Specimen Collection

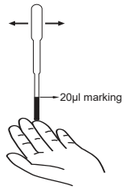
1) **Venous blood collection:** Collect the Whole blood in the collection tubes containing anticoagulants like EDTA, Heparin, Sodium citrate or ACD by venipuncture.
2) **Plasma collection:** Collect the Whole blood in the collection tubes containing anticoagulants like EDTA, Heparin, Sodium citrate or ACD by venipuncture and centrifuge it at 3000 g for 10-15 minutes to obtain Plasma.
   Serum collection: Collect Whole blood in the collection tubes without
3) having any anticoagulants by venipuncture. Keep it in standing position for 30 minutes and centrifuge it at 3000 g for 10-15 minutes to obtain serum.
4) **Capillary whole blood specimen collection:**

- Wear gloves and massage the fingertip gently. It will help to obtain a round drop of blood.
- Wipe the complete fingertip with the alcohol swab provided and wait until the fingertip is dried completely.

Side lock confirms integrity of lancet. Verify the seal before detaching the cap.

- Verify the seal before detaching the cap. Side lock confirms integrity of sterile twist lancet. Detach the protective cap of the sterile twist lancet. Squeeze the fingertip then prick the lateral side (avoid callus) of the fingertip with sterile twist lancet provided. Safely dispose of the used sterile twist lancet in sharps container immediately after use.

- Wipe the first drop of the blood using sterile gauze. Without pressing too hard, gently squeeze fingertip once again to obtain second drop of blood(~40-50 µl).



- Take the specimen transfer device provided and hold it vertically. Gently squeeze the bulb of specimen transfer device and immerse open end in the center of a blood drop and release the bulb slowly to draw up the blood up to the 20 µl marking line on the specimen transfer device.
- Do not use the specimen transfer device having no marking. After completion of specimen collection, take the sterile gauze and apply pressure to the wound site to stop the bleeding.Specimen transfer device is for single use only.

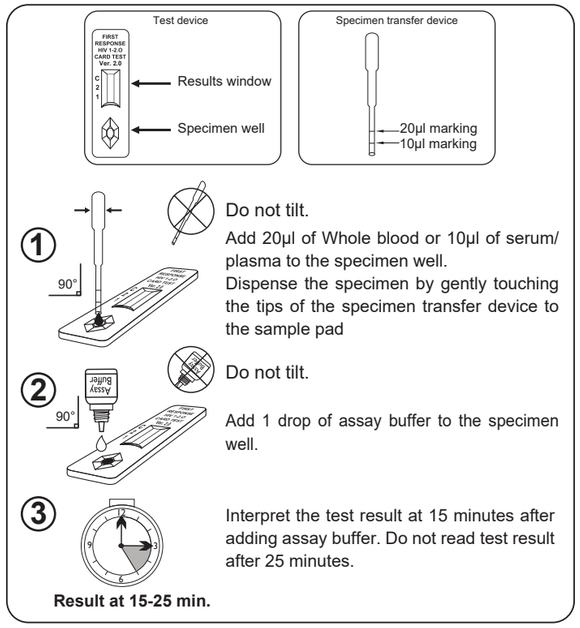
Note : Sterile twist lancet is for single use only. Do not share used sterile twist lancets with another person. Dispose of used sterile twist lancets in sharp box and alcohol swab in biohazard waste container immediately after use.
Do not use expired sterile twist lancet. Use of any expired sterile twist lancet may cause infections at the punctured skin due to expiry of its sterility. Use new sterile twist lancet, alcohol swab and specimen transfer device and choose a different puncture site, if another finger pricking is required.

Specimen storage

1) Venous whole blood specimens should be used for testing immediately (within 1 hour) or shall be stored at 2-8°C for up to 72 hours (3 days). Do not use whole blood specimens stored for more than 3 days, it can cause a non-specific reaction. Do not freeze whole blood specimens.
   Note: Mix the whole blood specimens in the tube by inverting the tube 3 or 4 times before use.
2) If serum or plasma specimens are not immediately tested, then they should be refrigerated at 2-8°C. For storage period greater than 72 hours (3 days), freezing at ≤-20°C is recommended up to 4 months.
3) Venous whole blood, serum and plasma specimens stored at 2-8 °C must be brought to room temperature before use. Serum or plasma specimens stored at ≤-20°C must be thawed at 15 to 25°C. Avoid more than 2 freeze-thaw cycles.
4) Serum or plasma specimens containing precipitate may yield inconsistent test results. Such specimens must be centrifuged at 5000 g for 10 minutes and then use clear supernatants for testing.

