WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT
Product: HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma)
WHO reference number: PQDx 0387-051-00

HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) with product codes IHC-402WA, IHC-402WB, IHC-402WC, and IHC-402WD manufactured by ABON Biopharm (Hangzhou) CO., LTD, *Rest-of-World regulatory version*, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 8 November 2023.

Summary of WHO prequalification assessment for HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma)

	Date	Outcome
Prequalification listing	8 November 2023	listed
Dossier assessment	28 March 2023	MR
Site inspection(s) of quality management system	7-9 June 2023	MR
Product performance evaluation	3rd and 4th quarters of 2019	MR

MR: Meets Requirements

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	Date of report amendment
2.0	Closure of dossier commitment to prequalification. The manufacturer submitted the validation report, which was acceptable.	14 March 2024

Intended use

According to the intended use claim from ABON Biopharm (Hangzhou) CO., LTD, *"HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) is a single use, visually read, rapid chromatographic immunoassay for the qualitative detection of antibodies to Hepatitis C Virus in human venous and capillary whole blood, serum or plasma. The test is intended to be used as an aid in the diagnosis of individuals at risk of Hepatitis C infection.*

The test provides preliminary results. Negative or positive results do not preclude Hepatitis C infection and may need to be confirmed using other methods according to current guidelines.
The HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma) is not automated and is intended for professional use in a laboratory or near-patient environment. This test device is not intended for self-testing or testing in infants younger than 18 months of age and must not be used for blood donation screening."

Assay description

According to the claim of assay description from ABON Biopharm (Hangzhou) CO., LTD, "*The HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma or whole blood. The membrane is coated with recombinant HCV antigen on the test line region of the device. During testing, the serum or plasma or whole blood specimen reacts with the recombinant HCV antigen coated particles.*
The mixture migrates upward on the membrane by capillary action to react with recombinant HCV antigen on the membrane and generates a colored line. Presence of this colored line indicates a reactive result, while its absence indicates a non-reactive result. To serve as a procedural control, a colored line will always appear in the control line region. If the control line does not appear, the test result is invalid."

Test kit contents

Component	**40 Tests/kit (T/k) (product code IHC-402WA)**	**25 T/kit (product code IHC-402WB)**	**40 T/k (product code IHC-402WC)**	**25 T/kit (product code IHC-402WD)**
Test device	40	25	40	25
3mL Buffer (Phosphate buffer 0.2M pH7.4 and sodium azide 0.09%)	x 2	x 1	x 2	x 1
Specimen Dropper for Serum/Plasma/Venipuncture Whole Blood	x 40	x 25	x 40	x 25
Alcohol pads	\	\	40	25
Single-use lancet	\	\	40	25
Specimen Dropper for Fingerstick Whole Blood	\	\	40	25
Instructions for Use	x 1	x 1	x 1	x 1

Items required but not provided:

- **For product codes IHC-402WA and IHC-402WB.**
  - Timer,
  - Single-use lancets, alcohol prep pads, cotton wool or gauze pads (for fingerstick whole blood only)
  - Heparinized capillary tubes with 50 µL mark line and dispensing bulb (for fingerstick whole blood only).
  - Biohazard waste containers for sharps and non-sharps.

- ***For product codes IHC-402WC and IHC-402WD.***
  - Timer
  - Specimen collection equipment and containers
  - Centrifuge (for plasma only)
  - Cotton wool or gauze pad (for fingerstick whole blood only)
  - Biohazard waste containers for sharps and non-sharps.

Storage

The test kit should be stored at 2-30 °C.

Shelf-life upon manufacture

24 months.

Warnings/limitations

Please 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 HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) was given priority for WHO prequalification assessment.

Dossier assessment

ABON Biopharm (Hangzhou) CO.,LTD. submitted a product dossier for HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) as 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 *28-03-2023.*

Commitment for prequalification

The manufacturer committed to submit validation report by September 2023 to the WHO demonstrating that the performance of the comparator test has been compared to that of two other HCV ELISAs that have been approved by a stringent regulatory authority, according to the WHO definition of a stringent regulatory authority. The manufacturer submitted the validation report, which was acceptable. The commitment was closed.

Based on the product dossier screening and assessment findings, the product dossier for HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) meets WHO prequalification requirements.

