WHO Prequalification of In Vitro Diagnostics Programme
PUBLIC REPORT

Product: First Response® HIV 1-2-0 Card Test
Number: PQDx 0018-010-00

Abstract

First Response® HIV 1-2-0 Card Test with **product codes I05FRC100, I05FRC60, I05FRC30, and I05FRC05**, manufactured by **Premier Medical Corporation**, **rest of world (RoW) regulatory version**, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 14 July 2016.

Intended use:
First Response® HIV 1-2-0 Card Test is a qualitative in vitro diagnostic test (immunochromatographic rapid diagnostic test) for the detection of antibodies of all classes specific to HIV-1 (including Group O) and HIV-2 in human serum, plasma and venous or capillary whole blood. The test kit is not automated and does not require any additional instrument, it is intended for use by healthcare professionals. Reactive specimens should be confirmed by other methods.

Test principle:
First Response® HIV 1-2-0 Card test contains a membrane strip, which is pre-coated with recombinant HIV-1 capture antigens (gp41 including subtype O and p24) on test band "1" region and with recombinant HIV-2 capture antigen (gp36) on test band "2" region, respectively on the test device. The recombinant HIV-1 and 2 antigens (gp41, p24 and gp36) colloidal gold conjugate and specimen moves along the membrane chromatographically to the test region and forms a visible line (test line) as the antigen-antibody-antigen gold particle complex.

Test kit contents:

	5 tests Product code (I05FRC05)	**30 tests Product code (I05FRC30)**	**60 tests Product code (I05FRC60)**	**100 tests Product code (I05FRC100)**
Test devices Wrapped with 1 **sample pipette** and **desiccant**	5	30	60	100
Buffer Carbonate buffered	1 bottle of 0.5 ml	1 bottle of 2.5 ml	2 bottles of 2.5ml	4 bottles of 2.5 ml

saline containing proteins and preservative				
Lancets Sterile, single use	5	30	60	100
Alcohol swabs 70% Isopropyl Alcohol	5	30	60	100
Instructions for use	1	1	1	1

Storage:
The test kit should be stored at 4 °C to 30 °C.

Shelf-life:
24 months.

Reading time:
Interpret test results at 15 minutes. Do not interpret after 15 minutes.

Summary of prequalification status for First Response® HIV 1-2-0 Card Test

	Initial acceptance	
	Date	**Outcome**
Status on PQ list	14 July 2016	listed
Dossier assessment	29 June 2016	MR
Inspection status	3 December 2014	MR
Laboratory evaluation	15 September 2014	MR

MR: Meets Requirements
NA: Not Applicable

First Response® HIV 1-2-0 Card Test was accepted for the WHO list of prequalified in vitro diagnostics on the basis of data submitted and publicly available information.

Background information

Premier Medical Corporation submitted an application for prequalification of First Response® HIV 1-2-0 Card Test. Based on the established prioritization criteria, First Response® HIV 1-2-0 Card Test was given priority for prequalification.

Product dossier assessment

Premier Medical Corporation submitted a product dossier for First Response® HIV 1-2-0 Card Test as per the "Instructions for compilation of a product dossier" (PQDx_018 v1). The information submitted in the product dossier was reviewed by WHO staff and external experts (assessors) appointed by WHO in accordance with the internal report on the screening and assessment of a product dossier (PQDx_009 v2). Based on the product dossier screening and assessment findings, a recommendation was made to accept the product dossier for First Response® HIV 1-2-0 Card test for prequalification.

Commitments for prequalification:

Commitment 1: the manufacturer has agreed to carry out additional studies to demonstrate precision (repeatability and reproducibility) taking into consideration WHO recommendations.

Commitment 2: the manufacturer has agreed to carry out additional shipping stability study as per the agreed protocol and recommendations from WHO.

Manufacturing site inspection

A comprehensive inspection was performed at the sites of manufacture (**Nani Daman**: 32-35 Shri Ganesh Industrial Estate, Kachigam Nani Daman, 396215, India and **Sarigam**: A1-302, GIDC, Sarigam 396155 Dist Valsad, Gujarat, India) of the First Response® HIV 1-2-0 Card Test in July 2014 as per the "Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics" (PQDx_014 v1). The inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality. The manufacturer's responses to the nonconformities found at the time of the inspection were accepted 3 December 2014.