Test Procedure

1) Ensure that the test device & other components are at room temperature (15°C to 30°C) before starting the procedure.
2) Open the device pouch, take out the test device from aluminum pouch. Do not use the test device if the desiccant color has changed from orange to green.
3) Label the test device with the patient identification number. Place the test device on a flat, clean and dry surface. Take out the specimen transfer device from the plastic bag provided inside the kit.
4) Gently squeeze the bulb of specimen transfer device and immerse the open end in the specimen and release the bulb slowly to draw up the serum/plasma up to 10 µl marking line and for the capillary or venous whole blood up to 20 µl marking line on the specimen transfer device.
5) Gently wipe away the excess specimen from the outer surface of the specimen transfer device with tissue paper before dispensing the specimen into the specimen well.
6) Gently squeeze the bulb of specimen transfer device to add 20 µl of whole blood or 10 µl of serum/ plasma to the specimen well by gently touching the tips of the specimen transfer device to the sample pad.
   Caution: Dispose of used specimen transfer device and tissue paper as biohazard waste immediately after use.
7) Hold the assay buffer bottle vertically and add one drop of assay buffer to the specimen well.
8) Observe for development of purple colored lines in the results window. Interpret test results at 15 minutes after adding assay buffer to the specimen well.
9) Do not interpret the test result after 25 minutes.



Caution

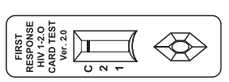
- Add exactly 1 drop of assay buffer. Adding more than 1 drop of assay buffer may cause over flooding or reverse migration phenomenon, which may lead to inaccurate results of the test.
- Do not read the test results after 25 minutes. Reading the results after 25 minutes window may give inaccurate results. After recording the results, dispose of used test device as a biohazard waste.

Internal Quality Control

The visualization of the purple colored control line in First Response® HIV 1-2.O Card Test (Ver. 2.0) indicates that the active ingredient of the strips are functional and the migration is successful. The control line is a procedural control, serves to demonstrate functional reagents and correct migration of fluid.

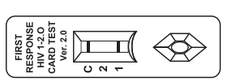
How to Interpret test results

Negative Results



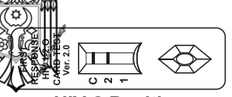
If only a single purple colored line appears, at the control line 'C' as in the figure, then the specimen is non-reactive for antibodies to HIV-1 and 2.

Positive Results



HIV-1 Positive

If two purple colored lines appear, one at the control line 'C' and other at the test line HIV-1 '1' as in the figure, then the specimen is reactive for antibodies to HIV-1. Interpret purple colored faint line as a reactive line.



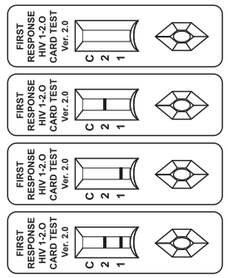
HIV-2 Positive

If two purple colored lines appear, one at the control line 'C' and other at the test line HIV-2 '2' as in the figure, then the specimen is reactive for antibodies to HIV-2. Interpret purple colored faint line as a reactive line.

HIV-1 & HIV-2 Positive

If all three purple colored lines appear, one at the control line 'C' and other two at the test lines HIV-1 '1' and HIV-2 '2' as in the figure, then the specimen is reactive for antibodies to HIV-1 and 2. Interpret purple colored faint line as a reactive line.

Invalid Results



No presence of purple colored control line 'C' in the results window (irrespective of presence of test lines) indicates an invalid result.

The directions may not be followed correctly or the test may have deteriorated.

The Invalid test results should be retested with new test device.

Performance Characteristics

First Response® HIV 1-2.O Card Test (Ver. 2.0) has been tested using an in-house panel of positive and negative clinical specimens characterized by a commercial anti HIV ELISA kit. First Response® HIV 1-2.O Card Test (Ver. 2.0) showed 100% sensitivity and 100% specificity. First Response® HIV 1-2.O Card Test (Ver. 2.0) showed 100% agreement with reference assays.

