WHO Prequalification of In Vitro Diagnostics
PUBLIC ASSESSMENT REPORT

Product: First Response HIV 1-2.O Card test (Version 2.0)
WHO reference number: PQDx 0363-010-00

First Response HIV 1-2.O Card test (Version 2.0) with product codes PI05FRC05, PI05FRC10, PI05FRC25, PI05FRC30, PI05FRC50, PI05FRC60 and PI05FRC100 manufactured by Premier Medical Corporation Private Limited, Rest of World regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 16 September 2019

Summary of the WHO prequalification assessment for the First Response HIV 1-2.O Card test (Version 2.0)

	Date	Outcome
Prequalification listing	16 September 2019	listed
Dossier assessment	19 August 2019	MR
Product performance evaluation	Third quarter of 2018	MR

MR: Meets Requirements

Report amendments and/or product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendment and change request reference, where applicable.	Date of report amendment
2.0	1. Addition of two new bulk packs added, as 5 test pack and 10 test packs. 2. Replacement of twist lancet with Auto safety lancet for the catalogue no. PI05FRC60. 3. A new specimen transfer device having "10 µl & 20 µl marking line" was introduced to make it more user friendly. This involved a change to components and to labelling for the existing and new pack sizes.	12 March 2020
3.0	The introduction of new suppliers for Alcohol Swab and Twist Lancet resulted in the change of labels.	12 March 2025
4.0	1. Change in the regulatory certification and labelling of the supplier for sterile lancet "Shandong Lianfa Medical Plastic Products	12 September 2025

	Co., Ltd." 2. Change in the label of the alcohol swab supplied by Medtrue Enterprises Co.,Limited. 3. Additional supplier for Sterile auto safety lancet, resulting in additional auto safety lancet label.	
5.0	Changes to the assay buffer bottle supplied with the IVD for the First Response product line. There are no changes to the assay buffer itself (PQC-IVD-2025-0015).	12 January 2026

Intended use

According to the claim of intended use from Premier Medical Corporation Private Limited,
"*First Response HIV 1-2.O Card Test (Version 2.0) is intended for use by healthcare professionals and qualified laboratory personnel. It is a rapid, 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 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 instrument. Reactive specimens should be confirmed by supplemental testing. The product is not intended for blood donor screening*".

Test kit contents

Component	5 tests (product code PI05FRC05)	10 tests (product code PI05FRC10)	25 tests (product code PI05FRC25)	30 tests (product code PI05FRC30)	50 tests (product code PI05FRC50)	60 tests (product code PI05FRC60)	100 tests (product code PI05FRC100)
Test device pouch containing: 1 test device, 1 desiccant	5	10	25	30	50	60	100
Specimen transfer device	5	10	25	30	50	60	100
Assay buffer bottle	1 x 2.5 ml	1 x 2.5 ml	1 x 2.5 ml	1 x 2.5 ml	2 x 2.5 ml	4 x 2.5 ml	4 x 2.5 ml
Sterile lancets	5	10	25	30	50	60 (auto safety)	100
Alcohol swabs	5	10	25	30	50	60	100
Instructions for use	1	1	1	1	1	1	2

Items required but not provided

- New pair of disposable gloves and face mask for each test to be conducted/specimen collected by fingerstick.
- Sterile gauze pad
- 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

The test kit must be stored between 4 and 30 °C.

Shelf-life upon manufacture[1]

24 months.

Dossier assessment

Premier Medical Corporation Private Limited submitted a product dossier for First Response HIV 1-2.O Card Test (Version 2.0) as per the "*Instructions for compilation of a product dossier*" (PQDx_018 version 3). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 19 August 2019.

Based on the product dossier screening and assessment findings, the product dossier for the First Response HIV 1-2.O Card Test (Version 2.0) meets WHO prequalification requirements.

Manufacturing site inspection

The inspection of the manufacturing site(s) was conducted to assess whether the manufacturer's quality management system (QMS) and manufacturing practices are in alignment with:
(i) applicable international standards, such as ISO 13485 (Medical devices – Quality management systems – Requirements for regulatory purposes);
(ii) the manufacturer's own documented procedures and quality requirements; and
(iii) other relevant international standards and guidelines applicable to in vitro diagnostic (IVD) medical devices. The WHO's Public Inspection Reports are accessible at:

https://extranet.who.int/pqweb/vitro-diagnostics/who-public-inspection-reports

[1] The assigned device shelf-life is based on stability data generated from the date of manufacture. The finished goods shelf-life, calculated from the date of packaging completion, may be shorter depending on the time elapsed between manufacture and final packaging of the device.

Product performance evaluation

First response HIV 1-2.O Card Test (Version 2.0) (Premier Medical Corporation Private Limited) was evaluated by WHO at the Institute of Tropical Medicine in the third quarter of 2018 using serum/plasma specimens. From this evaluation, we drew the following conclusions:

First response HIV 1-2.O Card Test (Version 2.0) (Premier Medical Corporation Private Limited) is a qualitative rapid immunochromatographic assay for discriminatory detection of HIV-1/2 antibodies in human serum/plasma and venous/capillary whole blood specimens (using EDTA, heparin or Sodium citrate as anticoagulants). A volume of 10 µL of serum/plasma and 20 µL of whole blood 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 settings. Reading of the results can be done visually i.e. subjectively read.

