

First Response®

HIV 1-2-0

Human Immunodeficiency Virus Rapid Test Strip (Serum/Plasma/Whole Blood)

A rapid test for the qualitative detection of antibodies to Human Immunodeficiency Virus -1 and/or -2 in serum, plasma, or whole blood.

For professional *in vitro* test use only.

INTENDED USE

The *First Response*® HIV 1-2-0 Test Strip (Serum/Plasma/Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Human Immunodeficiency Virus (HIV) type-1 and/or type-2 in serum, plasma, or whole blood.

SUMMARY

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 a high potential risk for developing AIDS (1). HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals (2). Both HIV-1 and -2 elicit an immune response (3). Detection of HIV antibodies in serum or 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 characteristics, serological activities and genome sequences of HIV-1 and -2 show strong antigenic cross-reactivity (5, 6). Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.

PRINCIPLE

The *First Response*® HIV 1-2-0 Test Strip (Serum/Plasma/Whole Blood) is a qualitative, membrane based immunoassay for the detection of antibody to HIV in serum, plasma, or whole blood. The membrane is coated with recombinant HIV antigens on the test area of the device. When a serum or plasma or whole blood specimen is applied to the test strip, it reacts with recombinant antigen coated colored particle. The mixture then migrates towards the Result Window of the strip and reacts with the recombinant HIV antigens on the membrane in the test area. If the specimen contains antibodies to HIV-1 or HIV-2, the colored line will appear in

the test area, 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. A colored line will always appear at the control area if the test has been performed properly.

PRECAUTIONS

- For professional *in vitro* use only.
- Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as though 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 protectors when specimens are assayed.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30 °C. The test strip is stable until the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

- The *First Response*® HIV 1-2-0 Test Strip (Serum/Plasma/whole blood) can be performed using serum, plasma, or whole blood.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis when serum or plasma is used. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. The plasma or serum may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- 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 federal regulations for transportation of etiologic agents.

PROCEDURE

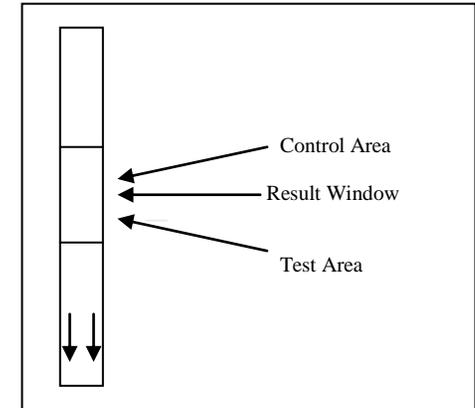
Materials Provided

- Test strip in a foil pouch
- Assay Buffer
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Test Tube
- Pipette
- Timer

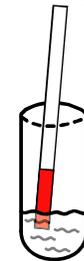
DIRECTIONS FOR USE



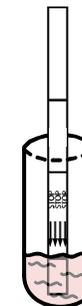
Allow test device, reagents, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing. Use a new pipette for each sample/test.



1. Dispense 1 drop of Assay Buffer (35 µL) into the test tube.



2. Add 10 µL of serum or plasma, or 20 µL of whole blood into the test tube.



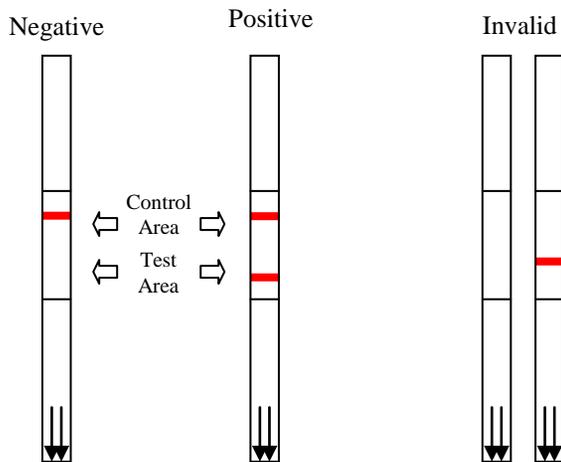
3. Place the test strip in the test tube, making sure that the "T" side downwards into the solution.



4. Leave the test strip in the test tube for 10 minutes and then remove and interpret the results.



EXAMPLES OF VALID RESULTS



INTERPRETATION OF RESULTS

POSITIVE: Two bands will appear in the control and test areas, which indicate a positive result for HIV-1 and/or HIV-2, respectively.

NEGATIVE: A color band will appear in the control area only, which indicates a negative result.

INVALID: If the color band is not visible within the control area after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

NOTE: A positive result will not change once it has been established at 10 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 10 minutes.

QUALITY CONTROL

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

LIMITATION

1. The *First Response*® HIV 1-2-0 Test Strip is for *in vitro* use only. The test should be used for the detection of antibodies to HIV in specimen.
2. The *First Response*® HIV 1-2-0 Test Strip 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 infection.
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.

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.

PERFORMANCE CHARACTERISTICS

Accuracy

The *First Response*® HIV 1-2-0 Test Strip has passed Anti-HIV1 Low Titer Performance Panel (PRB107(M)), and Worldwide HIV Performance Panel (WWRB303) and has also been compared with leading commercial HIV EIA test using clinical specimens.

The *First Response*®™ HIV 1/2 Test Strip is highly specific for anti-HIV-1 and/or -2 compared to a leading commercial HIV EIA test.

	HIV ELISA		
	Positive	Negative	Total
<i>First Response</i> ®			
Positive	238	2	240
Negative	0	436	436
Total	238	438	676
Relative Sensitivity:	100%		
Relative Specificity:	99.5%		

Precision: Intra-Assay

Within-run precision has been determined by using 20 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified 100% of the time.

Precision: Inter-Assay

Between-run precision has been determined by 20 independent assays on the same three specimens: a negative, a low positive and a high positive. The specimens were correctly identified 100% of the time.

REFERENCES

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