Reference Method	Specimen details	First Response® HIV 1-2.O Card Test (Ver 2.0)				
		HIV-1 Positive	HIV-1 Negative	HIV-2 Positive	HIV-2 Negative	Total
ELISA/ RDT Commercially available	HIV-1 Positive and HIV-2 Negative plasma specimens					
	HIV-1 Positive plasma specimen	171	0	0	171	171
	HIV-2 Positive and HIV-1 Negative plasma specimens					
	HIV-2 Positive plasma specimen	0	6	6	0	6
	HIV-1 and HIV-2 Negative plasma specimens					
	Negative plasma specimen	0	370	0	370	370
	Total plasma specimens	171	376	6	541	547
	HIV-1 Positive and HIV-2 Negative serum specimens					
	HIV-1 Positive serum specimen	404	0	0	404	404
	HIV-2 Positive and HIV-1 Negative serum specimens					
	HIV-2 Positive serum specimen	0	100	100	0	100
	HIV-1 and HIV-2 Negative serum specimens					
	Negative serum specimen	0	3455	0	3455	3455
	Total serum specimens	404	3555	100	3859	3959
	HIV-1 Positive and HIV-2 Negative whole blood specimens					
	HIV-1 Positive whole blood specimen	73	0	0	73	73
	HIV-2 Positive and HIV-1 Negative whole blood specimens					
	HIV-2 Positive whole blood specimen	0	8	8	0	8
	HIV-1 and HIV-2 Negative whole blood specimens					
	Negative whole blood specimen	0	344	0	344	344
	Total whole blood specimens	73	352	8	417	425

Reference Method	Specimen details		First Response® HIV 1-2.O Card Test (Ver. 2.0)			
	Test Marker	Parameter	Positive	Negative	Total Result	Sensitivity/Specificity (95% Confidence Interval)
ELISA/ RDT Commercially available	Plasma specimens					
	HIV-1	Sensitivity	171	00	171	100% (97.26% - 100%)
		Specificity	00	376	376	100% (98.73% - 100%)
	HIV-2	Sensitivity	6	00	6	100% (51.68% - 100%)
		Specificity	00	541	541	100% (99.12% - 100%)
	Serum specimens					
	HIV-1	Sensitivity	404	00	404	100% (98.82% - 100%)
		Specificity	00	3555	3555	100% (99.86% - 100%)
	HIV-2	Sensitivity	100	00	100	100% (95.38% - 100%)
		Specificity	00	3859	3859	100% (99.87% - 100%)
	Whole blood specimens					
	HIV-1	Sensitivity	73	00	73	100% (93.77% - 100%)
		Specificity	00	352	352	100% (98.65% - 100%)
	HIV-2	Sensitivity	8	00	8	100% (59.77% - 100%)
		Specificity	00	417	417	100% (98.86% - 100%)

Seroconversion Panel Testing

The Analytical sensitivity of the First Response® HIV 1-2.O Card Test (Ver.2.0) was carried out by testing commercially available seroconversion panels. A commercially available rapid lateral flow test was used as a reference kit for comparative performance study. Twenty one seroconversion panels were tested, in-house.

Analytical Sensitivity - In - House Evaluation							
Total Seroconversion Panels	Total Specimens	First Response® HIV 1-2.O Card Test (Ver.2.0)			Reference rapid lateral flow test.		
		Positive	Negative	Detection Index**	Positive	Negative	Detection Index**
21	121	33	88	0.27	32	89	0.26

** Detection Index = Total number of positive specimen by test kit / Total number of specimens.

Cross- Reactivity Study

First Response® HIV 1-2.O Card Test (Ver. 2.0) was tested with other diseases/conditions, which may give cross-reactivity with the test. The following 19 potential cross-reacting diseases/conditions did not affect the performance of First Response® HIV 1-2.O Card Test (Ver. 2.0).