Laboratory evaluation

First Response® HIV 1-2-0 Card Test (Premier Medical Corporation Ltd) was evaluated by WHO in the first quarter of 2012 at the Institute of Tropical Medicine, Belgium – a WHO Collaborating Centre for HIV/AIDS Diagnostics and Laboratory Support The laboratory evaluation was conducted according to the "WHO Protocol for the laboratory evaluation of HIV serology assays" (PQDx_030 V1.0), and drew the following conclusions:

First Response® HIV 1-2-0 Card Test (Premier Medical Corporation Ltd) is an immunochromatographic rapid diagnostic test for the discriminatory detection of HIV-1/HIV-2 antibodies in human serum, plasma, and venous and capillary whole blood. A volume of 10 µL of specimen is needed to perform the assay. This type of assay requires

no sophisticated equipment and can therefore be performed in laboratories with limited facilities and non-laboratory testing settings. Reading of the results can be done visually i.e. subjectively read.

In this limited evaluation on a panel of 1079 specimens, we found an initial sensitivity (95% CI) of 100% (99.1-100%) and an initial specificity (95% CI) of 98.94% (97.8-99.6%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.1-100%) and the final specificity (95% CI) was 99.39% (98.5-99.8%) compared to the reference assays. Lot to lot variation observed was within the acceptance criteria for all but one dilution series.

For eight seroconversion panels, First Response® HIV 1-2-0 Card Test detected on average 0.25 specimens earlier than the benchmark assay (Enzygnost Anti-HIV 1/2 Plus [Siemens Healthcare Diagnostics]).

For the mixed titer panel, First Response® HIV 1-2-0 Card Test correctly classified all specimens. For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], First Response® HIV 1-2-0 Card Test detected all HIV-1 subtypes tested (HIV-1 A, HIV-1 B, HIV-C, HIV-1 CRF01_AE, and HIV-2) with the exception of HIV-1 type O.

In this study, 0% of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the overall inter-reader variability was 2.04% (0.83% for HIV-1 band, 1.21% for HIV-2 band). The invalid rate was 0%.