Manufacturing site inspection

An onsite inspection of Abon Biopharm (Hangzhou) CO.,LTD. located 198# 12th Street East, Economic and Technological Development Area, 310018 Hangzhou, China, was conducted from the 7th to the 9th of June 2023. 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 the 30th of October, 2023, with commitments. Based on the site inspection and corrective action plan review, the quality management system for the HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) meets WHO prequalification requirements.

Product performance evaluation

HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) was evaluated by the National Serology Reference Laboratory (NRL), Melbourne, Australia, on behalf of WHO in the 3rd and 4th quarter of 2019, 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: 97.7% - 100%)
Specificity % (N= 320)	100% (95% CI: 98.8% - 100%)
Invalid rate % (N= 483)	0%
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 (DiaSorin Murex Anti-HCV EIA (version 4.0))	Of a total of 26 specimens, 12 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 10 dilution series.

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	50 µL (2 drops) of serum, plasma (EDTA, sodium citrate, sodium heparin, lithium heparin), venous whole blood (EDTA, sodium citrate) or capillary whole blood
Number of steps*	2 steps in total 1 step with precision pipetting (optional, only for serum/plasma)
Time to result	10 minutes
Endpoint stability (interval)	10 minutes (the test can be read between 10 and 20 minutes after addition of buffer)
Internal QC	Yes, reagent addition control

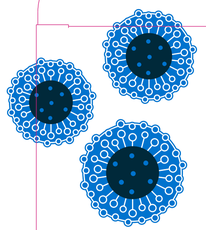
** Definition: each action required to obtain a result (excluding specimen collection, device preparation – opening the pouch), e.g. for RDTs: add specimen, add buffer (2 steps).*

Based on these results, the performance evaluation for the HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) meets the WHO prequalification requirements.

Labelling

1.1 Packaging boxes

Product codes IHC-402WA and IHC-402WC (40 T/kit)



2°C 30°C IVD

ABON™
HCV HEPATITIS C VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

Abbott

Pantone 2925 C
Pantone 303 C
Pantone 285 C

1135929801

Abbott

ABON™
HCV HEPATITIS C VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

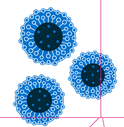
2°C 30°C IVD

ABON™
HCV HEPATITIS C VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

Abon Biopharm (Hangzhou) Co., Ltd.
#198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R.China
www.globalpointofcare.abbott

ABON™
HCV HEPATITIS C VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

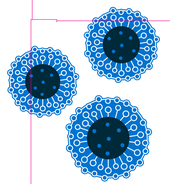
2°C 30°C IVD



ABON™
HCV HEPATITIS C VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

Label

Product codes IHC-402WB and IHC-402WD (25 T/kit)



ABON™
HCV HEPATITIS C VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

2°C 30°C IVD

Abbott

ABON™
HCV HEPATITIS C VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

2°C 30°C IVD

1135929901

Pantone 2925 C
Pantone 303 C
Pantone 285 C

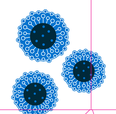
ABON™
HCV HEPATITIS C VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

Abbott

Abon Biopharm (Hangzhou) Co., Ltd.
#198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R.China
www.globalpointofcare.abbott