Specimen Details	HIV-1 Negative	HIV-1 Positive	HIV-2 Negative	HIV-2 Positive	Specimen Details	HIV-1 Negative	HIV-1 Positive	HIV-2 Negative	HIV-2 Positive
P. falciparum Malaria Positive	05	Not Tested	05	Not Tested	HSV 1/2 Positive#	05	08	05	08
P. vivax Malaria Positive	05	Not Tested	05	Not Tested	HTLV - I Ab Positive#	07	04	07	04
Dengue NS1 Positive#	05	04	05	04	HTLV- II Ab Positive#	09	04	09	04
Pregnant Woman^	110	02	112	00	HSV- IgG Positive#	08	04	08	04
CMV Positive#	03	04	03	04	Rubella IgG & IgM Positive #	15	08	15	08
ANA Positive#	04	04	04	04	HBV Positive#	103	04	103	04
HAV Positive#	04	04	04	04	Chikungunya Positive#	Not Tested	04	Not Tested	04
EBV Positive#	02	04	02	04	Anti-malarial drug medication#	04	04	04	04
HCV Positive#	103	04	103	04	Anti-TB drug medication#	05	05	05	05
Syphilis positive	122	Not Tested	122	Not Tested					

^ Note: Specimens from pregnant women infected with HIV-1 and HIV-2. HIV-2 infected women tested as part of the Zimbabwe External Evaluation Report.
# Spiked HIV-1 & 2 positive specimens.

Potential interfering substances

First Response® HIV 1-2.O Card Test (Ver. 2.0) was tested with potential interfering substances. The following 8 potential interfering substances did not affect the performance of the First Response® HIV 1-2.O Card Test (Ver. 2.0). However, Haemolysed specimens and lipaemic specimens showed poor background clearance, hence not recommended for testing. Lipaemic specimens can be used for the testing after centrifugation. Such specimens must be centrifuged at 5000 g for 10 minutes and use the clear supernatants for testing.

Specimen Details	HIV-1 Negative	HIV-1 Positive	HIV-2 Negative	HIV-2 Positive
Lipaemic specimen#	25	04	25	04
Icteric specimens#	05	04	05	04
Haemolytic specimens^	04	01	05	00
High Hematocrit specimens	05	Not tested	05	Not tested
Low Hematocrit specimens	05	Not tested	05	Not tested
Whole blood specimen in ACD anticoagulant^	180	02	182	00
RF Ab Positive#	09	04	09	04
dsDNA Antibody Positive Plasma#	01	04	01	04

Note : ^HIV-1 positive specimens and #Spiked HIV-1 & 2 positive specimens.

Potential interfering Drug substances

The details of potentially interfering drugs are mentioned in the following table. Each drug was spiked into either HIV-1 or HIV-2 positive specimens, or HIV negative specimens to a final concentration of 250 µg/ml.
The following 22 potential interfering drug substances did not affect the performance of the First Response® HIV 1-2.O Card Test (Ver. 2.0).

Diclofenac	Acetaminophen	Aspirin
Folic acid	Pyrazinamide	Ampicillin Sodium salt
Ecosprin	Cholecalciferol	Nevirapine
Magnesium sulphate	Ritonavir	Ibuprofen
Daruvir	Rifampicin	Ascorbic Acid (Limec)
Naproxen IP	Metformin	Hydrochlorothiazide
Pantoprazole	Isoniazid	Ferrous Ascorbate
Cyclobenzaprine Hydrochloride		

Precision

a) Within-run precision was determined by using 15 replicates of 15 different specimens containing different concentrations of antibodies. Within-run, precision was observed as 100%.

b) Between-run, precision was determined by using the 15 different specimens containing different concentrations of antibody in 5 different replicates with 3 different lots of test devices. Between run, precision was observed as 100%.

External Evaluation Report

Place of Evaluation	Year	Sensitivity		Specificity	
		HIV-1	HIV-2	HIV-1	HIV-2
Zimbabwe	2016	100% (96.84%-100%)	100% (86.65%-100%)	100% (96.92%-100%)	100% (98.23%-100%)
Ghana	2016	100% (94.29%-100%)	NA(#) (NA)	100% (98.42%-100%)	100% (98.75%-100%)
Ghana (Capillary vs Venus whole blood specimen)	2018	100% (96.13%-100%)	100% ** (19.78%-100%)	100% (96.13%-100%)	100% (98.02%-100%)
Institute of Tropical Medicine Antwerp, Belgium	2018	100% (99.20%-100%)		100% (99.50%-100%)	
Zimbabwe (Pregnant women whole blood specimen)^	2019	100% (96.42%-100%)	100% ** (46.29%-100%)	100% (96.80%-100%)	100% (98.25%-100%)

(#): No HIV-2 positive specimen tested.
**: Lower CI value due to less number of HIV-2 positive specimen tested.