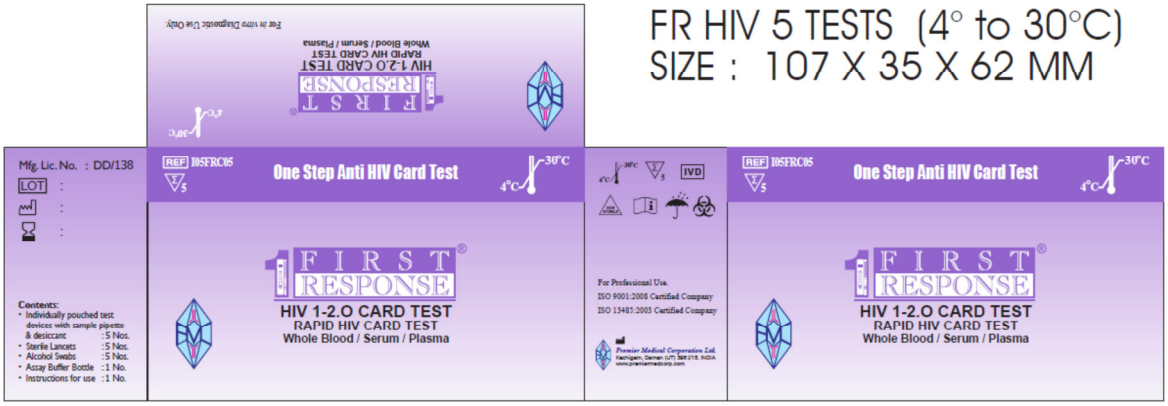
Labelling

1. **Labels**
2. **Instructions for use**

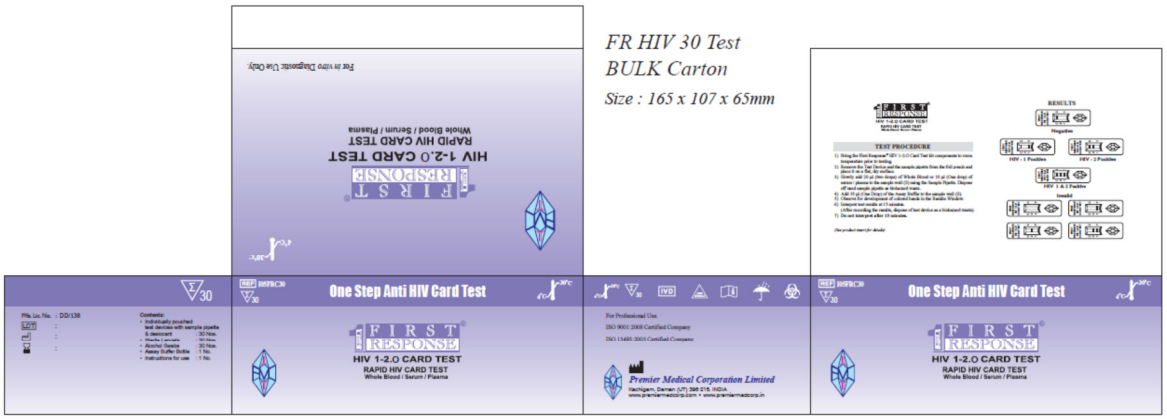
1. Labels

Outer box labels

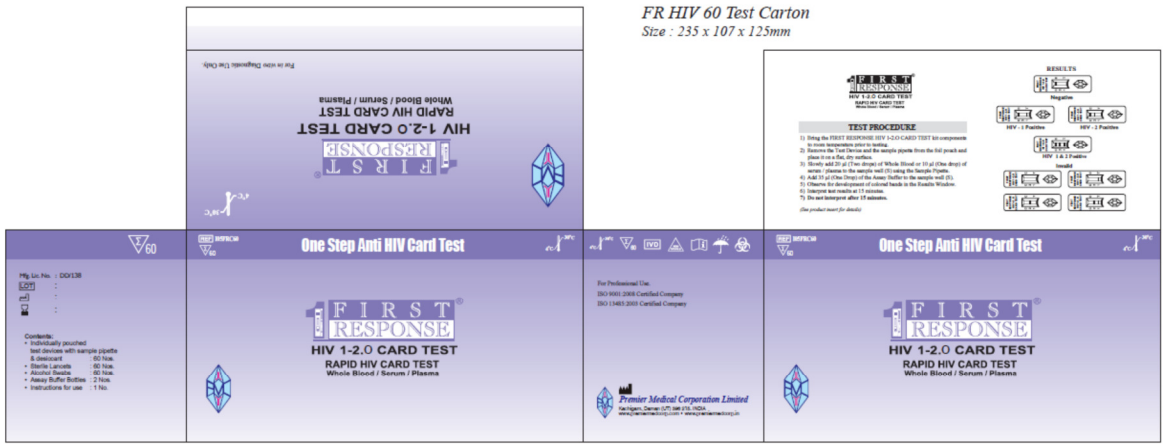
First Response® HIV 1-2-0 Card Test kit box: 5 Tests



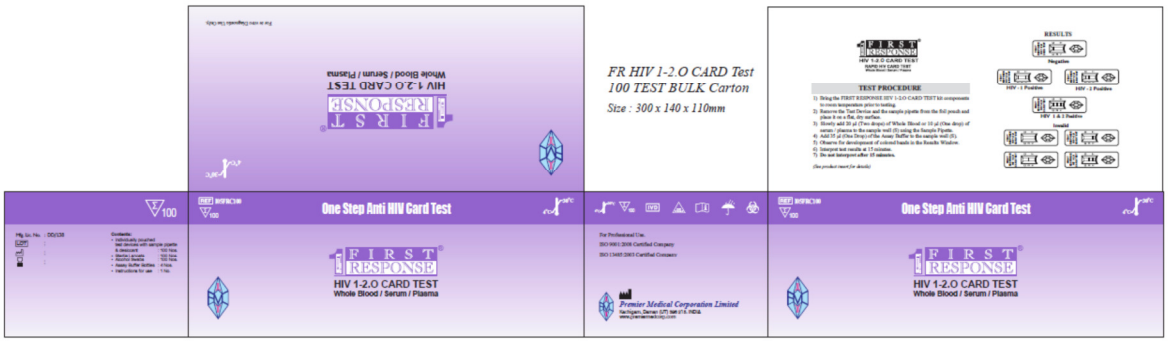
First Response® HIV 1-2-0 Card Test kit box: 30 Tests



