WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: First Response HCV Card Test
WHO reference number: PQDx 0469-010-00

First Response HCV Card Test with product codes PI03FRC25, PI03FRC50, and PI03FRC100, 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 13 November 2023.

Summary of WHO Prequalification Assessment for First Response HCV Card Test

	Date	Outcome
Prequalification listing	13 November 2023	listed
Dossier assessment	2 March 2023	MR
Site inspection(s) of quality management system	15 October 2022	MR
Product performance evaluation	4th quarter of 2019 and 1st quarter of 2020	MR

MR: Meets Requirements

Intended use

According to the intended use claim from Premier Medical Corporation Private Limited, " *First Response HCV Card Test is a chromatographic immunoassay for the qualitative detection of the antibodies against hepatitis C virus (HCV Ab) in human serum, plasma or whole blood (capillary whole blood & venous whole blood) specimens. It is intended to be performed by trained users (in either laboratory or point of care settings). The product is intended to use as an aid for the diagnosis of patients related to infection with hepatitis C. The product may only be used for screening of blood volunteer donors as an option of last resort, where no other testing method is available. The use must be limited to remote or poorly supported areas where blood is needed urgently, and banked blood is not readily available. The test kit is not automated and does not require any additional instrument. Reactive samples should be confirmed by supplemental testing."*

Assay description

According to the claim of assay description from Premier Medical Corporation Private Limited, "*First Response HCV Card Test is based on the principle of immunochromatographic lateral flow device in a cassette format. Control line gold nanoparticles are conjugated with chicken IgY antibodies. Test line gold nanoparticles are conjugated with recombinant HCV Antigen. HCV antigens are immobilized at the Test Zone (T), and Control line protein are*

immobilized at the Control Zone (C). When the specimen and assay buffer is added, it migrates by capillary diffusion rehydrating the gold conjugate. If specimens contain Anti-HCV antibodies it will bind to gold conjugated recombinant HCV antigen. These complexes will continue to migrate laterally on the strip until the Test zone (T) where complex are captured by the HCV antigens and form a visible red-colored line. The unbound gold conjugate will continue to move and bind with control line protein at the Control Zone (C) forming a visible red colored line. If no HCV antibodies in the sample, only a red colored line appears at the Control Zone (C), which indicates the validity of the test."

Test kit contents

Materials provided	**25 Tests/kit (T/k) (product code PI03FRC25)**	**50 T/k (product code PI03FRC50)**	**100 T/k (product code PI03FRC100)**
Test device pouch containing: 1 test device, 1 desiccant.	25	50	100
Specimen transfer device.	25	50	100
Assay buffer bottle.	1	2	4
Sterile lancets.	25	50	100
Alcohol swabs.	25	50	100
Instructions for use.	1	1	2

Items required but not provided

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

Storage

The test kit should be stored at 4-30°C.

Shelf-life upon manufacture

24 months.

Warnings/limitations

Refer to the current version of the manufacturer's instructions for use attached to this public report.

Prioritization for Prequalification Assessment

Based on the established eligibility criteria, the First Response HCV Card Test was given priority for the WHO prequalification assessment.

Dossier assessment

Premier Medical Corporation Private Limited submitted a product dossier for the First Response HCV Card Test, per the "Instructions for compilation of a product dossier" (PQDx_018). 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 2 March 2023.

Based on the product dossier screening and assessment findings, the product dossier for the First Response HCV Card Test meets WHO prequalification requirements.

Manufacturing site inspection

An onsite inspection of Premier Medical Corporation Ltd., at A1-302 and 3704-05, GIDC, Sarigam INA, 396155 Gujarat, India, was conducted from the 15th to the 17th of October 2022. At the time of considering the product application for Prequalification, the Manufacturer of the product had a well-established quality management system and manufacturing practices in place that would support the manufacture of a product of consistent quality. Routine inspections of the Manufacturing site will be conducted with copies of the WHO Public Inspection Report (WHOPIR) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. Note that a WHOPIR reflects the information on the most current assessment performed at a manufacturing site for in vitro diagnostic products and summarises the assessment findings.

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

All published WHOPIRs are with the agreement of the manufacturer.

The onsite inspection was accepted on 25 September 2023.

Based on the site inspection and corrective action plan review, the quality management system for the First Response HCV Card Test meets WHO prequalification requirements.

Product performance evaluation

The First Response HCV Card Test was evaluated by the National Serology Reference Laboratory, Melbourne, Australia, on behalf of WHO in the fourth quarter of 2019 and first quarter of 2020, according to protocol PQDx_040, version 6.