Limitations

1) The assay procedure and interpretation of assay result sections must be followed closely. Failure to follow the procedure may lead to inaccurate test results.
2) First Response® HIV 1-2.O Card Test (Ver. 2.0) is designed to detect antibodies to HIV-1 and HIV-2 in human serum, plasma, and whole blood. Other body fluids or pooled specimens may not give accurate results.
3) First Response® HIV 1-2.O Card Test (Ver. 2.0) rapid test is limited to the qualitative detection of HIV-1 or HIV-2 antibodies in human serum, plasma or whole blood. The intensity of the test line does not correlate with the antibody titer of the specimen.
4) Haemolytic specimen may give reddish background even after end of test interpretation time.
5) High lipaemic specimens/ turbid specimens must be centrifuged and use clear supernatant for testing.
6) Interpret the purple colored faint line as a reactive line. Repeat the test in case of very faint test line or if have any doubt for test line.
7) A non-reactive result for an individual subject indicates the absence of detectable HIV-1 or HIV-2 antibodies. However, a non-reactive result can occur if the quantity of the HIV-1 or HIV-2 antibodies present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during stage of the disease/condition (person on ART treatment, window period, immune collapse, Infected but non-seroconverted) in which a specimen is collected.
8) All three lines (1,2 and C) may develop when tested with specimens containing high titers of HIV-1 and/or HIV -2 antibodies. The reactive test bands for both HIV-1 and HIV-2 may not always indicate mixed infection. The genomic structural similarity of HIV-1 and HIV-2 may give cross-reactivity. The western blot or PCR should be used to differentiate virus type or co-infection.
9) Heparin, EDTA, sodium citrate, and ACD anticoagulants have been validated for use with this test.
10) False negative results may occur as a result of a very high antibody titre in a specimen". In such instances "Contact the manufacturer (or distributor) for further instruction.
11) Although a reactive result may indicate infection with HIV-1 or HIV-2 virus, a diagnosis of HIV infection can only be made on clinical grounds, if an individual meets the case definition for AIDS established by the Centers for Disease Control. For specimens repeatedly tested reactive, more specific supplemental tests must be performed.
12) Immunochromatographic testing alone cannot be used to diagnose HIV infection even if the antibodies against HIV-1/HIV-2 are present in a patient specimen. A negative result at any time does not preclude the possibility of HIV-1 or HIV-2 infection.

SYMBOL LEGENDS

Symbol	Explanation of symbol	Symbol	Explanation of symbol
	Consult instructions for use		Contains sufficient for < n > tests
NON STERILE	Non Sterile	REF	Product Code
IVD	In vitro diagnostic medical device	LOT	Lot Number
4°C 30°C	Store at 4-30 °C		Manufacturer
	Caution		Date of manufacture (YYYY-MM)
	Keep dry		Expiration Date (YYYY-MM)
	Do not reuse		Do not use if test device pouch is damaged
	Keep away from sunlight		

References

1) Essex, M. (1999) Human immunodeficiency viruses in the developing world. Adv Virus Res 53 : 71-88.
2) Mi Jin Sohn, Young Hae Chong, Ji Eun Chang, Young IK Lee : Overexpression and simple purification of human Immunodeficiency virus-1 gag epitope derived from a recombinant antigen in E. coli and its use in ELISA. Journal of Biotechnology 34 (1994) 149-155.
3) https://www.cdc.gov/hiv/basics/whatishiv.html.
4) Travers, K, Mboup, S, Marlink, R, Gueye-Nidaye, A, Siby, T, Thior, I, Traore, I, Dieng-Sarr, A, Sankale, JL and Mullins, C. Natural protection against HIV-1 infection provided by HIV-2. Science (1995) 268:1612-1615.
5) Global guidance on criteria and processes for validation: Elimination of Mother-to-child transmission of HIV and Syphilis, second edition 2017.
6) Global health sector strategy on HIV, 2016-2021; WHO/HIV/2016.05, June 2016
7) https://www.who.int/hiv/data/2016_global_summary_web4.pptx
8) http://vassarstats.net/clin1.html#def , Richard Lowry.
9) TGS-5: Designing Instruction for use for in vitro diagnostic medical devices.

