381	0	381
	Negative	0	671	671
Total		381	671	1052

The agreement between these two devices is 100% for positive specimens, and 100% for negative specimens. This study demonstrated that the CLUNGENE® HIV 1/2 Rapid Test is substantially equivalent to the commercial device.

Agreement with EIA

A total of 650 samples from susceptible subjects were tested with the CLUNGENE® Test and by a commercial HIV EIA test. Comparison for all subjects is showed in the following table:

		EIA		Total
		Positive	Negative	
SPESERA®	Positive	220	1	221
	Negative	3	426	429
Total		223	427	650

A statistical comparison was made between the results yielding a clinical sensitivity of 98.7%, a clinical specificity of 99.8% and an accuracy of 99.4%.

Cross Reactivity and Interference

1. Other common causative agents of infectious diseases were evaluated for cross reactivity with the test. Some positive serum specimens of other common infectious diseases were spiked into the HIV1/2 positive and negative specimens and tested separately. No cross reactivity was observed with specimens from patients infected with HAV, HBsAg, HCV, HTLV, CMV and TP.

2. Potentially cross-reactive endogenous substances including common serum components, such as lipids, hemoglobin, bilirubin, were spiked at high concentrations into the HIV1/2 positive and negative specimens and tested, separately. No cross reactivity or interference was observed to the device.

Analytes	Conc.	Specimens	
		Positive	Negative
Albumin	20mg/ml	+	-
Bilirubin	20µg/ml	+	-
Hemoglobin	15mg/ml	+	-
Glucose	20mg/ml	+	-
Uric Acid	200µg/ml	+	-
Lipids	20mg/ml	+	-

3. Some other common biological analytes were spiked into the HIV1/2 positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

Analytes	Conc. (µg/ml)	Specimens	
		Positive	Negative
Acetaminophen	200	+	-
Acetoacetic Acid	200	+	-
Acetylsalicylic Acid	200	+	-
Ampicillin	200	+	-
Ascorbic Acid	200	+	-
Atropine	200	+	-
Benzoylecgonine	100	+	-
Caffeine	200	+	-
EDTA	800	+	-
Ethanol	1.0%	+	-
Gentisic Acid	200	+	-
β - Hydroxybutyrate	20,000	+	-
Methanol	10.0%	+	-
Phenothiazine	200	+	-
Phenylpropanolamine	200	+	-
Salicylic Acid	200	+	-
Tetracycline	200	+	-

Reproducibility

Reproducibility studies were performed for CLUNGENE® HIV 1/2 Rapid Test at three physician office laboratories (POL). Sixty (60) clinical serum specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 100% at two sites, and 99.4% at one site. The inter-site agreement was 99.8%.

Bibliography

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Index of Symbols


Do not reuse


Stored between 4-30 °C


Caution


Use by


Keep away from sunlight


Manufacturer



For in vitro diagnostic use only


Consult instruction for use



Lot number


Contains sufficient for <n> tests


Keep dry


Do not use if package is damaged

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