ABON™
HCV HEPATITIS C VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

2°C 30°C IVD

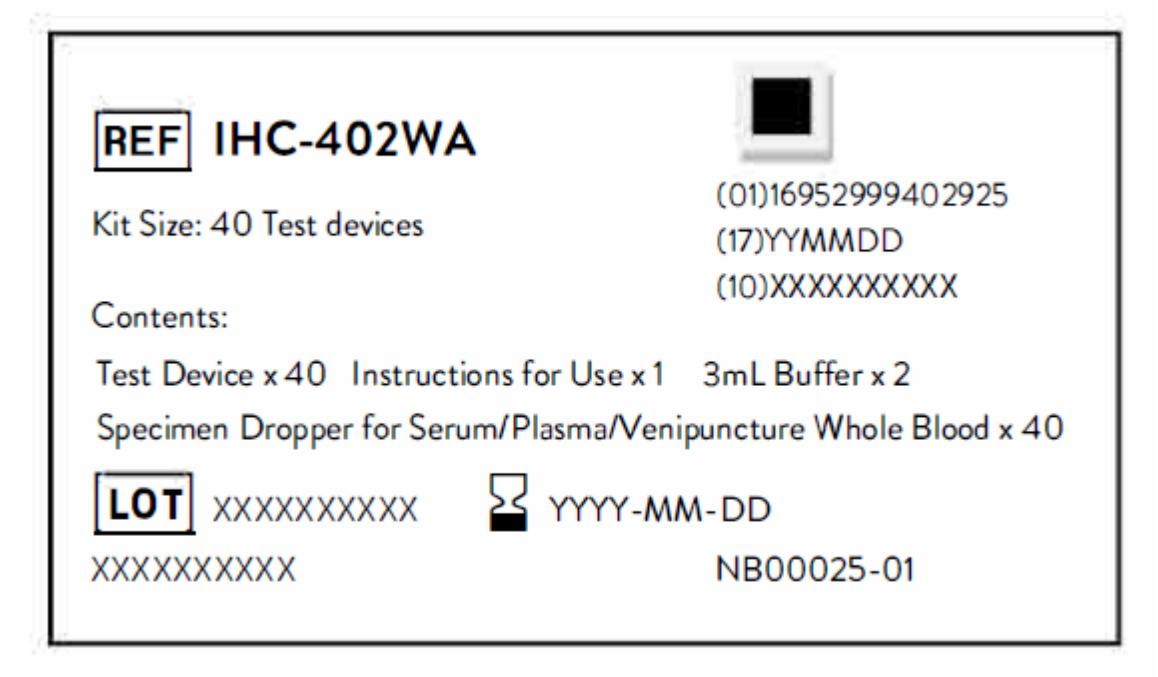


ABON™
HCV HEPATITIS C VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

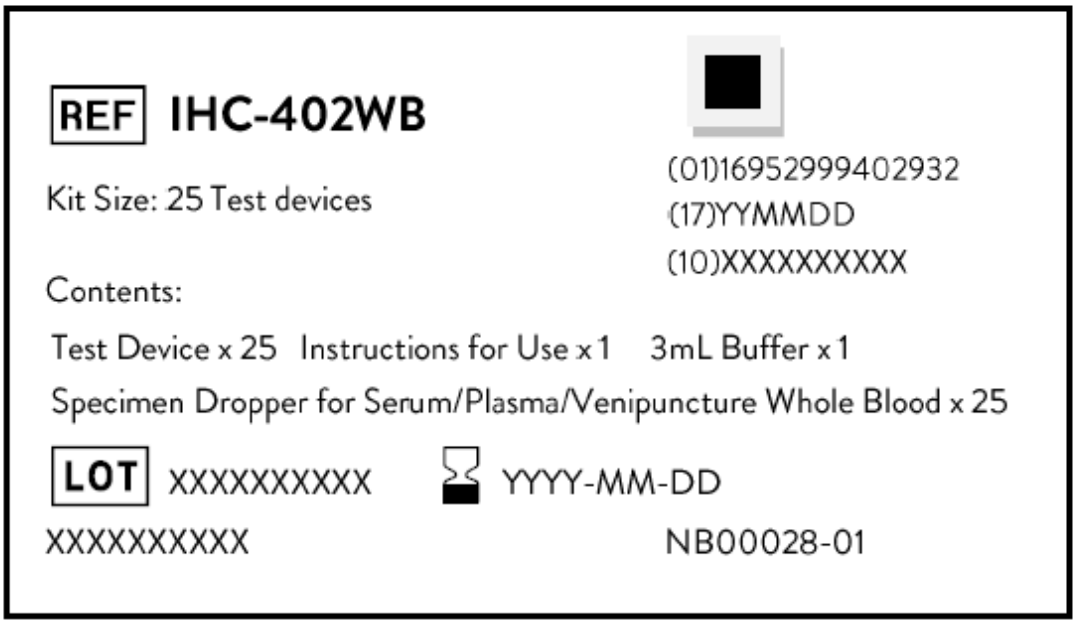