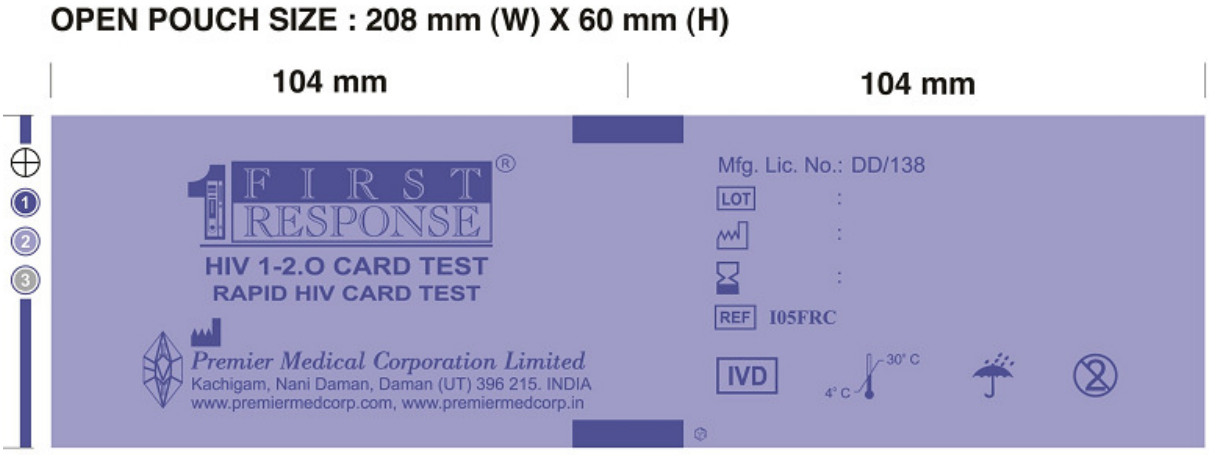
First Response® HIV 1-2-0 Card Test kit box: 60 Tests



First Response® HIV 1-2-0 Card Test kit box: 100 Tests



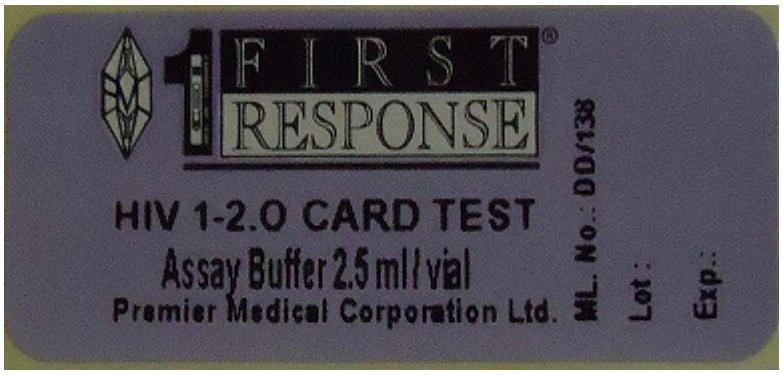
Aluminium pouch label



Assay buffer labels

Assay buffer label: 0.5 ml

Assay buffer label: 2.5 ml



2. Instructions for use

FIRST RESPONSE® HIV 1-2.O CARD TEST

Rapid Immunochromatographic Card Test for the detection of Antibodies to HIV 1 & 2 in Human Whole Blood/Serum/Plasma

REF I05FRC30 4°C 30°C IVD

Intended Use:

First Response® HIV 1-2.O Card Test is intended for use by healthcare professionals and is a qualitative, screening, in vitro diagnostic test for detection of antibodies specific to HIV-1 (including Group O) and HIV-2 in human serum, plasma or venous and capillary blood. The test kit is not automated and does not require any additional instrument. Reactive samples should be confirmed by supplemental testing.

Introduction:

HIV (Human Immunodeficiency Virus) is recognized as the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virus is transmitted by sexual contact, exposure to infected blood, certain bodily fluids or tissues, and from mother to fetus or child during the prenatal period. The clinical diagnosis of HIV has been done by detection of HIV 1 and HIV 2 antibodies in human plasma, serum, or venous/capillary whole blood by immunoassay. Researchers have constructed HIV-1 and -2 genes for the expression of recombinant antigens in bacterium systems such as *E. coli* and focused on HIV-1 and -2 proteins, which are definitely immunogenic. The major immunoreactive antigens of these proteins have been reported to have HIV-1 gp41, p24, and HIV-2 gp36 based on western blot analysis.

First Response® HIV -1-2-0 Card Test is a 3rd generation HIV immunoassay. The design of 3rd generation assays allows the detection of HIV specific IgG as well as IgM, which may occur early in infection.

Assay Principle:

The First Response® HIV 1-2.O Card Test is a 3rd generation lateral flow chromatographic immunoassay. The test cassette consists of: 1) a purple colored conjugate pad containing HIV-1 and -2 specific recombinant antigens (gp41 including Group O, gp36 and p24) and control protein conjugated with colloidal gold particles; and 2) a nitrocellulose membrane strip containing two test lines (1 and 2) and a control line (C). Test line '1' is pre-coated with HIV-1 recombinant antigens (gp41 including Group O and p24) for the detection of antibodies to HIV-1. Test line '2' is pre-coated with HIV-2 recombinant antigen (gp36) for the detection of antibodies to HIV-2. The Control line is pre-coated with a control line protein.