Product Disclaimer and Warnings

Every warnings and precaution should be taken into consideration before using the test. Failure to consider "Precaution, Warning, and Limitations" may not ensure the diagnostic ability and accuracy of this product. The test result may accordingly be affected by environmental factors and/or user error outside of the control of the Manufacturer and Distributor.

A definitive clinical diagnosis should not be based on the results of a single test, but it should be made by the physician after all clinical and laboratory findings have been evaluated.

"In no event shall our company or its distributor is liable for any direct, indirect, punitive, unforeseen, incidental, special consequential damages, to property or life, whatsoever arising out of or connected with an incorrect diagnosis, whether positive or negative, in the use or misuse of this product".

In the event of performance changes or product malfunction, please contact manufacturer.

Manufactured by
Premier Medical Corporation Private Limited
A1-302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA.
Customer support e-mail : info@premiermedcorp.com
Tel.: +91 2602780112/113 •Website : www.premiermedcorp.com
• ISO 13485 & EN ISO 13485 Certified Company
Part No.: (S)PI05-INS-009, Rev.: AB, Date:2020-02-13 ENGLISH
Note : Instructions for use will be printed in local language of the country using the test, if required.

FIRST RESPONSE® HIV 1-2.O CARD TEST (Version 2.0)

Rapid Immunochromatographic Card Test for the detection of antibodies to HIV-1 and HIV-2 in human whole blood/ serum/plasma

4°C 30°C IVD

REF PI05FRC05, PI05FRC10, PI05FRC25, PI05FRC30, PI05FRC50 & PI05FRC100

Intended Use

First Response® HIV 1-2.O Card Test (Ver. 2.0) is intended for use by healthcare professionals and qualified laboratory personnel. It is a rapid, qualitative screening, in vitro diagnostic test for the detection of antibodies specific to HIV-1 (including Group O) and HIV-2 in human serum, plasma or venous and capillary whole blood. The test can be used as an aid in the diagnosis of HIV-1 and HIV-2. The product can be used for symptomatic, asymptomatic and pregnant women populations. The test kit is not automated and does not require any additional instruments. Reactive specimens should be confirmed by supplemental testing. The product is not intended for blood donor screening.

Introduction

HIV (Human Immunodeficiency Virus) is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from the host cell membrane[1]. Each virus contains two copies of positive-sense genomic RNAs. HIV-1 has been isolated from patients with AIDS and AIDS-related complex[2]. HIV attacks the body's immune system, specifically the CD4 cells (T cells), which help the immune system to fight off infections. Untreated, HIV reduces the number of CD4 cells (T cells) in the body, making the person more likely to get other infections[3,4]. HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals[2]. 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[5]. By 2016 Globally 36.7 million individuals estimated to be living with HIV/AIDS (17.8 million women,16.7 million men and 2.1 million children)[6,7].

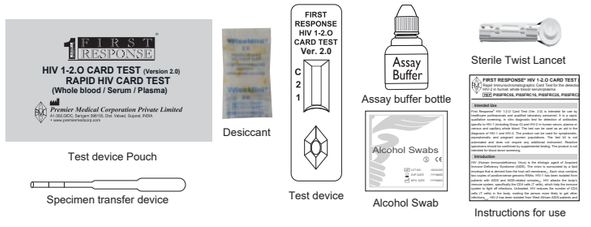
WHO targets for 2020 across the globe to reduce new HIV infections to less than 500000; zero new infections among infants. Reduce HIV-related deaths to below 500000. 90% people living with HIV tested; 90% treated; 90% virally suppressed[6].

The First Response® HIV 1-2.O Card Test (Ver.2.0) is an immunochromatographic (rapid) qualitative test for the detection of antibodies specific to HIV-1 (including Group O) and HIV-2 in human serum, plasma or whole blood.

Assay Principle

First Response® HIV 1-2.O Card Test (Ver.2.0) is based on the principle of immunochromatography for the qualitative detection of antibodies specific for HIV-1 and HIV-2. The nitrocellulose membrane is coated with recombinant HIV-1 capture antigens (gp41 including Group O) on test line "1" region and with recombinant HIV-2 capture antigen (gp36) on test line "2" region and control reagent coated at control line "C". When serum or plasma or whole blood (venous or capillary) specimen is applied followed by assay buffer addition to the specimen well of the test device, the recombinant HIV-1 and 2 antigens (gp41 and gp36) conjugated with colloidal gold particles(CGC) bind to HIV-1 and 2 antibodies present in the test specimen. This conjugated antigen-antibody complex moves through the nitrocellulose membrane and bind to the corresponding immobilized HIV-1 antigen and HIV-2 antigen (Test Lines) leading to the formation of purple colored visible line as the capture antigen-antibody-conjugated antigen complex, indicating reactive results. Purple colored control line will appear irrespective of the reactive or non-reactive specimen. The control line is a procedural control, serves to demonstrate functional reagents and correct migration of fluid.