In this limited evaluation on a panel of 1200 clinically-derived stored serum/plasma specimens, compared to the reference algorithm (Vironostika HIV Ag/Ab [bioMérieux] and Enzygnost Anti-HIV 1/2 [Siemens Healthcare Diagnostics]; followed by INNO-LIA HIV I/II Score [Fujirebio]), the following performance characteristics were obtained:

Performance characteristics in comparison with an agreed reference standard		
	Initial (95% CI)	**Final (95% CI)**
Sensitivity % (N=470)	100 (99.2-100)	100 (99.2-100)
Specificity % (N=730)	99.7 (99.0-100)	100 (99.5-100)
Invalid rate %	0	
Inter-reader variability % (N=1200)	3.1*	

* *all discrepant results between readers were among HIV-positive specimens and the majority (37/39) showed discrepant readings of the HIV-2 band, while the HIV-1 band reading was concordant.*

Out of 449 HIV-1 positive specimens, First response HIV 1-2.O Card Test (Version 2.0) test showed presence of the HIV-2 band in 66 (14.7%) specimens. While out of 21 HIV-2 positive specimens, 11 (52.4%) showed presence of the HIV-1 band. This indicates significant cross reactivity between HIV-1 and HIV-2 bands on First response HIV 1-2.O Card Test (Version 2.0).

In addition, analytical performance characteristics were assessed using commercially available and locally-made panels and the following results were obtained:

Additional performance characteristics	
Sensitivity during seroconversion on 8 seroconversion panels in comparison with a benchmark assay (Enzygnost Anti-HIV 1/2 Plus)	Seroconversion sensitivity index of -0.125, therefore detection is 0.125 days earlier than the benchmark assay.
Analytical sensitivity on a mixed titer panel (PRB205, SeraCare Life Science Inc.)	All 25 specimens of the mixed titer panel were correctly classified.
HIV subtype detection using WHO reference panel for anti-HIV (NIBSC code 02/210)	All specimens containing anti-HIV-1 group M subtypes and anti-HIV-2 were correctly identified. The specimen containing anti-HIV-1 group O was not detected.
Lot to lot variation on a dilution panel in comparison with an agreed reference standard	Acceptable

Key operational characteristics	
Validated specimen types	Serum, plasma (EDTA, heparin or sodium citrate), venous whole blood, capillary whole blood
Number of steps	2 without precision required
Time to result	15 minutes
Endpoint stability	10 minutes (do not read after 25 minutes)
Internal QC	Yes, specimen addition control
In-use stability of reagents	Opened buffer vials are stable until the expiry date when stored at 4-30°C. Test should be used immediately after removing from the aluminum pouch.

Labelling review

The labelling submitted for the First Response HIV 1-2.O Card Test (Version 2.0) was reviewed by WHO staff and external technical experts appointed by WHO. The review evaluated the labelling for clarity and consistency with the information submitted in the product dossier, alignment with international guidance and standards, and suitability for

the intended users and settings in WHO Member States, including low- and middle-income countries.

The table below provides traceability of the labelling documents reviewed during the assessment, including document titles, version numbers, approval dates, and control identifiers.