Label

1.2 Box labels

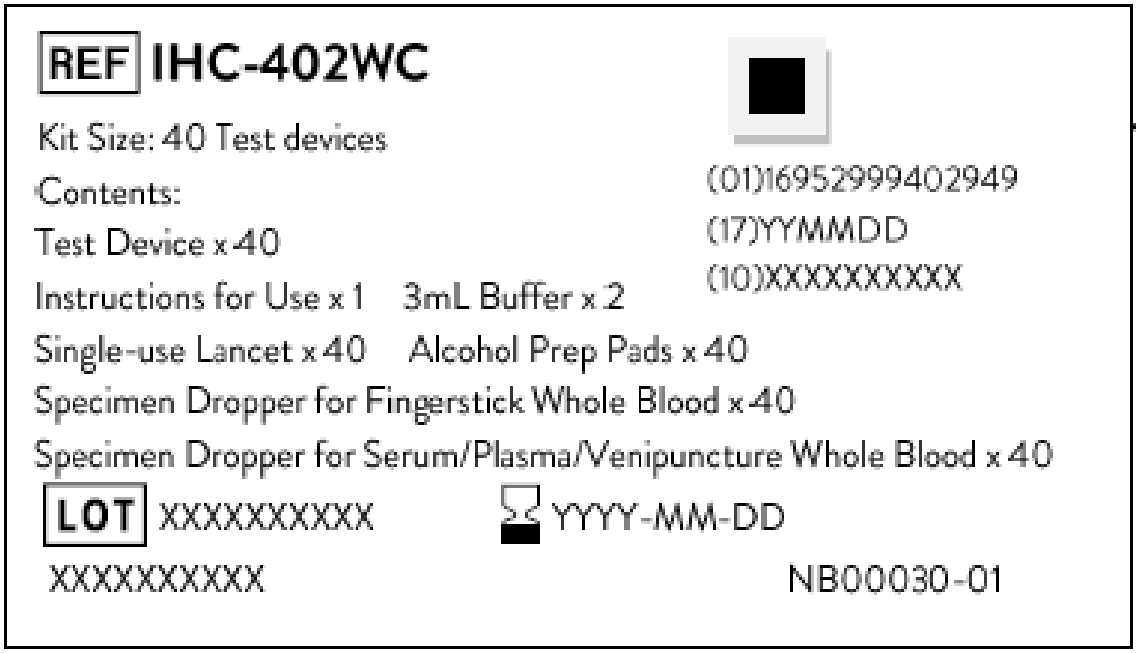
1.2.1 Product code IHC-402WA



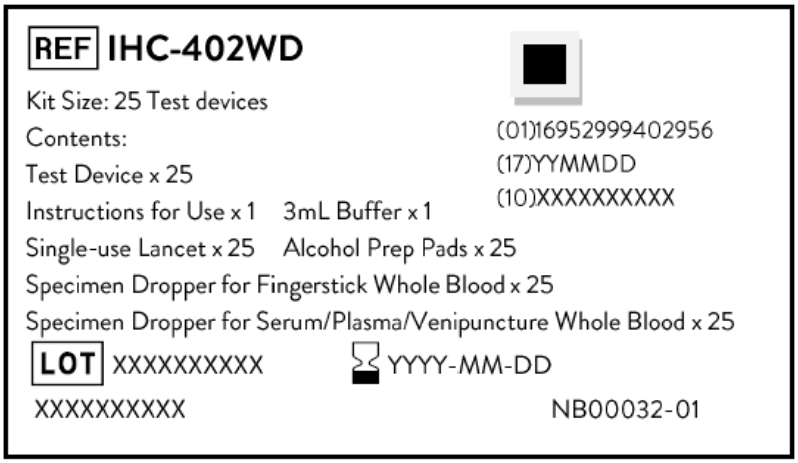
1.2.2 Product code IHC-402WB



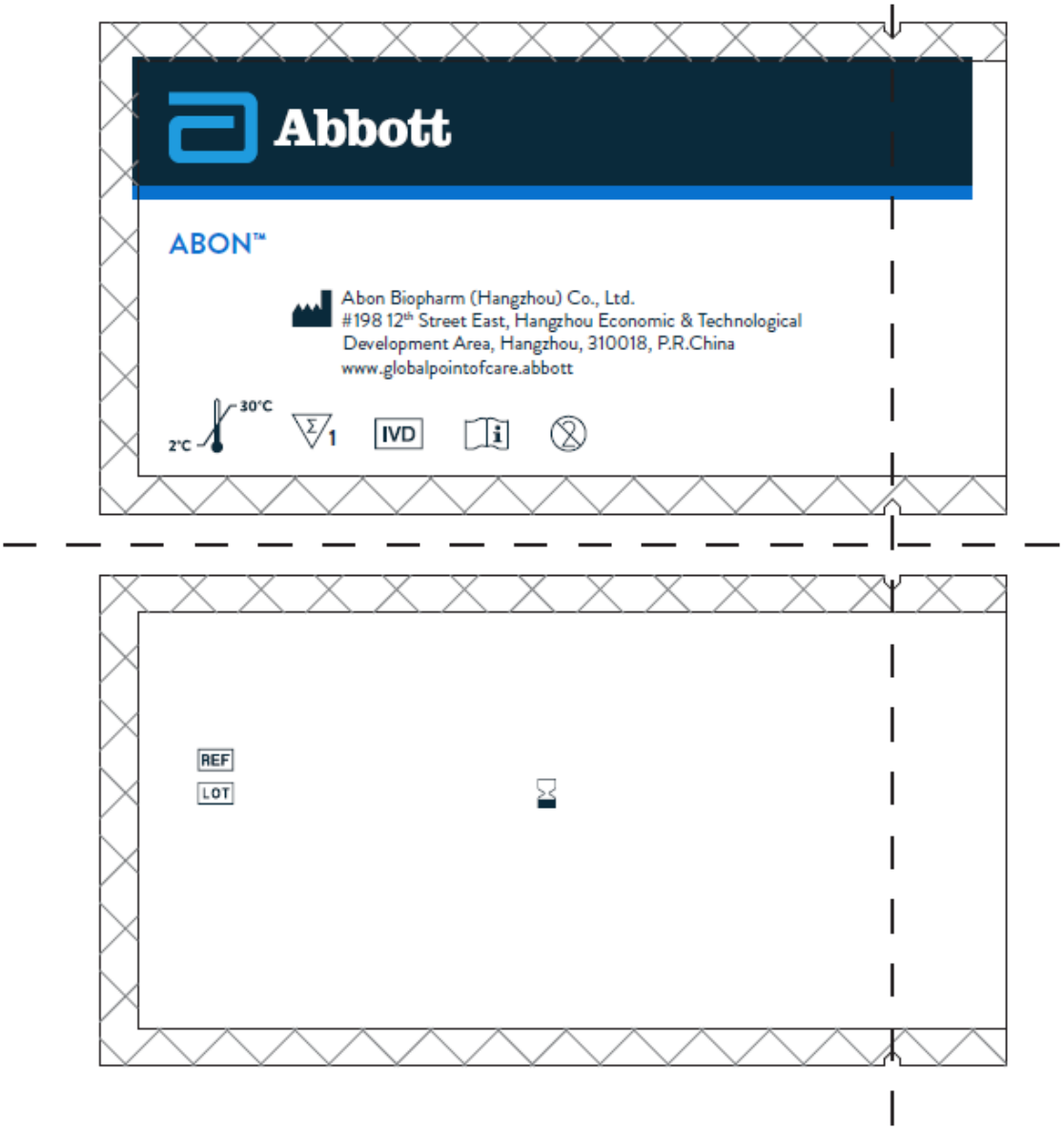
1.2.3 product code IHC-402WC