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the strip. HIV-1 antibodies, if present in the specimen, migrate through the conjugate pad where they bind to the HIV-1 conjugates. The immune-complex is then captured on the membrane by the pre-coated HIV-1 antigen forming a purple colored line at test line "1", indicating a HIV-1 antibody positive or reactive test result. Lack of color development on test line "1" suggests an HIV-1 antibody negative or non-reactive result.

HIV-2 antibodies, if present in the specimen, migrate through the conjugate pad where they bind to the HIV-2 conjugates. The immune-complex is then captured on the membrane by the pre-coated HIV-2 antigen forming a purple colored line at test line "2", indicating a HIV-2 antibody positive or reactive test result. Lack of color development on test line "2" suggests a HIV-2 antibody negative or non-reactive result.

The test contains an internal control line ("C"), which should exhibit a purple colored line of the immune-complex of the control proteins regardless of color development on the test lines. If the "C" line does not develop, the test result is invalid and the specimen must be retested with another device. The control line in test device is not a specimen addition control.

Materials Provided

- 30 cassette packages (foil pouches), each containing:
  - 1 device
  - 1 desiccant
  - 1 specimen transfer device (sample pipette)
- 1 assay buffer bottle - 2.5 ml
- 30 sterile single-use lancets (optional)
- 30 alcohol swabs (optional)
- 1 instructions for use

Materials Required but Not Provided

- New pair of disposable gloves
- Pen
- Timer
- Extra lancets and alcohol swabs, if needed
- Sharps disposable box
- Venipuncture blood collection materials and precision pipette plus tips (if whole blood is collected by venipuncture)
- Biohazardous waste container

Storage and Stability:

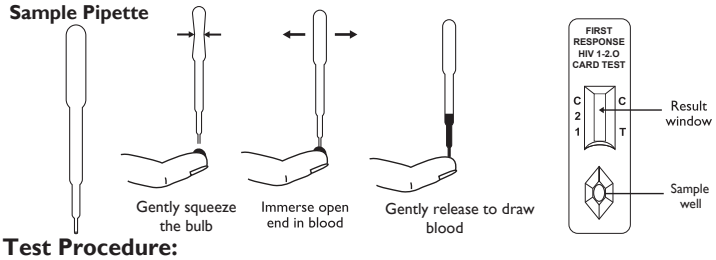
First Response® HIV 1-2.O Card Test should be stored at 4-30 °C. Do not freeze the kit or components. Assay buffer (opened or unopened) and the unopened test device are stable until the expiry date printed on the label when stored at 4-30 °C. The test device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the foil pouch. The shelf life of the kit is as indicated on the outer package. Do not use the test device and assay buffer beyond the date of expiry.

Precautions:

1) For *in vitro* diagnostic use only.
2) This package insert must be read completely before performing the test. Failure to follow the insert may lead to inaccurate test results.
3) Test devices and assay buffer of different lots must not be used.
4) Do not use the test device if the pouch is not intact.
5) Do not use the lancet if the seal is broken.
6) Check the desiccant for saturation immediately after opening the pouch.
7) Bring all reagents to room temperature (15-30 °C) before use.
8) Do not smoke, eat or drink while handling specimens or performing the Test Procedure.
9) The test device, alcohol swab, lancet and sample pipette are each intended for a single use only.
10) Follow the Test Procedure strictly. Any deviation will invalidate the results.
11) Perform the test by using the assay buffer included with this kit. Any other buffer or fluid will invalidate the results.
12) Do not touch the tip of the assay buffer bottle to any surface. This may contaminate the assay buffer.
13) Wear protective gloves while handling specimens. Dispose of used gloves as biohazardous waste. Wash hands thoroughly afterwards.
14) Avoid splashing or aerosol formation.
15) Clean up spills thoroughly using an appropriate disinfectant.
16) Handle the negative and positive controls in the same manner as the patient specimens.
17) Decontaminate and dispose of all used specimens, test devices, alcohol swabs and sample pipettes as infectious waste using an appropriate biohazardous waste container. Dispose of used lancets in a sharps box.
18) Users of this test should follow the US CDC Universal Precautions for Preventing Transmission of Bloodborne Infections.