Materials Provided



Note: Materials provided other than assay buffer bottle are for single use only.

Materials provided	PI05FRC05	PI05FRC10	PI05FRC25	PI05FRC30	PI05FRC50	PI05FRC100
Test device pouch containing: 1 test device, 1 desiccant	05 Nos.	10 Nos.	25 Nos.	30 Nos.	50 Nos.	100 Nos.
Specimen transfer device	05 Nos.	10 Nos.	25 Nos.	30 Nos.	50 Nos.	100 Nos.
Assay buffer bottle (2.5 ml)	1 No.	1 No.	1 No.	1 No.	2 Nos.	4 Nos.
Sterile twist lancets	05 Nos.	10 Nos.	25 Nos.	30 Nos.	50 Nos.	100 Nos.
Alcohol swabs	05 Nos.	10 Nos.	25 Nos.	30 Nos.	50 Nos.	100 Nos.
Instructions for use	1 No.	1 No.	1 No.	1 No.	1 No.	2 Nos.

Materials Required but Not Provided

- New pair of disposable gloves and face mask for each test conducted/specimen collected by fingerstick.
- Sterile gauze pad and tissue paper.
- Permanent marker pen and timer.
- Extra sterile twist lancets, alcohol swabs and specimen transfer device, if needed.
- Sharp disposable box and biohazardous waste container.
- Venipuncture blood collection kit (if whole blood is collected by venipuncture).

Storage and Stability

1) First Response® HIV 1-2.O Card Test (Ver. 2.0) kit should be stored at 4-30°C.
2) Do not freeze the kit or components.
3) The kit is sensitive to humidity and heat. Do not store the kit at temperatures above 30°C and in humid conditions.
4) Assay buffer (opened and unopened) and unopened test device are stable until the expiry date printed on the label when stored at 4-30°C.
5) Perform the test immediately after removing the test device from the aluminium pouch. If a desiccant color has changed from orange to green, do not use the test device.
6) The test device is stable until the printed expiry date on the pouch/external secondary packaging.

Precautions

1) Wear protective gloves and face mask while handling specimens.
2) Dispose of used gloves as biohazard waste. Wash hands thoroughly afterward.
3) Avoid splashing or aerosol formation.
4) Clean up spills thoroughly using an appropriate disinfectant.
5) Decontaminate and dispose of all used specimens, test devices, alcohol swabs, and specimen transfer devices as infectious waste, in a biohazardous waste container. Dispose of used sterile twist lancets in a sharps box and face mask in a waste container.

Warnings

1) For in vitro diagnostic use only.
2) Read the instructions carefully before performing the test, any deviation will invalidate the test results.
3) Apply standard biosafety precautions for handling and disposal of potentially infective materials including human biological specimens irrespective of disease state.
4) Do not drink the assay buffer. It contains sodium azide as a preservative which may be toxic if ingested. When disposed of through sink, flush with a large quantity of water.
5) Devices and assay buffer from different lot must not be used.
6) Do not use the test device if the pouch is not intact.
7) Do not use the sterile twist lancet, if the side lock is not intact.(Refer specimen collection section).
8) Do not use the test device if the desiccant color has changed from orange to green.
9) Do not smoke, eat or drink while handling specimens and performing a test.
10) Do not re-use the test device, alcohol swab, sterile twist lancet and specimen transfer device as these are for single use only.
11) Perform the test by using kit assay buffer, any other buffer or fluid will invalidate the test results.
12) Do not allow the tip of assay buffer bottle to touch the specimen well, as it may contaminate the assay buffer.
13) Do not use the test device or assay buffer beyond the date of expiry.
14) Do not eat the desiccant.
15) Do not use any other specimen other than human whole blood/serum/plasma. Do not mix and interchange different specimens.