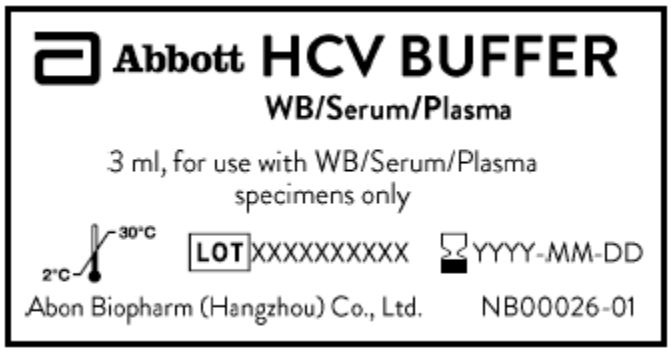
1.2.4 Product code IHC-402WD



1.2.5 Device Pouch Label



1.2.6 Buffer label



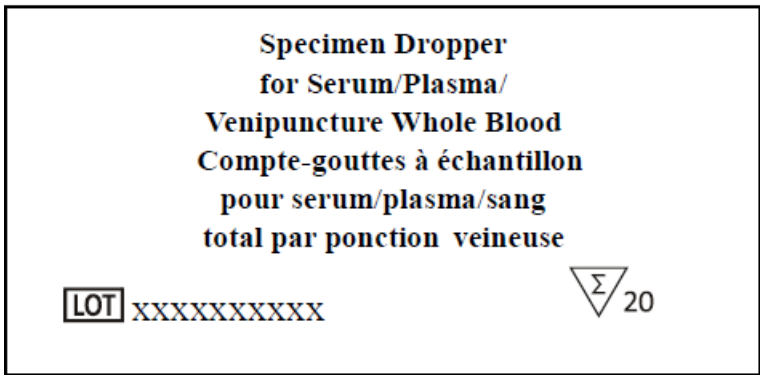
1.2.7 Alcohol pads label

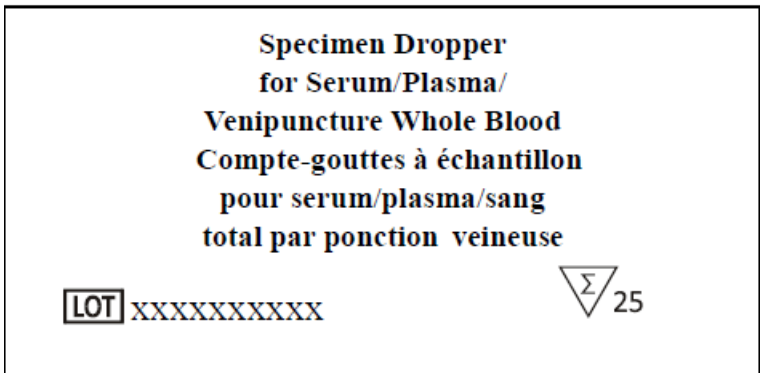
1.2.8 Single-use lancet