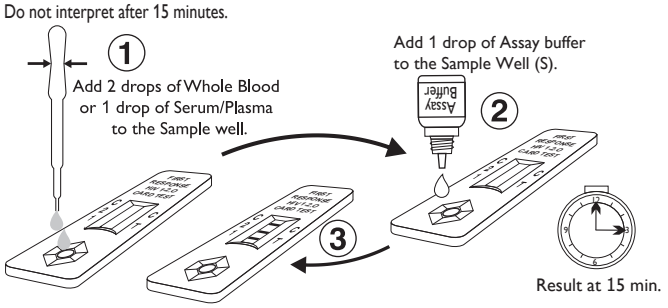
Specimen Collection and Storage:

1) Capillary blood collection: Clean the area to be lanced with an alcohol swab and allow it to air dry. Pierce the skin with a sterile lancet provided. Wipe away first drop of blood and use second drop for collection. Take a 20 µl (two drops) sample pipette provided and squeeze the large bulb. Immerse the open end in the blood drop and then release the pressure to draw blood into the sample pipette.
2) Venous Blood collection: Collect the whole blood by venipuncture in to collection tube containing anticoagulants (EDTA, Heparin, ACD and Sodium Citrate anticoagulants have been validated for use with this test.)
3) Plasma collection: Collect the whole blood in collection tubes containing anticoagulants (such as EDTA, Heparin, ACD or Sodium Citrate) by venipuncture. Centrifuge the tube at 3000 RPM for 10-15 min to obtain plasma (supernatant).
4) Serum: Collect whole blood in collection tubes without having any anticoagulants by venipuncture. Keep the tube in an upright position for 30 minutes and then centrifuge it at 3000 rpm for 10-15 minutes to obtain serum (supernatant).
5) Whole blood specimens collected in appropriate anticoagulant may be used for testing immediately or may be stored at 2-8 °C for up to 3 days. Do not freeze whole blood specimen.
6) If serum or plasma specimens are not immediately tested, they should be refrigerated at 2-8 °C. For storage periods greater than three days, freezing at -20 °C is recommended. They should be brought to room temperature prior to use.
7) Serum or plasma specimens containing precipitate or high lipemia may yield inconsistent test results. Such specimens must ALWAYS be centrifuged prior to assaying.



Test Procedure:

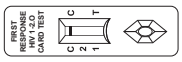
1) Bring the First Response® HIV 1-2.O Card Test kit components to room temperature prior to testing.
2) Remove the test device and the sample pipette from the foil pouch and place them on a flat, clean and dry surface.
3) Slowly add 20 µl (two drops) of whole blood or 10µl (one drop) of serum or plasma to the sample well (S) using the sample pipette. Dispose of the used sample pipette as biohazardous waste.
4) Add 35 µl (one drop) of the assay buffer to the sample well (S).
5) Observe for development of colored bands in the results window.
6) Interpret the test results at 15 minutes. After recording the results, dispose of the test device as biohazardous waste.
7) Do not interpret after 15 minutes.



Interpretation of the Test:

Non-reactive Result

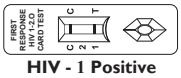
If only one color line appears at control line 'C' as in the figure, the specimen is non-reactive.



Negative

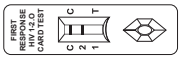
Reactive Results

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



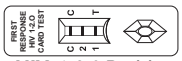
HIV - 1 Positive

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



HIV - 2 Positive

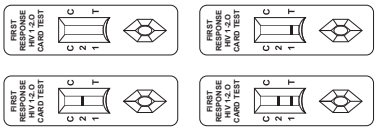
If two color lines appear, one at control line 'C' and the other at test line HIV-2 '2' as in the figure, the specimen is reactive for antibodies to HIV-2. Interpret a faint line as a reactive line.



HIV 1 & 2 Positive

Invalid Result:

If no color line appears at the control line 'C' within the stipulated time then the result is invalid. The result is also invalid if a color band appears only at test line '1' and/or '2'. If there is high background coloring and incomplete migration along the test strip then the result is invalid.



Invalid

Limitations:

1) The "Test Procedure" and "Interpretation of the Test" 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 is designed to detect antibodies to HIV-1 and HIV-2 in human serum, plasma and whole blood. Other bodily fluids or pooled specimens may not give accurate results.
3) The First Response® HIV 1-2.O Card Test 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) There is potential for interference when testing is performed with hemolytic specimens. Hemolytic specimens may produce a reddish background even after the reading time.
5) Highly lipemic samples or turbid samples shall be centrifuged and the resultant supernatant shall be used for testing.

