# WHO Prequalification of In Vitro Diagnostics
# PUBLIC ASSESSMENT 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 the WHO Prequalification Assessment for the First Response HCV Card Test

| | Date | Outcome |
|---|---|---|
| **Prequalification listing** | 13 November 2023 | listed |
| **Dossier assessment** | 2 March 2023 | MR |
| **Product performance evaluation** | 4th quarter of 2019 and 1st quarter of 2020 | MR |

MR: Meets Requirements

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which the 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. Change in the regulatory certification and labelling of the supplier for sterile lancet "Shandong Lianfa Medical Plastic Products Co., Ltd."<br>2. Change in the label of the alcohol swab supplied by Medtrue Enterprises Co., Limited. | 23 September 2025 |
| 3.0 | 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 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."*

**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:<br>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 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 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

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

## 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.

[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.

**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 %<br>(N=163) | 100% (95% CI: 97.8-100%) |
| Specificity %<br>(N= 320) | 99.7% (95% CI: 98.3-99.9%) |
| Invalid rate %<br>(N= 483) | 0.4% |
| Inter-reader variability %<br>(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<br>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 review

The labelling submitted for the First Response HCV Card Test 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 – 25 Tests | AB | 2020-11 | FM-QA-40 |
| | Carton – 50 Tests | AA | 2024-03 | FM-QA-40 |
| | Carton – 100 Tests | AA | 2025-12 | FM-QA-40 |
| | Carton – 50 Tests Inner | AA | 2025-12 | FM-QA-40 |
| **Pouch / Device label** | Aluminium Pouch | 01 | 2024-08-23 | FM-QA-40 |
| **Reagent bottle labels** | Assay Buffer Bottle Label DBS-032 | 01 | 2024-08-23 | FM-QA-40 |
| **Accessories 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-007) | 01 | 2024-08-23 | FM-QA-40 |
| | Dropper (25 Nos.) (DRO-003) | 01 | 2024-08-23 | FM-QA-40 |
| **Instructions for Use (IFU)** | (S)PI03-INS-001 | AD | 2023-09-19 | FM-QA-40 |

**Labels**

Carton - 25 Tests

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**

Carton - 50 Tests


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 | : 02 Nos. |
| • Instructions for use | : 01 No. |

Rev.: AA, 2024-03

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**

Carton – 100 Tests

For *in vitro* Diagnostic Use Only.

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

FIRST RESPONSE

30°C
4°C

REF PI03FRC100
Σ 100 Tests/kit

**One Step Anti HCV Card Test**

30°C
4°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.:AA, 2025-12

FIRST RESPONSE

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

30°C
4°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
Σ 100 Tests/kit

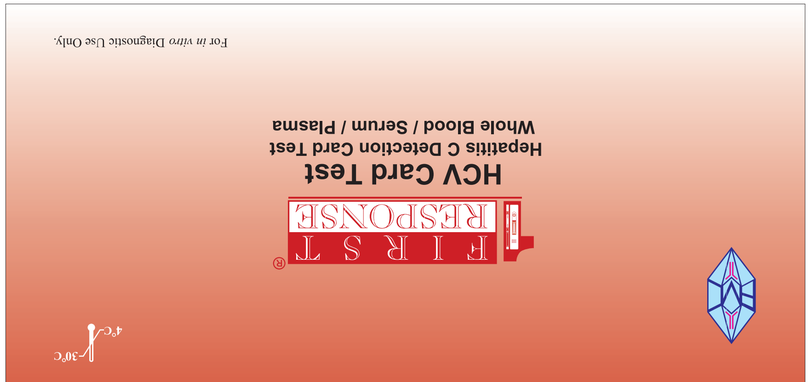
One Step Anti HCV Card Test

30°C
4°C

FIRST RESPONSE

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

Carton – 50 Tests Inner




50 Tests/kit

**One Step Anti HCV Card Test**

4°C 30°C

IVD

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

Rev.: AA, 2025-12

FIRST RESPONSE

**HCV Card Test**

**Hepatitis C Detection 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

FIRST RESPONSE

**HCV Card Test**

**Hepatitis C Detection Card Test**

**Whole Blood / Serum / Plasma**

Aluminium Pouch

FIRST RESPONSE®

**HCV CARD TEST**

**Hepatitis C Detection Rapid Card Test**
**(Whole blood / Serum / Plasma)**

*Premier Medical Corporation Private Limited*
A1 - 302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA
www.premiermedcorp.com

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

LOT :

:

:

REF **PI03FRC**

IVD 4°C 30°C Σ 1

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. | : | 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

# SPECIMEN TRANSFER DEVICE

35 ul 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

## 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.

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

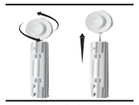
1) **Venous blood collection:** Collect the Whole blood in the collection tubes containing anticoagulants like EDTA, Heparin or Sodium citrate by venipuncture.

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.

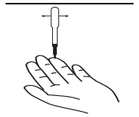
4) **Capillary blood specimen collection:**

- 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.

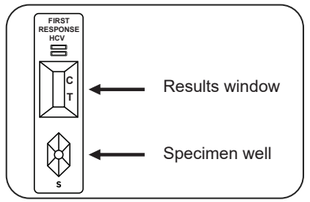
Use new lancet and choose a different puncture site, if repeat the finger prick.

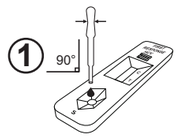
## Specimen storage

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

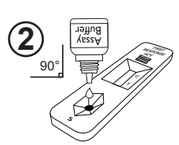
1) Ensure that the test device & other components are at room temperature (20°C to 30°C) before starting the procedure.
2) Take the test device and the specimen transfer device from the Kit. Do not use the test device if the desiccant found saturated.
3) Label the test device with the patient identification 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.



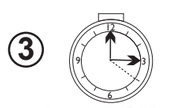

Do not tilt.

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.

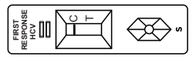
## Procedural Control

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.



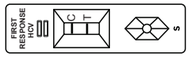
## How to Interpret test results

**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.

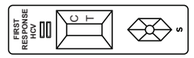
**Positive Results**

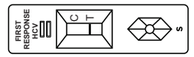


If two red colored lines appears, one at the control line ‘C’ and other at the test line ‘T’as in the figure, the specimen is reactive for antibodies to HCV.

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.

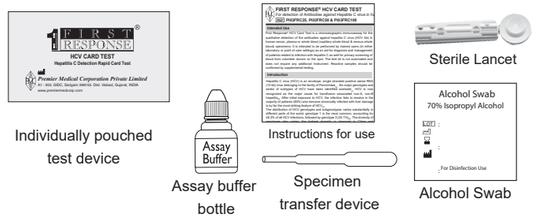
## Introduction

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.