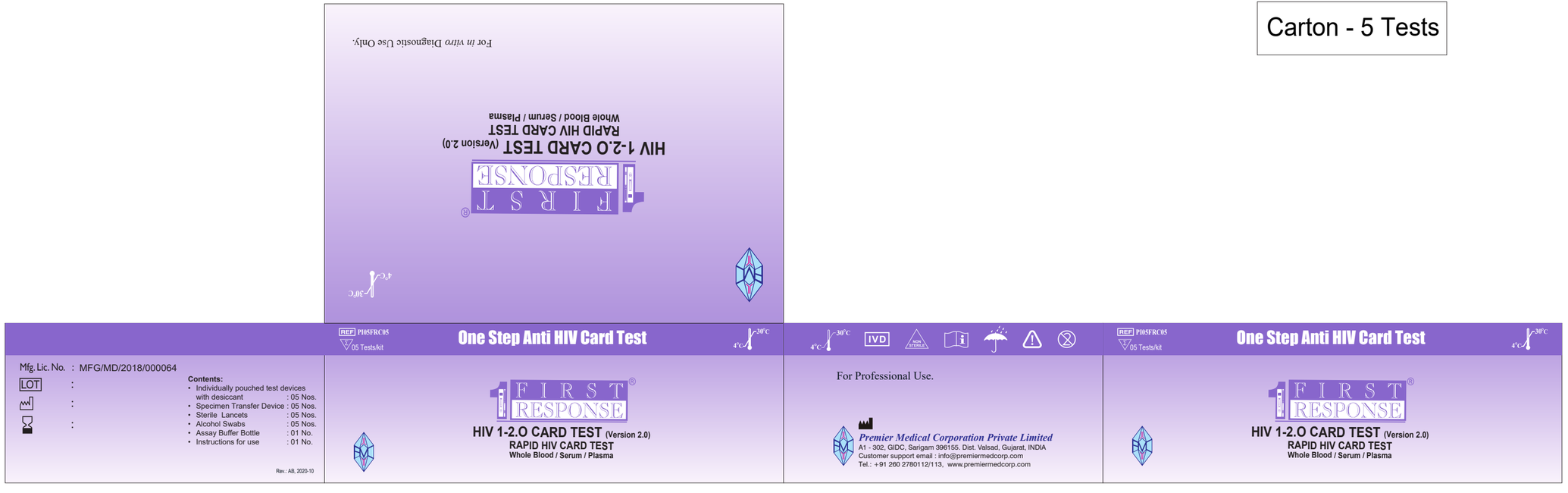
Controlled Labelling References

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer box artwork	Carton 5 tests	AB	2020-10	FM-QA-40
	Carton 10 tests	AB	2023-10	FM-QA-40
	Carton 25 tests	AD	2022-11	FM-QA-40
	Carton 30 tests	AD	2021-01	FM-QA-40
	Carton 50 tests	AA	2020-10	FM-QA-40
	Carton 60 tests	AB	2020-09	FM-QA-40
	Carton 100 tests	AB	2020-08	FM-QA-40
	Carton 50 tests inner	AB	2020-08	FM-QA-40
Pouch / Device label	Aluminium Pouch	01	2024-08-23	FM-QA-40
Reagent bottle labels	Assay Buffer Bottle Label - DBS-028	01	2024-08-23	FM-QA-40
Accessory labeling	Alcohol Swab (Medtrue)	02	2025-11-25	FM-QA-40
	Alcohol Swab (Phoenix)	01	2024-08-23	FM-QA-40
	Sterile Twist Lancet – (LAN-012)	01	2024-08-23	FM-QA-40
	Sterile Twist Lancet – (LAN-013)	01	2024-08-23	FM-QA-40
	Sterile Twist Lancet – (LAN-007)	01	2024-08-23	FM-QA-40
	Sterile Twist Lancet – (LAN-008)	01	2024-08-23	FM-QA-40
	Sterile Safety Lancet – (LAN-011)	01	2025-02-10	FM-QA-40
	Specimen Transfer Device (05 Nos.)	01	2024-08-23	FM-QA-40
	Specimen Transfer Device (10 Nos.)	01	2024-08-23	FM-QA-40
	Specimen Transfer Device (25 Nos.) (STD-005)	01	2024-08-23	FM-QA-40

	Specimen Transfer Device (30 Nos.) (STD-006)	01	2024-08-23	FM-QA-40
	Specimen Transfer Device (65 Nos.) (STD-007)	01	2024-08-23	FM-QA-40
Instructions for Use (IFU)	(S)PI05-INS-006	AB	2020-02-13	FM-QA-40
	(S)PI05-INS-009	AB	2020-02-13	FM-QA-40

Labels

Carton - 5 Tests



Carton - 10 Tests

For *in vitro* Diagnostic Use Only.

HIV 1-2.O CARD TEST (Version 2.0)
RAPID HIV CARD TEST
Whole Blood / Serum / Plasma

30°C 4°C

Mfg. Lic. No. : MFG/MD/2018/000064

LOT :

:

:

Contents:

- Individually pouched test devices with desiccant : 10 Nos.
- Specimen Transfer Device : 10 Nos.
- Sterile Lancets : 10 Nos.
- Alcohol Swabs : 10 Nos.
- Assay Buffer Bottle : 01 No.
- Instructions for use : 01 No.

Rev.: AB, 2023-10

REF PI05FRC10

10 Tests/Kit

One Step Anti HIV Card Test

4°C 30°C

FIRST RESPONSE

HIV 1-2.O CARD TEST (Version 2.0)
RAPID HIV CARD TEST
Whole Blood / Serum / Plasma

4°C 30°C IVD NON STERILE

For Professional Use.

Premier Medical Corporation Private Limited
A1 - 302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA
Customer support email : info@premiermedcorp.com
Tel.: +91 260 2780112/113, www.premiermedcorp.com

REF PI05FRC10

10 Tests/Kit

One Step Anti HIV Card Test

4°C 30°C

FIRST RESPONSE

HIV 1-2.O CARD TEST (Version 2.0)
RAPID HIV CARD TEST
Whole Blood / Serum / Plasma

Carton - 25 Tests

For *in vitro* Diagnostic Use Only.

HIV 1-2.O CARD TEST (Version 2.0)
RAPID HIV CARD TEST
Whole Blood / Serum / Plasma

FIRST RESPONSE

4°C 30°C

Mfg. Lic. No. : MFG/MD/2018/000064

LOT :

:

:

Contents:

- Individually pouched test devices with desiccant : 25 Nos.
- Specimen Transfer Device : 25 Nos.
- Sterile Lancets : 25 Nos.
- Alcohol Swabs : 25 Nos.
- Assay Buffer Bottle : 1 No.
- Instructions for use : 1 No.

Rev.: AD, 2022-11

REF PI05FRC25

Σ 25 Tests/kit

One Step Anti HIV Card Test

4°C 30°C

FIRST RESPONSE®

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

RAPID HIV CARD TEST

Whole Blood / Serum / Plasma

4°C 30°C IVD NON STERILE

For Professional Use.

Premier Medical Corporation Private Limited
A1 - 302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA
Customer support email : info@premiermedcorp.com
Tel.: +91 260 2780112/113, www.premiermedcorp.com

REF PI05FRC25

Σ 25 Tests/kit

One Step Anti HIV Card Test

4°C 30°C

FIRST RESPONSE®

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

RAPID HIV CARD TEST

Whole Blood / Serum / Plasma

Carton - 30 Tests

For *in vitro* Diagnostic Use Only.