Clinical performance evaluation

In this limited laboratory-based evaluation of clinical performance characteristics, a panel of 483 plasma specimens was used. The specimens were characterized using the following reference algorithm: Murex anti-HCV (version 4.0) [DiaSorin S.A Italy] and Monolisa Anti-HCV PLUS version 2.0 [Bio-Rad Laboratories] in parallel, followed by CHIRON RIBA 3.0 HCV 3.0 Strip Immunoassay or MP Diagnostics HCV BLOT 3.0 WB on initially reactive specimens.

Clinical performance characteristics in comparison with an agreed reference standard	
Sensitivity % (N=163)	100% (95% CI: 97.8-100%)
Specificity % (N= 320)	99.7% (95% CI: 98.3-99.9%)
Invalid rate % (N= 483)	0.4%
Inter-reader variability % (N= 483)	0%

Analytical performance evaluation

Analytical performance characteristics	
Sensitivity during seroconversion on 4 seroconversion panels in comparison with a benchmark assay (Murex Anti-HCV (version 4.0))	Of a total of 26 specimens, 14 were detected by the assay under evaluation versus 21 specimens detected by the benchmark assay.
Analytical sensitivity on a mixed titer panel (0810-0175, SeraCare Life Science Inc.)	All 15 positive and 1 negative specimens were correctly classified.
Analytical sensitivity on a low titer panel (0810-0192, SeraCare Life Science Inc.)	8 of 10 positive specimens and 1 negative specimen were correctly classified.
Lot to lot variation on a dilution panel	Lot to lot variation was within +/- 1 two-fold dilutions for all 8 dilution series where the endpoint dilution could be determined for both lots.

Operational characteristics and ease of use

This assay does not require laboratory equipment and can be performed in laboratories with limited facilities or non-laboratory settings.

The assay was found easy to use by the operators performing the evaluation.

Key operational characteristics	
Specimen type(s) and volume	1 drop (35µL) of serum, plasma (EDTA, heparin or sodium citrate), venous whole blood (EDTA, heparin or sodium citrate) or capillary whole blood
Number of steps*	2 steps in total 0 step with precision pipetting
Time to result	15 minutes
Endpoint stability (interval)	5 minutes (the test can be read between 15 and 20 minutes after the addition of assay buffer)
Internal QC	Yes, reagent addition control

** Definition: each action required to obtain a result (excluding specimen collection, device preparation – opening the pouch), e.g. for RDTs: add specimen, add buffer (2 steps).*

Based on these results, the performance evaluation for First Response HCV Card Test meets the WHO prequalification requirements.

Labelling

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

1. Labels

1.1 Packaging box for product code PI03FRC25 (25 T/k)

Product Name : F.R HCV Card Test
Pack Size : 25 Tests / bulk

For *in vitro* Diagnostic Use Only.

HCV Card Test
Hepatitis C Detection Card Test
Whole Blood / Serum / Plasma

FIRST RESPONSE

4°C 30°C

REF PI03FRC25
Σ 25 Tests/kit

One Step Anti HCV Card Test

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.: AB, 2020-11

FIRST RESPONSE

HCV Card Test
Hepatitis C Detection 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 PI03FRC25
Σ 25 Tests/kit

One Step Anti HCV Card Test

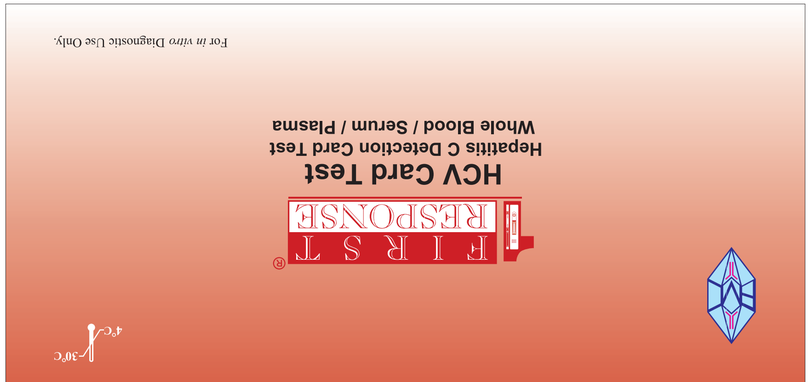
4°C 30°C

FIRST RESPONSE

HCV Card Test
Hepatitis C Detection Card Test
Whole Blood / Serum / Plasma

1.2 Packaging box for product code PI03FRC50 (50 T/k)

Product Name : F.R HCV Card Test
Pack Size : 50 Tests / bulk



REF PI03FRC50
Σ 50 Tests/kit

One Step Anti HCV Card Test

4°C 30°C

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

LOT :

:

:

Contents:

- Individually pouched test devices with desiccant : 50 Nos.
- Specimen Transfer Device : 50 Nos.
- Sterile Lancets : 50 Nos.
- Alcohol Swabs : 50 Nos.
- Assay Buffer Bottle : 2 Nos.
- Instructions for use : 1 No.