FIRST RESPONSE® HIV 1-2.O CARD TEST

Rapid Immunochromatographic Card Test for the detection of Antibodies to HIV 1 & 2 in Human Whole Blood/Serum/Plasma

REF I05FRC30 4°C 30°C IVD

6) A non-reactive result for an individual subject indicates an 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 the stage of disease in which a sample is collected.
7) Immunochromatographic testing alone cannot be used to diagnose AIDS even if the antibodies against HIV-1 and/or HIV-2 are present in a patient's specimen sample. A negative result at any time does not preclude the possibility of HIV-1 or HIV-2 infection.
8) All three test lines (1, 2 and C) may develop when tested with samples containing high titers of HIV-1 antibodies. Hence, reactive test bands for both HIV-1 and HIV-2 may not indicate mixed infection but may result from the cross-reactivity of HIV-1 and HIV-2 because of the similarity of their genomic structure. To differentiate virus type or co-infection accurately, one must perform a confirmatory test such as Western blot or PCR.
9) EDTA, Heparin, ACD or Sodium Citrate anticoagulants have been validated for use with this test.
10) False negative results may arise because of the hook effect due to very high titer of antibodies in the sample.
11) Although a reactive result may indicate infection with HIV-1 or HIV-2 virus, a diagnosis of AIDS can only be made on clinical grounds. This shall be based on the case definition for AIDS established by the Centers for Disease Control and Prevention. For samples repeatedly tested and found to be reactive, more specific supplemental testing must be performed.

Performance Characteristics:

(A) Clinical Specificity and Sensitivity

(A.1) In-house Evaluation: First Response® HIV 1-2.O Card Test has been tested using an in-house panel of Positive and Negative clinical samples confirmed by a leading commercial anti-HIV-1 and -2 ELISA kit. The result shows that First Response® HIV 1-2.O Card Test is very accurate compared to other commercial ELISA kit. In a comparison of the First Response® HIV 1-2.O Card Test versus a leading commercial anti-HIV-1 and -2 ELISA and rapid test, results gave a sensitivity of 100%, a specificity of 100% and total agreement of 100%.

Specimen type	Specimen Nos.	Reference Commercial ELISA		First Response® HIV 1-2.O Card Test		Clinical Sensitivity	Clinical Specificity
Samples		Positive	Negative	Positive	Negative		
HIV 1 Positive Serum	400	400	0	400	0	100 %	---
HIV 2 Positive Serum	100	100	0	100	0	100 %	---
HIV 1 positive Plasma (Blood Donors)	09	09	00	09	00	100 %	---
Negative plasma (Healthy Blood Donors)	1122	00	1122	00	1122	---	100 %
Negative serum	700	0	700	0	700	---	100 %
Negative whole blood	100	0	100	0	100	---	100 %
Pregnant woman negative sample	210	0	210	0	210	---	100 %
HIV negative clinical samples#	105	0	105	0	105	---	100 %

HIV negative clinical sample includes 35 HBsAg positive, 35 HCV positive and 35 Syphilis positive samples.

(A.2) External Evaluation: The Performance of First Response®HIV 1-2.O Card Test was evaluated at various external laboratories and institutes. The summary of reports is as follows:

Name of the Institute	Year of Testing	Clinical Sensitivity	Clinical Specificity
HIV Assays: Operational Characteristics, WHO Report No.: 12.	2000	100%	98.8%
National Institute of Biologicals, India	2003	100 %	99.87 %
Ghana Health Service, Ghana	2004	100 %	100 %
National Institute for Communicable Diseases, South Africa	2004	100 %	100 %
Virology Laboratory, University Teaching Hospital, Zambia	2006	100 %	100 %
HIV Assays Lab. Performance and Other Operational Characteristics. WHO Report No. 18.	2014	100%	99.4%
Centre Internatonal De Référence "Chantal Biya", Cameroon.	2015	100%	100%

(B) Analytical Specificity and Sensitivity:

(B.1) Analytical Specificity:

(B.1.1)Potential Interfering Substances:

The interfering substances that may affect performance of First Response® HIV 1-2.O Card Test were tested. The results are presented in the following tables and demonstrate that the tested substances do not interfere with the performance of the First Response® HIV 1-2.O Card Test. **However, hemolyzed specimens and lipemic specimens showed poor background clearance. Therefore, it is not recommended to use such specimens for this assay. The lipemic specimens can be successfully used for testing after centrifugation.

Sample Details	Sample size	HIV 1/ 2 Reactivity	Sample Details	Sample size	HIV 1/ 2 Reactivity
Lipemic samples**	05	Negative	Low Hematocrit samples	05	Negative
Icteric samples	05	Negative	Whole blood specimen in ACD anticoagulant	05	Negative
Hemolytic samples**	05	Negative	RF Ab 4001-5000 IU/mL Plasma	04	Negative
High Hematocrit samples	05	Negative	dsDNA Antibody Positive Plasma	01	Negative

(B.1.2) Cross Reactivity Study:

First Response® HIV 1-2.O Card Test was tested with other diseases/conditions, which may show cross reactivity with the test. The results are presented in the following table and demonstrate that First Response® HIV 1-2.O Card Test shows no cross reactivity with the tested diseases/conditions samples.