HIV 1-2.O CARD TEST (Version 2.0)
RAPID HIV CARD TEST
Whole Blood / Serum / Plasma

FIRST RESPONSE

REF P105FRC30
30 Tests/kit

One Step Anti HIV Card Test

Mfg. Lic. No.: MFG/MD/2018/000064

LOT :

:

:

Contents:

- Individually pouched test devices with desiccant : 30 Nos.
- Specimen Transfer Device : 30 Nos.
- Sterile Lancets : 30 Nos.
- Alcohol Swabs : 30 Nos.
- Assay Buffer Bottle : 1 No.
- Instructions for use : 1 No.

Rev.: AD, 2021-01

FIRST RESPONSE

HIV 1-2.O CARD TEST (Version 2.0)
RAPID HIV CARD TEST
Whole Blood / Serum / Plasma

For Professional Use.

Premier Medical Corporation Private Limited
A1 - 302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA
Customer support email : info@premiermedcorp.com
Tel.: +91 260 2780112/113, www.premiermedcorp.com

REF P105FRC30
30 Tests/kit

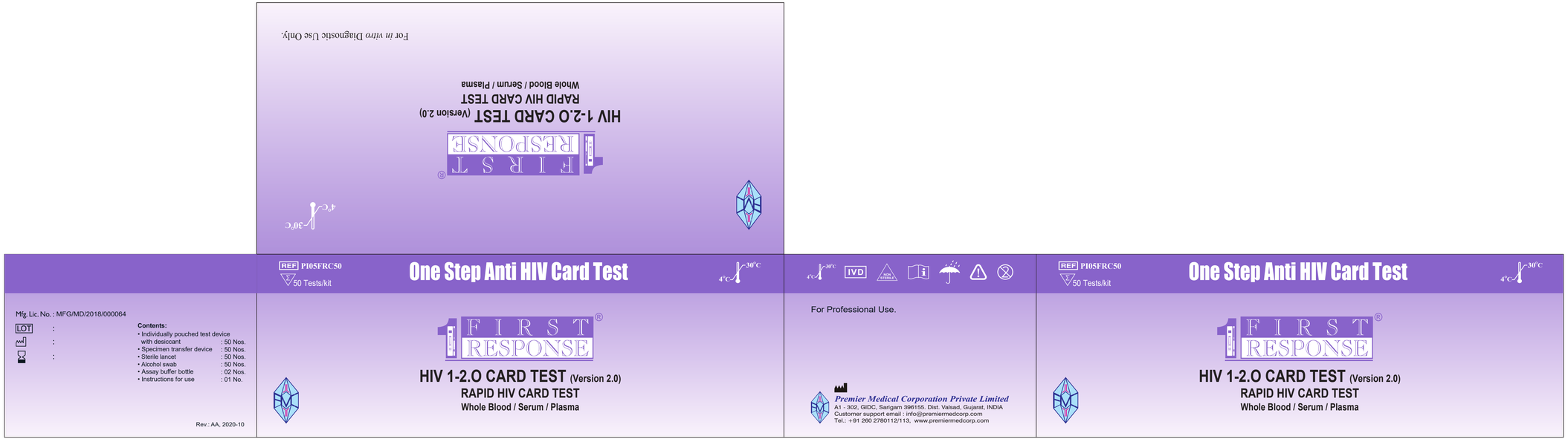
One Step Anti HIV Card Test

4°C 30°C

FIRST RESPONSE

HIV 1-2.O CARD TEST (Version 2.0)
RAPID HIV CARD TEST
Whole Blood / Serum / Plasma

Carton - 50 Tests



Carton - 60 Tests

HIV 1-2.O CARD TEST (Version 2.0)
RAPID HIV CARD TEST
Whole Blood / Serum / Plasma

For *in vitro* Diagnostic Use Only.

REF PI05FRC60
60 Tests/kit

One Step Anti HIV Card Test

4°C – 30°C

Mfg. Lic. No. : MFG/MD/2018/000064

LOT :

:

:

Contents:

- Individually pouched test device with desiccant : 60 Nos.
- Specimen transfer device : 60 Nos.
- Auto Safety lancet : 60 Nos.
- Alcohol swab : 60 Nos.
- Assay buffer bottle : 04 Nos.
- Instructions for use : 01 No.

Rev : AB, 2020-09

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

RAPID HIV CARD TEST

Whole Blood / Serum / Plasma

4°C – 30°C IVD NON STERILE

For Professional Use.

Premier Medical Corporation Private Limited
A1 - 302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA
Customer support email : info@premiermedcorp.com
Tel.: +91 260 2780112/113, www.premiermedcorp.com

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

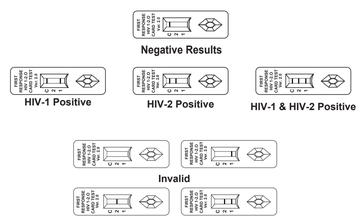
RAPID HIV CARD TEST

Whole Blood / Serum / Plasma

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.

RESULTS



REF PI05FRC60
60 Tests/kit

One Step Anti HIV Card Test

4°C – 30°C

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

RAPID HIV CARD TEST

Whole Blood / Serum / Plasma

Carton - 100 Tests

For *in vitro* Diagnostic Use Only.

HIV 1-2.O CARD TEST (Version 2.0)
RAPID HIV CARD TEST
Whole Blood / Serum / Plasma

FIRST RESPONSE

4°C - 30°C

REF PI05FRC100
Σ 100 Tests/kit

One Step Anti HIV Card Test

4°C - 30°C

Mfg. Lic. No. : MFG/MD/2018/000064
LOT :
:
:

Contents:

• Individually pouched test device with desiccant	: 100 Nos.
• Specimen transfer device	: 100 Nos.
• Sterile lancet	: 100 Nos.
• Alcohol swab	: 100 Nos.
• Assay buffer bottle	: 04 Nos.
• Instructions for use	: 02 Nos.