Rev.: DRAFT

FIRST RESPONSE®

HCV Card Test

Hepatitis C Detection 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 PI03FRC50
Σ 50 Tests/kit

One Step Anti HCV Card Test

4°C 30°C

FIRST RESPONSE®

HCV Card Test

Hepatitis C Detection Card Test

Whole Blood / Serum / Plasma

1.3 Packaging box for product code PI03FRC100 (100 T/k)

Product Name : F.R HCV Card Test
Pack Size : 100 Tests / bulk

For *in vitro* Diagnostic Use Only.

HCV Card Test
Hepatitis C Detection Card Test
Whole Blood / Serum / Plasma

FIRST RESPONSE

4°C – 30°C

REF PI03FRC100
100 Tests/kit

One Step Anti HCV Card Test

4°C – 30°C

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

LOT :

:

:

Contents:

- Individually pouched test devices with desiccant : 100 Nos.
- Specimen Transfer Device : 100 Nos.
- Sterile Lancets : 100 Nos.
- Alcohol Swabs : 100 Nos.
- Assay Buffer Bottle : 4 Nos.
- Instructions for use : 2 Nos.

Rev.: DRAFT

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 PI03FRC100
100 Tests/kit

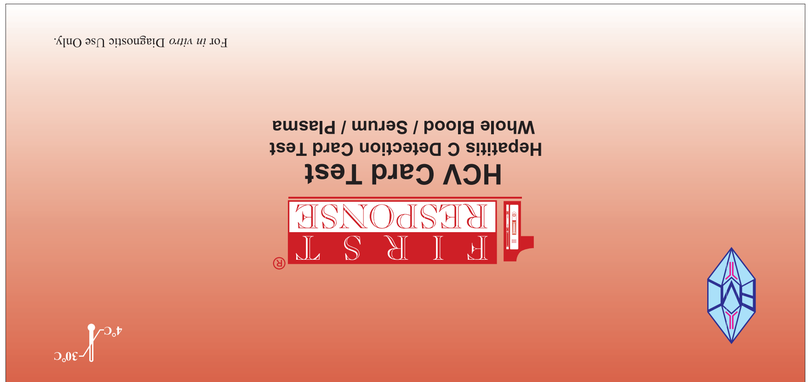
One Step Anti HCV Card Test

4°C – 30°C

FIRST RESPONSE

HCV Card Test
Hepatitis C Detection Card Test
Whole Blood / Serum / Plasma

Product Name : F.R HCV Card Test
Pack Size : 50 Tests Inner Carton



50 Tests/kit

One Step Anti HCV Card Test

4°C 30°C

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

LOT :

:

:

Contents:

- Individually pouched test devices with desiccant : 50 Nos.
- Instructions for use : 1 No.