a) Product codes IHC-402WA and IHC-402WC (2 x 2 bags)

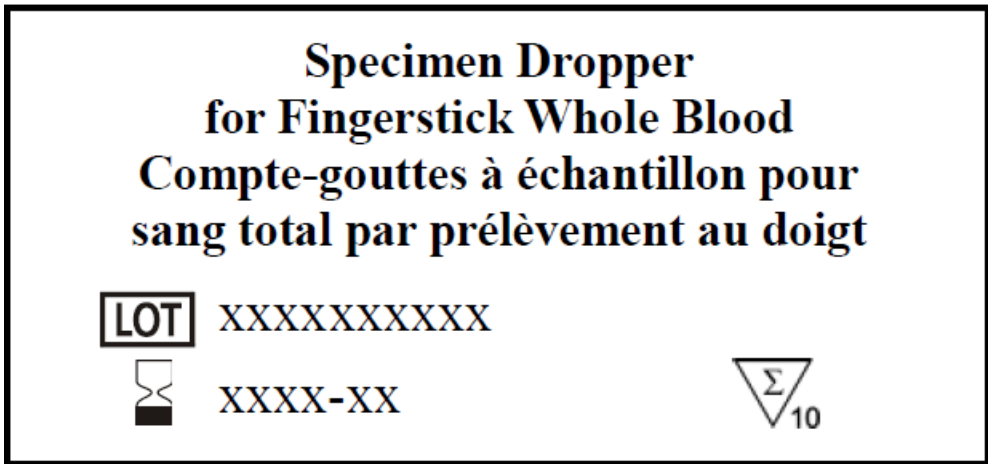
b) Product codes IHC-402WB and IHC-402WD

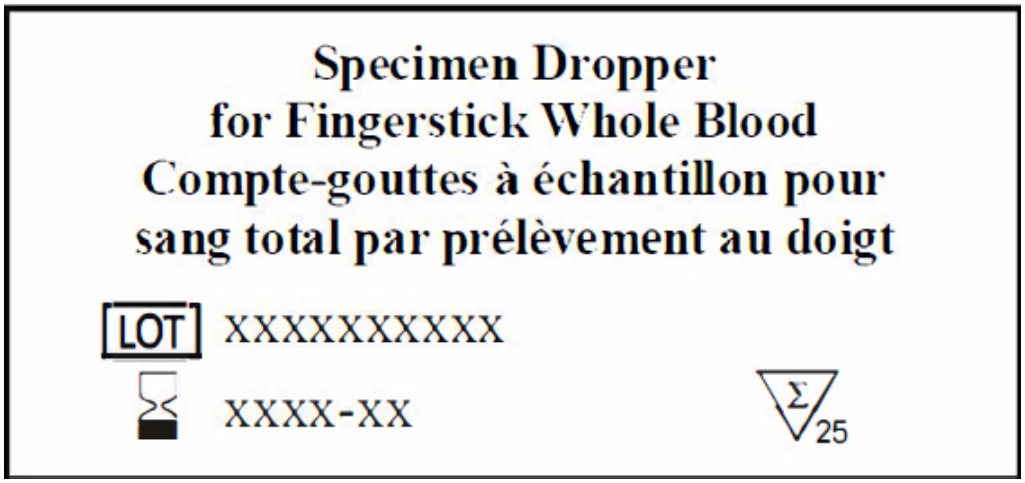
1.2.9 Specimen Dropper for Serum/Plasma/Venipuncture Whole Blood