Rev.: AB, 2020-08

FIRST RESPONSE

HIV 1-2.O CARD TEST (Version 2.0)
RAPID HIV CARD TEST
Whole Blood / Serum / Plasma

4°C - 30°C IVD NON STERILE

For Professional Use.

Premier Medical Corporation Private Limited
A1 - 302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA
Customer support email : info@premiermedcorp.com
Tel.: +91 260 2780112/113, www.premiermedcorp.com

REF PI05FRC100
Σ 100 Tests/kit

One Step Anti HIV Card Test

4°C - 30°C

FIRST RESPONSE

HIV 1-2.O CARD TEST (Version 2.0)
RAPID HIV CARD TEST
Whole Blood / Serum / Plasma

Carton - 50 Tests Inner

For *in vitro* Diagnostic Use Only.

FIRST RESPONSE®

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

RAPID HIV CARD TEST

Whole Blood / Serum / Plasma

4°C 30°C

Σ 50 Tests/kit | **One Step Anti HIV Card Test** | 4°C 30°C

Mfg. Lic. No. : MFG/MD/2018/000064

LOT :

:

:

Contents:

- Individually pouched test device with desiccant : 50 Nos.
- Instructions for use : 01 No.

Rev.: AB, 2020-08

FIRST RESPONSE®

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

RAPID HIV CARD TEST

Whole Blood / Serum / Plasma

4°C 30°C IVD NON STERILE

For Professional Use.

Premier Medical Corporation Private Limited

A1 - 302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA

Customer support email : info@premiermedcorp.com

Tel.: +91 260 2780112/113, www.premiermedcorp.com

Σ 50 Tests/kit | **One Step Anti HIV Card Test** | 4°C 30°C

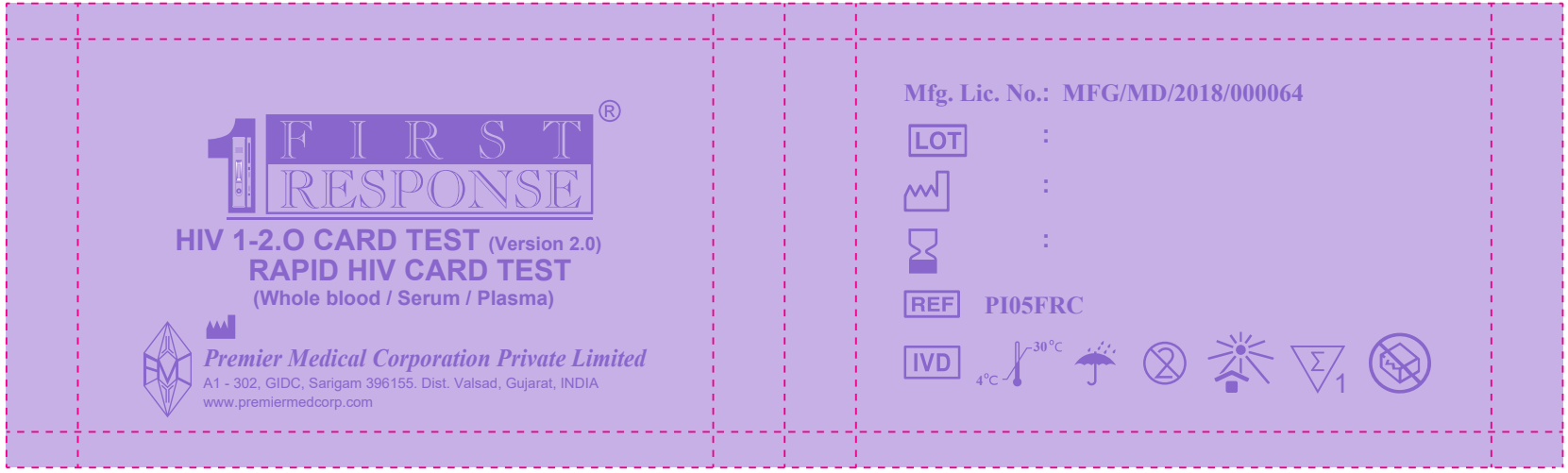
FIRST RESPONSE®

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

RAPID HIV CARD TEST

Whole Blood / Serum / Plasma

Aluminium Pouch



Assay Buffer Label

MEDTRUE®

Alcohol Swabs

CE

CODE:MT59010102

LOT LOT NO. : XXXXXX

MFG. DATE : YYYYMMDD

EXP. DATE : YYYYMMDD

For External Use Only

CONTAIN:One pad saturated with 70% Isopropyl Alcohol.

DIRECTION:Cleaning the required area.

Discard after single use.