Rev.: Draft

FIRST RESPONSE

HCV Card Test

Hepatitis C Detection 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

50 Tests/kit

One Step Anti HCV Card Test

4°C 30°C

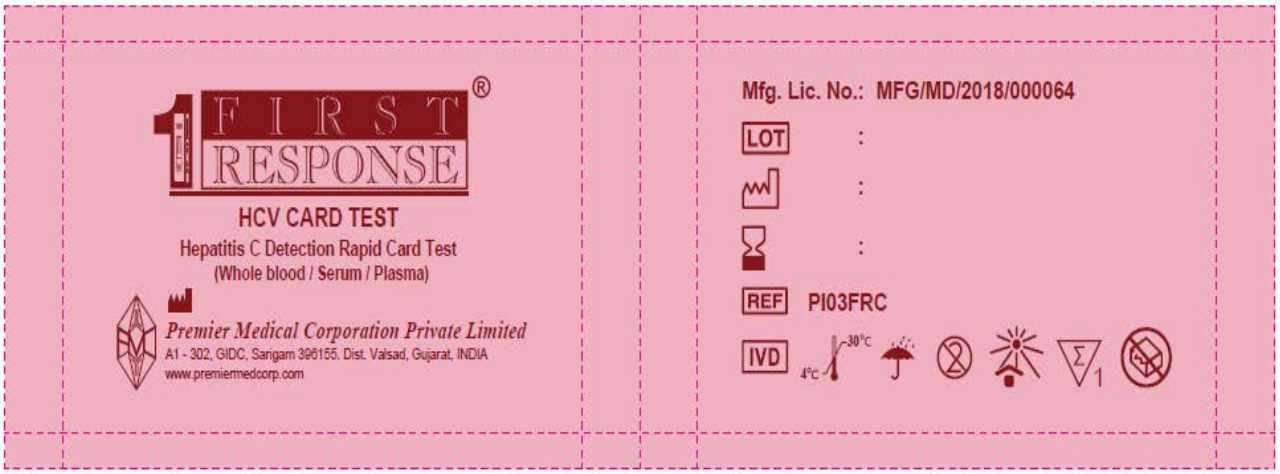
FIRST RESPONSE

HCV Card Test

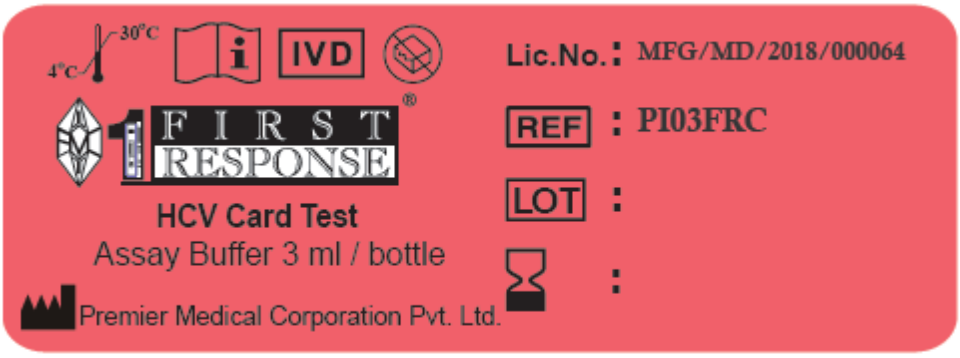
Hepatitis C Detection Card Test

Whole Blood / Serum / Plasma

1.4 Test device pouch label



1.5 Assay buffer label



1.6 Alcohol swab label

1.7 Sterile twist lancet labels


Sterile Twist Lancet
LOT
LOT NO. : 20210710
MFG. DATE : 2021-07-10
EXP. DATE : 2026-07-09
QTY : 30pcs
30T
STERILE EO
EC REP
Lotus NL B.V.
Koningin Julianaplein 10,le Verd,2595AA,The Hague,Nertherl
Hangzhou Rely Medtech Co., Ltd.
Room 221,Building 2E NO.688,Binan Road,Changhe Street,
Binjiang District,310063 Hangzhou City,China.

2. Instructions for use[1]

[1] 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.

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, it contaminate the assay buffer.

13) Do not use the test device and assay buffer beyond the date of expiry.

14) Do not use any other specimen other than human Whole blood/Serum/Plasma. Do not mix and interchange different specimens.

Specimen Collection

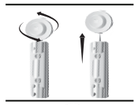
1) **Venous blood collection:** Collect the Whole blood in the collection tubes containing anticoagulants like EDTA, Heparin or Sodium citrate by venipuncture.

2) **Plasma collection:** Collect the Whole blood in the collection tubes containing anticoagulants like EDTA, Heparin or Sodium citrate by venipuncture and centrifuge it at 3000 rpm 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 rpm for 10-15 minutes to obtain serum.

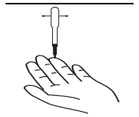
4) **Capillary blood specimen collection:**

- 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 dried completely.



- Detach the protective cap of the lancet. Squeeze the fingertip then prick the lateral side of the fingertip with sterile lancet provided. Safely dispose of the used lancet.

- Wipe the first drop of the blood using sterile gauze. Without pressing too hard, gently squeeze your fingertip once again to obtain a large second drop of blood.



- Take the specimen transfer device provided and hold it vertically. Gently squeeze the bulb of the specimen transfer device and immerse open end in the center of a blood drop and release the bulb slowly to draw up the blood.
  After completion of specimen collection, take the sterile gauze and apply pressure to the wound site to stop the bleeding.

Note : Lancet is for single use only. Do not share used lancets with another person. Dispose of used lancets in sharp box and alcohol swab in biohazard waste container immediately after use.

Do not use expired lancet. The use of any expired lancet may cause any infection at the punctured skin due to cease to exist its sterility.

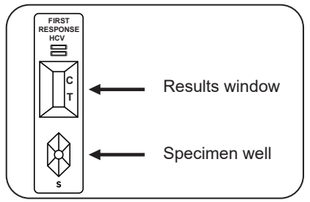
Use new lancet and choose a different puncture site, if repeat the finger prick.