1.2.10 Specimen Dropper for Fingerstick Whole Blood





2.0 Instructions for Use[1]

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

Abbott

1156214401

Revision date: 2023-10-08
IFU version 04

ABON™
HCV HEPATITIS C VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

REF IHC-402WA REF IHC-402WB IVD

Instructions for Use **English**

INTENDED USE

The HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma) is a single use, visually read, rapid chromatographic immunoassay for the qualitative detection of antibodies to Hepatitis C Virus in human venous and capillary whole blood, serum or plasma. The test is intended to be used as an aid in the diagnosis of individuals at risk of Hepatitis C infection.
The test provides preliminary results. Negative or positive results do not preclude Hepatitis C infection and may need to be confirmed using other methods according to current guidelines.
The HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma) is not automated and is intended for professional use in a laboratory or near patient environment. This test device is not intended for self-testing or testing in infants younger than 18 months of age and must not be used for blood donation screening.

SUMMARY

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in most patients with well-documented non-A, non-B hepatitis[1].
Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens[2]. Compared to the first generation HCV EIA using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests[3].
The HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a serum or plasma or whole blood specimen. The test utilizes a combination of recombinant HCV antigen coated particles and recombinant HCV proteins to selectively detect antibody to HCV in serum or plasma or whole blood. The recombinant HCV antigens used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

PRINCIPLE

The HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma or whole blood. The membrane is coated with recombinant HCV antigen on the test line region of the device. During testing, the serum or plasma or whole blood specimen reacts with the recombinant HCV antigen coated particles. The mixture migrates upward on the membrane by capillary action to react with recombinant HCV antigen on the membrane and generates a colored line. Presence of this colored line indicates a reactive result, while its absence indicates a non-reactive result. To serve as a procedural control, a colored line will always appear in the control line region. If the control line does not appear, the test result is invalid.

REAGENTS

The test device contains recombinant HCV antigen coated particles and another recombinant HCV antigen coated on the membrane.

PRECAUTIONS

- Proper storage condition is critical to product performance, the kit should be stored at 2-30°C.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection before the test. Handle all specimens and controls as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing. Standard personal hygiene measures should be taken in the case of ingestion or direct eye contact with the buffer. If the buffer comes into contact with the eyes or skin, wash affected area immediately, and seek medical attention if necessary.
- Bystanders may be contaminated with the biological material and sample in the testing process, so stay away from bystanders.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- For professional *in vitro* diagnostic use only, do not use the test device if the expiration date on the foil pouch has passed, and do not use the buffer if the expiration date on the buffer bottle has passed.
- Do not use the test if pouch is damaged. Do not use the test device if the desiccant shows green when the pouch is opened.
- Do not eat the desiccant from the foil pouch. Do not drink the buffer which contains phosphate and 0.09% sodium azide. Dispose the used buffer according to standard procedures and local regulations. If unused assay buffer is discarded in a sink, it must be well rinsed with a copious quantity of water.
- Avoid touching a finger directly to the specimen pad, membrane or result window of the test as this can cause incorrect results.
- Each device is for single use only. Do not reuse the device.
- Humidity and temperature can adversely affect results. Test the product in the prescribed environmental condition (15-30°C). Once the foil pouch is opened, use the product as soon as possible.
- Do not mix or interchange components among different lots or those for other product.
- It is essential to use correct anticoagulant. Use EDTA-K_2/EDTA-K_3/Sodium citrate/Sodium heparin/Lithium heparin as anticoagulant to collect plasma for testing, while whole blood samples should only use EDTA-K_2/EDTA-K_3/Sodium citrate as anticoagulant.
- The instruction must be followed exactly to achieve accurate results. Read the results in the required time (10-20 min).
- Follow standard procedures and local regulations for proper disposal of specimens, controls, used test, buffer, dropper, foil pouch and desiccant.
- Repeat the test or use plasma sample if the whole blood sample doesn't migrate well. If the plasma sample still doesn't migrate well, stop using the test kit immediately and contact your local distributor.