MEDTRUE ENTERPRISE CO., LTD
Room No.301-302, Hongpujiezuo Mansion
186-1 Jiangdongzhonglu Road, 210019 Nanjing, China

CE EC REP RIOMAVIX SOCIEDAD LIMITADA
Calle de Almansa 55, 1D, Madrid 28039 Spain

TEAR HERE

PHX2006-NS

Phoenix
Healthcare Solutions, LLC
"An Innovative Medical Manufacturer"

Alcohol Prep Pad

70% v/v Isopropyl Alcohol

For External Use Only

1 Pad

Medium

Discard Prep Pad After Single Use

Directions:

Apply topically as needed to cleanse intended area

Phoenix Innovative Healthcare Manufacturers Pvt. Ltd.
EL-209, Shil Mahape Road, Electronic Zone,
MIDC, TTC Industrial Area, Mahape,
Navi Mumbai - 400 710 MH | India
Customer Care : 022-61075501
Email : customercare@phoenix-hs.com

NCE-MH/DRUGS/25-MH/101592

EC REP

Advena Ltd.,
Tower Business Centre,
2nd Flr, Tower Street,
Swatar, BKR 4013. Malta

CE

MD

NON STERILE

LOT XXXXXXXX

YYYY-MM

YYYY-MM

Rev.00

Blood Lancets (Sterile Lancet)

Model / Specification	:	I / 28G
LOT NO.	:	XXXXXXX
MFG. DATE	:	XXXX-XX-XX
EXP. DATE	:	XXXX-XX-XX
QTY	:	5pcs

UDI

(01)06949517008892(11)XXXXXX
(17)XXXXXX(10)XXXXXXXX

STERILE MD

STERILE R -20°C 40°C 0% 80%

CE 0197

EC REP **Linkfar Healthcare GmbH**
Niederrheinstraße 71, 40474 Düsseldorf, Germany
TEL: +49-21138530888

Shandong Lianfa Medical Plastic Products Co., Ltd.
No.1 Shuangshan Sanjian Road, Zhangqiu, Jinan City, 250200, Shandong P. R. China

Blood Lancets (Sterile Lancet)

Model / Specification : l / 28G

LOT LOT NO. : XXXXXXX

MFG. DATE : XXXX-XX-XX

EXP. DATE : XXXX-XX-XX

QTY : 10pcs

UDI

(01)06949517008908(11)XXXXXX
(17)XXXXXX(10)XXXXXXXX

STERILE MD

STERILE R -20°C 40°C 0% 80%

CE 0197

EC REP **Linkfar Healthcare GmbH**
Niederrheinstraße 71, 40474 Düsseldorf, Germany
TEL: +49-21138530888

Shandong Lianfa Medical Plastic Products Co., Ltd.
No.1 Shuangshan Sanjian Road, Zhangqiu, Jinan City, 250200, Shandong P. R. China

Blood Lancets (Sterile Lancet)

Model / Specification	:	I / 28G
LOT NO.	:	XXXXXXXXXX
MFG. DATE	:	YYYY-MM-DD
EXP. DATE	:	YYYY-MM-DD
QTY	:	25pcs

UDI

(01)06949517007109(11)YYMMDD
(17)YYMMDD(10)XXXXXXXXXX

STERILE MD

STERILE R

-20°C 40°C 0% 80%

CE 0197

EC REP

Linkfar Healthcare GmbH
Niederrheinstraße 71, 40474 Düsseldorf, Germany
TEL: +49-21138530888

Shandong Lianfa Medical Plastic Products Co., Ltd.
No.1 Shuangshan Sanjian Road, Zhangqiu, Jinan City, 250200, Shandong P. R. China

Blood Lancets (Sterile Lancet)

Model / Specification	:	I / 28G
LOT NO.	:	XXXXXXXXXX
MFG. DATE	:	YYYY-MM-DD
EXP. DATE	:	YYYY-MM-DD
QTY	:	30pcs

UDI

(01)06949517007116(11)YYMMDD
(17)YYMMDD(10)XXXXXXXXXX

STERILE MD

STERILE R

-20°C 40°C 0% 80%

CE 0197

EC REP

Linkfar Healthcare GmbH
Niederrheinstraße 71, 40474 Düsseldorf, Germany
TEL: +49-21138530888

Shandong Lianfa Medical Plastic Products Co., Ltd.
No.1 Shuangshan Sanjian Road, Zhangqiu, Jinan City, 250200, Shandong P. R. China

STERILANCE™ Press
Disposable Safety Lancet

Reorder No.: 05-052128
Spec: 21G / 2.8mm
Qty: 60Pcs/Bag

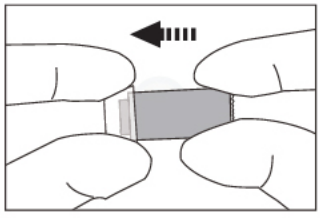
Intended use:
The safety lancet is used for capillary blood collection.
Contraindications: Unknown.

Caution:
1. Do not use if lancet cap has been previously removed from lancet.
2. Check the use-by date on the packaging, and do not use the lancet beyond the use-by date.
3. The safety lancet is for disposable use and do not reuse the lancet.
4. Discard the used lancet into a suitable sharps container.

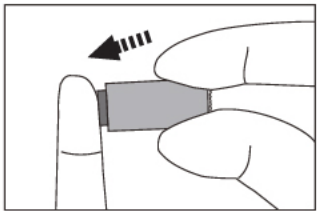
Symbolic interpretation:

STERILE R — Sterilized using irradiation
EC REP — European Authorized Representative
Do not re-use
LOT — Batch code
CE 0123 — Notified Body
Date of manufacture
Caution
MD — Medical Device
Manufacturer
Consult instructions for use
Use-by date

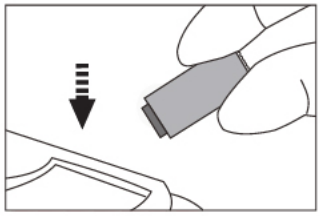
Instructions for Use :



1. Remove the protective cap.



2. Place the lancet firmly against the puncture site to activate. Do not remove the device until an audible click is heard.