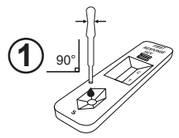
Specimen storage

1) Venous whole blood specimen may be used for testing immediately (within 1 hour) or may be stored at 2-8°C for maximum up to 72 hours (3 days). Do not use blood specimen stored for more than 3 days, it can cause non-specific reaction. Use capillary blood immediately after collection. Do not freeze Whole blood specimen.
2) If Serum or Plasma specimens are not immediately tested, they should be refrigerated at 2-8°C. For storage periods greater than 72 hours (3 days), freezing at -20°C is recommended up to 4 months. They should be brought to room temperature prior to use. For better product performance refrigerated serum and plasma specimen can be used up to 5 freeze thaw cycles after achieving room temperature.
3) Serum or Plasma specimens containing precipitate may yield inconsistent test results. Such specimens must be centrifuged at 5000 rpm for 10 minutes and use clear supernatants for testing.

Test Procedure

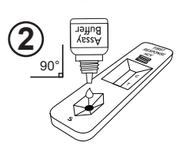
1) Ensure that the test device & other components are at room temperature (20°C to 30°C) before starting the procedure.
2) Take the test device and the specimen transfer device from the Kit. Do not use the test device if the desiccant found saturated.
3) Label the test device with the patient identification number. Place the test device on a flat, clean and dry surface.
4) Add one drop (35µl) of capillary or venous whole blood/ Serum/ Plasma to the specimen well using the specimen transfer device.
   Caution: Dispose of used specimen transfer device as biohazard waste immediately after use.
5) Hold the assay buffer bottle vertically and add one drop of the assay buffer to the specimen well. Do not touch the nozzle of buffer bottle to test device as it may contaminate buffer solution. Immediately start timer after buffer addition.
6) Observe for development of red colored lines in the results window.
7) Interpret test results at 15 minutes after adding assay buffer to the specimen well.
8) Do not interpret after 20 minutes.





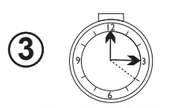
Do not tilt.

Add 1 drop (35µl) of capillary or venous whole blood / serum / plasma to the specimen well (S).



Do not tilt.

Add 1 drop of assay buffer to the specimen well (S).



Interpret the test result at 15 minutes after adding assay buffer. Do not read test result after 20 minutes.

Result at 15-20 min.

Caution

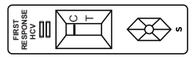
- Hold specimen transfer device and assay buffer bottle vertically, else it can lead to inaccurate results.
- Exactly 1 drop of assay buffer should be added. Adding more than 1 drop may cause over flooding or reverse migration phenomenon, which may lead inaccurate results of the test.
- Do not read the test result before 15 minutes after addition of buffer. Reading the result after 20 minutes may give inaccurate results. Read the results between 15 to 20 minutes after addition of buffer. After recording the results, dispose of used test device as a biohazard waste.
- Ensure that the lid of the assay buffer bottle is tightly closed to prevent evaporation. Evaporation of assay buffer may tend to inappropriate result.

Procedural Control

The visualization of the red colored Control line in First Response® HCV Card Test indicates that active ingredient related to the procedural control are functional and the migration is successful. The red colored Control line in First Response® HCV Card Test is not meant for specimen addition monitoring.

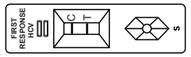
How to Interpret test results

Negative Results



If only a single red colored line appears, at the control line “C” as in the figure, the specimen is non-reactive for antibodies to HCV.

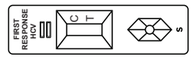
Positive Results

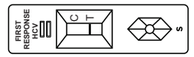


If two red colored lines appears, one at the control line ‘C’ and other at the test line ‘T’as in the figure, the specimen is reactive for antibodies to HCV.

Interpret faint line as reactive line

Invalid Results





No presence of red colored control line ’C’ in the results window (irrespective of presence of red colored 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 a new test device.