Sample Details	Sample size	HIV 1/ 2 Reactivity	Sample Details	Sample size	HIV 1/ 2 Reactivity
Pf positive whole blood	05	Negative	RF Positive samples	04	Negative
Pan Malaria positive blood	05	Negative	HSV 1 / 2 Positive	05	Negative
Dengue NS 1 Positive samples	05	Negative	Rubella Virus	05	Negative
Multipara (Pregnant Woman)	03	Negative	HTLV-I Ab Positive Plasma confirmed	07	Negative
CMV Positive samples	03	Negative	HTLV-II Ab Positive Plasma confirmed	09	Negative
ANA Positive samples	04	Negative	HSV-I IgG Positive Plasma	09	Negative
HAV Positive samples	05	Negative	Rubella IgG Positive Plasma	10	Negative
EBV Positive samples	02	Negative			

(B.2) Analytical Sensitivity

The Analytical Sensitivity of the First Response® HIV 1-2.O Card Test is determined by testing commercially available seroconversion panels. A commercially available CE-marked rapid lateral flow test is used as a reference test for the comparative performance study. The HIV seroconversion sample study is done as specified in CTS 2009/886/EC for *In Vitro* Diagnostics Medical Device. A total of 37 seroconversion panels were tested by the manufacturer (21 panels by internal evaluation) and entities other than the manufacturer (16 panels by external evaluation) to meet the criteria specified in CTS 2009/886/EC for *In Vitro* Diagnostics Medical Device.

(B2.1) Analytical Sensitivity- In-house Evaluation

The Analytical Sensitivity of the First Response® HIV 1-2.O Card Test was found by testing a total of 21 commercially available seroconversion panels. First Response® HIV 1-2.O Card Test showed a similar detection limit as compared to the reference CE-marked rapid test.

Analytical Sensitivity - In house Evaluation							
Total Seroconversion Panels	Total Specimens	First Response® HIV 1-2.O Card Test			Reference CE-marked rapid lateral flow test.		
		Positive	Negative	Detection Index**		Negative	Detection Index**
21	121	33	88	0.27	33	88	0.27

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

(B.2.2) Analytical Sensitivity- External Evaluation

The performance of First Response® HIV 1-2.O Card Test with sixteen (16) seroconversion panels is reported by two different study conducted by WHO. Full evaluation data is available in WHO Report 12, HIV Assays: Operational Characteristics (Phase I) and WHO Report 18, HIV Assays, Laboratory Performance and Other Operational Characteristics. Both studies reported that First Response® HIV 1-2.O Card Test showed a similar or higher panel detection score compared to other commercially available rapid tests in studies.

Analytical sensitivity- External evaluation							
Total Seroconversion Panels	Total Specimens	First Response® HIV 1-2.O Card Test			Reference rapid lateral flow test.		
		Positive	Negative	Detection Index**	Positive	Negative	Detection Index**
08	52	23	29	0.44	20	32	0.38
08	44	29	15	0.66	28	16	0.64

Precision:

a) Within-run precision was determined by using ten replicates of four different specimens containing different concentrations of antibodies. Within-run precision was observed as 100%.
b) Between-operator and -sites precision was determined by using six replicates of ten different specimens containing different concentrations of antibodies at two different sites and by two different operators. The test showed 100% precision at both sites with both operators.
c) Between-run precision was determined by using four different specimens containing different concentrations of antibodies in three different replicates with three different lots of test devices. Between-run precision was observed as 100%.

SYMBOL LEGENDS

Symbols	Explanation of symbol	Symbols	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
	Biological risks		Date of manufacture (YYYY-MM)
	Keep dry		Expiration Date (YYYY-MM)
	Do not reuse		

References:

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3) Lee Ratner, William Haseltine, Roberto Patarca, etc.: Complete nucleotide sequence of the AIDS virus, HTLV-III. Nature VOL. 313,24 January 1985.
4) V.S. Ivanov, Z.K. Suvorova, L.D. Tchikin, A.T. Kozhich and V.T. Ivanov : Effective method for synthetic peptide immobilization that increases the sensitivity and specificity of ELISA procedures. Journal of Immunological Methods, 153 (1992) 229-233.
5) 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.

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ISO 9001:2008 Certified Company
ISO 13485:2003 Certified Company EN ISO 13485:2012 Certified Company

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Note: Instructions for use will be printed in local language of the country using the test, if required.