3. Discard the used lancet into a suitable sharps container.

EC REP European Authorized Representative:
Emergo Europe B.V.
Westervoortsedijk 60,
6827 AT Arnhem, The Netherlands

Manufacturer:
SteriLance Medical (Suzhou) Inc .
No.168 PuTuoShan Road, New District,
215153 Suzhou, Jiangsu,
PEOPLE'S REPUBLIC OF CHINA
www.sterilance.com

(01)16945630134088
(11)YYMMDD
(17)YYMMDD
(10)XXXXX

LOT XXXXX
YYYY-MM-DD
YYYY-MM-DD

Revised date: June 19, 2023 (Version 03)

SPECIMEN TRANSFER DEVICE

10/20ul marking dropper Qty : 05 pcs/pack

V2 Manufacturers

5/7 BIDC Estate Gorwa Vadodara 390016 India

Lot No : NNNNNNNN

Mfg. Date : DD/MM/YYYY

Exp. Date : DD/MM/YYYY

Single Use Only

SPECIMEN TRANSFER DEVICE

10/20ul marking dropper Qty : 10 pcs/pack

V2 Manufacturers

5/7 BIDC Estate Gorwa Vadodara 390016 India

Lot No : NNNNNNNN

Mfg. Date : DD/MM/YYYY

Exp. Date : DD/MM/YYYY

Single Use Only

SPECIMEN TRANSFER DEVICE

10/20ul marking dropper Qty : 25 pcs/pack

V2 Manufacturers

5/7 BIDC Estate Gorwa Vadodara 390016 India

Lot No : NNNNNNNN

Mfg. Date : DD/MM/YYYY

Exp. Date : DD/MM/YYYY

Single Use Only

SPECIMEN TRANSFER DEVICE

10/20ul marking dropper Qty : 30 pcs/pack

V2 Manufacturers

5/7 BIDC Estate Gorwa Vadodara 390016 India

Lot No : NNNNNNNN

Mfg. Date : DD/MM/YYYY

Exp. Date : DD/MM/YYYY

Single Use Only

SPECIMEN TRANSFER DEVICE

10/20ul marking dropper Qty : 65 pcs/pack

V2 Manufacturers

5/7 BIDC Estate Gorwa Vadodara 390016 India

Lot No : NNNNNNNN

Mfg. Date : DD/MM/YYYY

Exp. Date : DD/MM/YYYY

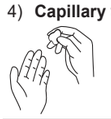
Single Use Only

2. Instructions for Use[2]

[2] English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

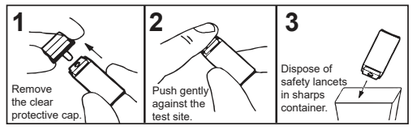
Specimen Collection

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.
3) **Serum collection:** Collect Whole blood in the collection tubes without 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:**

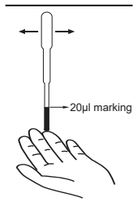


- Wear gloves and massage the fingertip gently. It will help to obtain a round drop of blood.
- Wipe the complete fingertip with the alcohol swab provided and wait until the fingertip is dried completely.

Auto Safety Lancet
(Sterile Pressure Activated Lancet)
Instructions for use →



- Do not use the auto safety lancet if the auto safety lancet found uncapped. Detach the protective cap of the auto safety lancet provided. Squeeze the fingertip then push gently at the lateral side (avoid callus) of the fingertip as shown in above figure. Safely dispose of the used auto safety 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.

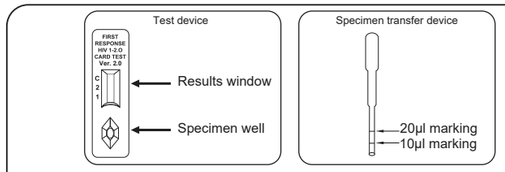
Note : Auto safety lancet is for single use only. Do not share used auto safety lancets with another person. Dispose of used auto safety lancets in sharp box and alcohol swab in biohazard waste container immediately after use.
Do not use expired auto safety lancet. Use of any expired lancet may cause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

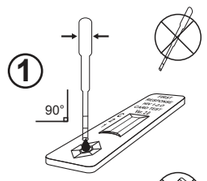
Specimen storage

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.

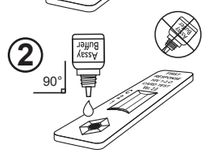
Test Procedure

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.



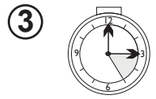


Do not tilt.
Add 20µl of Whole blood or 10µl of serum/ plasma to the specimen well.
Dispense the specimen by gently touching the tips of the specimen transfer device to the sample pad



Do not tilt.

Add 1 drop of assay buffer to the specimen well.



Interpret the test result at 15 minutes after adding assay buffer. Do not read test result after 25 minutes.

Result at 15-25 min.

Caution

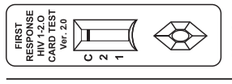
- Add exactly 1 drop of assay buffer. Adding more than 1 drop of assay buffer may cause over flooding or reverse migration phenomenon, which may lead to inaccurate results of the test.
- Do not read the test results after 25 minutes. Reading the results after 25 minutes window may give inaccurate results.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

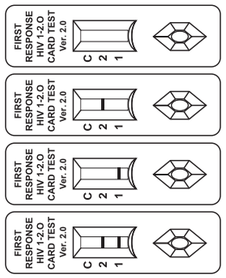
HIV-2 Positive

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-006, 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

REF **PI05FRC60**

4°C 30°C IVD

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].