Performance Characteristics

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

Reference Method	Specimen details	First Response® HCV Card Test		
		HCV Positive	HCV Negative	Total
ELISA/ RDT Commercial available	HCV Positive Plasma specimens			
	HCV Positive Plasma Specimen	171	00	171
	HCV Negative Plasma specimens			
	HCV Negative Plasma Specimen	00	395	395
	Total Plasma specimens	171	395	566
	HCV Positive Serum specimens			
	HCV Positive Serum Specimen	211	00	211
	HCV Negative Serum specimens			
	HCV Negative Serum Specimen	00	3534	3534
	Total Serum specimens	211	3534	3745
	HCV Positive Whole blood specimens			
	HCV Positive Whole blood specimen	121	00	121
	HCV Negative Whole blood specimens			
	HCV Negative Whole Blood Specimen	00	439	439
	Total Whole blood specimens	121	439	560

Reference Method	Specimen details		First Response® HCVCard Test			
	Test Marker	Parameter	Positive	Negative	Total Results	95% Confidence Interval
ELISA/RDT available	Plasma Specimens					
	HCV	Sensitivity	171	00	171	(97.26% - 100%)
		Specificity	00	395	395	(98.79% - 100%)
	Serum Specimens					
	HCV	Sensitivity	211	00	211	(97.77% - 100%)
		Specificity	00	3534	3534	(99.86% - 100%)
	Whole blood Specimens					
	HCV	Sensitivity	121	00	121	(96.16% - 100%)
		Specificity	00	439	439	(98.91% - 100%)

Seroconversion Panel Testing

The Analytical sensitivity of the First Response® HCV Card Test was carried out by testing commercially available seroconversion panel. The commercially available rapid lateral flow test was used as reference kit for comparative performance study. Thirty one (31) seroconversion panel were tested, in-house.

Analytical Sensitivity - In - House Evaluation

Total Seroconversion Panels	Total	First Response® HCV Card Test			Reference CE-marked rapid lateral flow test.		
	Specimens	Positive	Negative	Detection Index**	Positive	Negative	Detection Index**
31	249	99	150	0.39	97	152	0.38

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

British Working Standard for Anti-HCV were tested in First Response® HCV Card which shows 100% Sensitivity.

British Working Standard for Anti-HCV		
British Working Standard for Anti-HCV NIBSC code:14/240	First Response® HCV Card Test	Reference CE-marked rapid lateral flow test
	Positive	Positive

Cross Reactivity Study

First Response® HCV Card Test was tested with other diseases/conditions, which may give cross-reactivity with the test. The following 22 potential cross-reacting diseases/conditions did not affact the performace of First Response® HCV Card Test.

Specimen Details	HCV Negative	HCV Positive	Specimen Details	HCV Negative	HCV Positive
P. falciparum Malaria Positive	05	Not Tested	HSV 1/2 Positive#	06	08
P.*vivax* Malaria Positive	05	Not Tested	HTLV-I Ab Positive#	07	04
Dengue NS1 Positive#	05	04	HTLV-II Ab Positive#	09	04
Pregnant Woman^	173	05	HSV- I IgG Positive#	08	04
CMV Positive#	05	04	Rubella IgG & IgM Positive#	15	08
ANA Positive#	05	04	HBV Positive#	103	04
HAV Positive#	05	04	Chikungunya Positive#	Not Tested	04
EBV Positive#	05	04	Thyroiditis	05	Not Tested
HIV-1 Positive#	264	04	Anti-malarial drug medication#	03	03
HIV-2 positive	39	Not Tested	Anti-TB drug medication#	03	03
Syphilis positive	122	Not Tested	Rabbit anti E.coli antibody#	04	02

Note : ^ Naturally appeared HCV positive specimens.
Spiked HCV positive specimens.

Potential interference substances

First Response® HCV Card Test was tested with potential interfering substances. The following 8 potential interfering substances did not affect the performace of First Response® HCV Card Test. However, Hemolysed specimens and lipemic specimens showed poor background clearance, hence not recommended for testing. Lipemic specimens can be used for the testing after centrifugation. Such specimens must be centrifuged at 5000 rpm for 10 minutes and use the supernatants for testing.

Specimen Details	HCV Negative	HCV Positive	Specimen Details	HCV Negative	HCV Positive
Lipemic specimen#	25	04	Low Hematocrit specimens	05	Not Tested
Icteric specimens#	05	04	Whole blood specimen in ACD anticoagulant	193	Not Tested
Hemolytic specimens	05	Not Tested	RF Ab Positive#	09	08
High Hematocrit specimens	05	Not Tested	dsDNA Antibody Positive Plasma#	01	04

Note : # Spiked HCV positive specimens.

Potential interference Drug substances

The details of interference drug molecules are mentioned in following table. Each interfering drug molecule substances were spiked at final concentration of 250µg/ml in HCV positive specimen as well as negative specimens, respectively. No false positive or false negative results were observed with any of drug molecules, when tested with First Response® HCV Card Test.