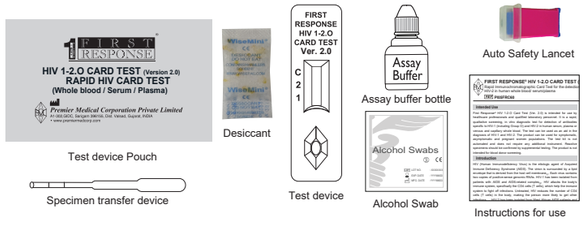
WHO targets for 2020 across the globe to reduce new HIV infections to less than 500000; zero new infections among infants. Reduce HIV-related deaths to below 500000. 90% people living with HIV tested; 90% treated; 90% virally suppressed[6].

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



Materials provided	PI05FRC60
Test device pouch containing: 1 test device, 1 desiccant	60 Nos.
Specimen transfer device	60 Nos.
Assay buffer bottle (2.5 ml)	4 Nos.
Auto Safety Lancet	60 Nos.
Alcohol swabs	60 Nos.
Instructions for use	1 No.

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

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 auto safety 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 auto safety 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 auto safety lancet if lancet found uncapped.(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, auto safety 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.

Specimen Collection

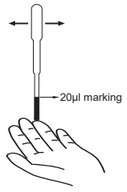
1) **Venous blood collection:** Collect the Whole blood in the collection tubes containing anticoagulants like EDTA, Heparin, Sodium citrate or ACD by venipuncture.
2) **Plasma collection:** Collect the Whole blood in the collection tubes containing anticoagulants like EDTA, Heparin, Sodium citrate or 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.

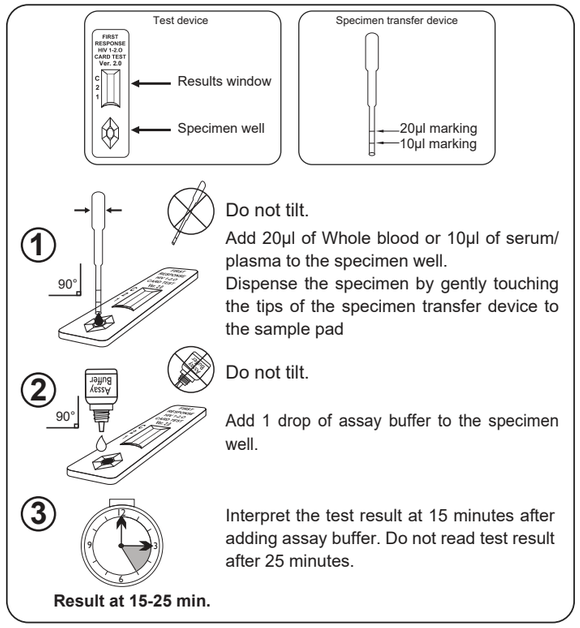
Note : Sterile twist lancet is for single use only. Do not share used sterile twist lancets with another person. Dispose of used sterile twist lancets in sharp box and alcohol swab in biohazard waste container immediately after use.
Do not use expired sterile twist lancet. Use of any expired sterile 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

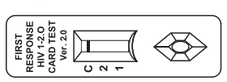
- Add exactly 1 drop of assay buffer. Adding more than 1 drop of assay buffer may cause over flooding or reverse migration phenomenon, which may lead to inaccurate results of the test.
- Do not read the test results after 25 minutes. Reading the results after 25 minutes window may give inaccurate results.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

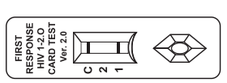
How to Interpret test results

Negative Results



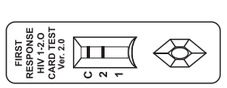
If only a single purple colored line appears, at the control line 'C' as in the figure, then the specimen is non-reactive for antibodies to HIV-1 and 2.

Positive Results



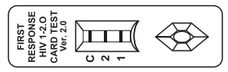
HIV-1 Positive

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

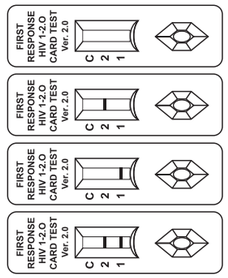
If two purple colored lines appear, one at the control line 'C' and other at the test line HIV-2 '2' as in the figure, then the specimen is reactive for antibodies to HIV-2. Interpret purple colored faint line as a reactive line.



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
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• 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

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].

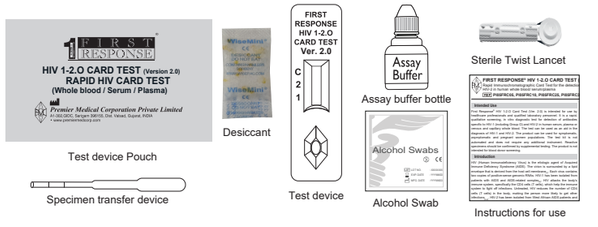
WHO targets for 2020 across the globe to reduce new HIV infections to less than 500000; zero new infections among infants. Reduce HIV-related deaths to below 500000. 90% people living with HIV tested; 90% treated; 90% virally suppressed[6].

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.