Abacavir	Cyclobenzaprine Hydrochloride	Folic acid	Metformin	Rifampicin
Acetaminophen	Daruvir	Hydrochlorothiazide	Naproxen IP	Ritonavir
Ampicillin Sodium salt	Diclofenac	Ibuprofen	Nevirapine	Cholecalciferol
Ascorbic Acid (Limec)	Ecosprin	Iron chloride	Pantoprazole	Ferrous Ascorbate
Aspirin	Ergocalciferol	Isoniazid	Penicillin G Benzathine	Magnesium sulphate
Pyrazinamide	Interferon alpha 2B	———		

Precision

a) Within-run precision was determined by using 5 replicates of 12 different specimens containing different concentrations of antibodies. Within-run, precision was observed as 100%.
b) Between-run, precision was determined by using the 12 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 of testing	Sensitivity	Specificity
Zimbabwe	2019	100%	100%

Independent evaluation performance

First Response® HCV Card Test was evaluated independently not by the manufacturer. First Response® HCV Card Test showed 100% specificity and 100% Sensitivity. The following cross-reacting diseases/conditions did not affect the performace of First Response® HCV Card Test.

Specimen Detail	Total	HCV Positive	HCV Negative
HIV/HCV coinfection	890	264	626
Pregnant woman whole blood	312	93	219

Limitations

1) Do not use anti-coagulants other than heparin, EDTA, and sodium citrate.
2) Do not use the hemolysed specimen. A hemolysed specimen may give reddish background even after the end of test time.
3) Interpret a faint line as a positive line. Repeat the test in case of very faint test line or if have any doubt for test line.
4) Although a reactive result may indicate infection with HCV virus, a diagnosis of HCV can only be made on clinical grounds, If an individual meets the case definition for HCV established by the centers for disease control. For samples repeatedly tested reactive, more specific supplemental tests must be performed.
5) For confirmation, further analysis of the specimens should be performed, such as ELISA, or western blot analysis for HCV. As with all diagnostic tests, results must be interpreted together with other clinical information available to the physician.
6) False negative results may arise because of hook effect due to a very high titer of antibody in a specimen. Repeat the test by using 1:10 dilution of the same specimen (01 portion) in respective non-reactive specimen matrix (09 portion).
7) A non-reactive result does not eliminate the possibility of infection with HCV Virus. The specimen may contain a low level of antibodies that cannot be detected by First Response® HCV Card Test. If a test result is non-reactive and clinical symptoms persists, additional testing using other reference method is recommended and/or retested for HCV antibodies after more than 21 days since the original testing.
8) The First Response® HCV Card Test rapid test is limited to the qualitative detection of Hepatitis C virus antibodies in human serum, plasma or whole blood. The intensity of the red colored test line does not correlate with the antibody titer of the specimen
9) Immunochromatographic testing alone cannot be used to diagnose HCV even if the antibodies against HCV are present in a patient specimen. A negative result at any time does not preclude the possibility of HCV 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) Simmonds P, Holmes E C, Cha T A, Chan S W, McOmish F, Irvine B, Beall E, Yap P L, Kolberg J, Urdea M S. (1993) Classification of hepatitis C virus into six major genotypes and a series of subtypes by phylogenetic analysis of the NS-5 region. J Gen Virol. ;74:2391–2399
2) Alter HJ., Purcell RH, Holland PV, et al. (1978) Transmissible agent in non-A, non-B hepatitis. Lancet I: 459-463.
3) NIZAR N. ZEIN (2000) Clinical Significance of Hepatitis C Virus Genotypes Clinical microbiological reviews,; p. 223–235.
4) World Health Organization (2016) Guidelines for the screening care and treatment of persons with chronic hepatitis C infection. Updated version.
5) World Health Organization (2016) global health sector strategy on viral hepatitis 2016–2021 towards ending viral hepatitis.
6) http://vassarstats.net/clin1.html#def , Richard Lowry.
7) TGS-5: Designing Instruction for use for in vitro diagnostic medical devices.

Product Disclaimer & 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”.

Manufactured by

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• ISO 13485 & EN ISO 13485 Certified Company

Part No.(S)PI03-INS-001, Rev.:AD, Date: 2023-09-19 ENGLISH
Note : Instructions for use will be printed in local language of the country using the test, if required.

FIRST RESPONSE® HCV CARD TEST

For detection of Antibodies against Hepatitis C virus in human whole blood/ serum/ plasma

REF PI03FRC25, PI03FRC50 & PI03FRC100

4°C 30°C IVD

Intended Use

First Response® HCV Card Test is a chromatographic immunoassay for the qualitative detection of the antibodies against hepatitis C virus (HCV Ab) in human serum, plasma or whole blood (capillary whole blood & venous whole blood) specimens. It is intended to be performed by trained users (in either laboratory or point of care settings). The product is intended to use as an aid for the diagnosis of patients related to infection with hepatitis C. The product may only be used for screening of blood volunteer donors as an option of last resort ,where no other testing method is available. The use must be limited to remote or poorly supported areas, where blood is needed urgently, and banked blood is not readily available. The test kit is not automated and does not require any additional instrument. Reactive samples should be confirmed by supplemental testing.

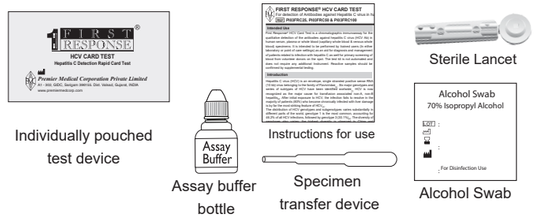
Introduction

Hepatitis C virus (HCV) is an envelope, single stranded positive sense RNA (10 kb) virus belonging to the family of Flaviviridae[3]. Six major genotypes and series of subtypes of HCV have been identified worlwide[1]. HCV is now recognized as the major cause for transfusion associated non-A, non-B hepatitis[2]. After initial exposure to HCV, the infection fails to resolve in the majority of patients (80%) who become chronically infected with liver damage is by far the most striking feature of HCV[3].
The distribution of HCV genotypes and subgenotypes varies substantially in different parts of the world, genotype 1 is the most common, accounting for 46.2% of all HCV infections, followed by genotype 3 (30.1%)[4]. The diversity of genotypes also varies; the highest diversity is observed in China and SouthEast Asia, while in some countries, such as Egypt and Mongolia, almost all HCV infections are due to a single genotype[4]. Globally, the prevalence of anti-HCV antibody is 67% among persons who inject drugs, HCV transmission risk is estimated as 4–8% among mothers without HIV infection. Transmission risk is estimated as 10.8–25% among mothers with HIV infection. Spontaneous clearance of acute HCV infection occurs within six months of infection in 15–45% of infected individuals in the absence of treatment. Almost all the remaining 55–85% of persons will harbour HCV for the rest of their lives (if not treated) and are considered to have chronic HCV infection. Screening for HCV infection is done using HCV serological testing. If positive, a NAT for HCV RNA is needed to confirm chronic HCV infection[4].
As per WHO baseline 2015, Between 6 and 10 million infections are reduced to 0.9 million infections by 2030 (80% decline in hepatitis C virus infections) and 1.4 million deaths reduced to less than 500 000 by 2030(65% for both viral hepatitis B and C)[5].

Assay Principle

First Response® HCV Card Test is based on the principle of immunochromatographic lateral flow device in a cassette format. Control line gold nanoparticles are conjugated with chicken IgY antibodies. Test line gold nanoparticles are conjugated with recombinant HCV Antigen. HCV antigens are immobilized at the Test Zone (T) and Control line protein are immobilized at the Control Zone (C). When the specimen and assay buffer is added, it migrates by capillary diffusion rehydrating the gold conjugate. If specimens contain Anti-HCV antibodies it will bind to gold conjugated recombinant HCV antigen. These complexes will continue to migrate laterally on the strip untill the Test zone (T) where complex are captured by the HCV antigens and form a visible red colored line. The unbound gold conjugate will continue to move and bind with control line protein at the Control Zone (C) forming a visible red colored line. If no HCV antibodies in the sample, only a red colored line appears at the Control Zone (C), which indicates the validity of the test.

Materials Provided



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

Materials provided	PI03FRC25	PI03FRC50	PI03FRC100
Test device pouch containing: 1 test device, 1 desiccant	25 Nos.	50 Nos.	100 Nos.
Specimen transfer device	25 Nos.	50 Nos.	100 Nos.
Assay buffer bottle	1 No.	2 Nos.	4 Nos.
Sterile lancets	25 Nos.	50 Nos.	100 Nos.
Alcohol swabs	25 Nos.	50 Nos.	100 Nos.
Instructions for use	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.
- Permanent marker pen and timer.
- Extra lancets and alcohol swabs, 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® HCV 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 temperature above 30°C and in humid conditions.
4) Assay buffer (opened & unopened) & the 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.
6) The shelf life of the kit is as indicated on the outer package.

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 device as infectious waste, in a biohazardous waste container. Dispose of used 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 material.
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 of a different lot must not be used.
6) Do not use the test device if the pouch is not intact.
7) Do not use the lancet if the seal is broken.
8) Do not eat desiccant. Do not use the test device if the desiccant found saturated.
9) Do not smoke, eat or drink while handling specimens and performing a test.
10) Do not re-use the test device, alcohol swab, lancet and specimen transfer device as are intended for single use only.