STORAGE AND STABILITY

The kit can be stored at 2-30°C. The test device is stable before the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) can be performed using either serum or plasma or whole blood (for venipuncture or fingerstick).
- To collect **Serum or Plasma or Venipuncture Whole Blood** specimens:
  - Collect according to safe phlebotomy procedures, using vacuum tubes for serum or plasma or venipuncture whole blood preparation.
  - Prepare serum or plasma from whole blood as soon as possible to avoid hemolysis. Don't use turbid or haemolysed specimens.
- To collect **Fingerstick Whole Blood** specimens (see illustration on the reverse side):
  Single-use lancet, antiseptic isopropyl alcohol 70%v/v and 50µL capillary tube are recommended for sample collection.
  - Clean entire fingertip (prefer middle or ring finger) with alcohol prep pads. Allow to dry (30 seconds).
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood at the puncture site.
  - Add the Fingersitck Whole Blood specimen to the test device by using a capillary tube:
    - Touch the end of the capillary tube to the blood until filled to mark line (approximately 50 µL). Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (S) of the test device.
- Separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum or plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept at -30 ~ -10°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 1 day of collection. Whole blood collected by fingerstick should be tested immediately. Do not freeze whole blood specimens.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing.
- No qualitative performance difference was observed between 11 non-reactive and 11 reactive specimens subjected to 3 freeze/thaw cycles; however, multiple freeze/thaw cycles should be avoided.
- If specimens are to be shipped, they should be packed in compliance with federal/country regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

Components	IHC-402WA	IHC-402WB
Test Device	x40	x25
3mL Buffer (Phosphate buffer 0.2M pH7.4 and sodium azide 0.09%)	x2	x1
Specimen Dropper for Serum/Plasma/Venipuncture Whole Blood	x40	x25
Instructions for Use	x1	x1

Materials Required But Not Provided

- Specimen collection equipment and containers
- Single-use lancets, alcohol prep pads, cotton wool or gauze pad (for fingerstick whole blood only)
- Centrifuge (for plasma only)
- Timer
- Heparinized capillary tubes with 50 µL mark line and dispensing bulb (for fingerstick whole blood only)
- Biohazard waste containers for sharps and non sharps

DIRECTIONS FOR USE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Transfer the specimen to the sample well.
   For **Serum/Plasma/Venipuncture Whole Blood** sample
   Transfer the specimen by a pipette or a dropper:
   - To use a **Pipette:** Transfer 50 µL of serum or plasma or venipuncture whole blood to the specimen well (S) of the test device, then add 1 full drop of buffer vertically (approximately 30 µL) and start the timer. Avoid trapping air bubbles in the specimen well (S).
   - To use a **Disposable Specimen Dropper:** Hold the dropper vertically, draw serum or plasma or venipuncture whole blood specimen. Transfer 2 full drops of the specimen vertically (approximately 50 µL) to the specimen well (S) of the test device, then add 1 full drop of buffer vertically (approximately 30 µL) and start the timer. Avoid trapping air bubbles in the specimen well (S).

   For **Fingerstick Whole Blood** sample
   - To use a **Capillary Tube:** Fill the capillary tube, transfer approximately 50 µL of fingerstick whole blood specimen to the specimen well (S) of test device, then add 1 drop of buffer vertically (approximately 30 µL) and start the timer.
3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

*Note: To assure there is accurate volume of fingerstick whole blood, the capillary tube is recommended to be used. Dispose the capillary tube in a biohazard waste container for sharps.

INTERPRETATION OF RESULTS

REACTIVE: Two distinct colored lines appear*. One line should be in the control region (C) and another line should be in the test region (T).
***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of HCV antibody present in the specimen. Therefore, any shade of color in the test region should be considered reactive.
NON-REACTIVE: One colored line appears in the control region (C). No colored line appears in the test region (T).
INVALID: No line appears in the control line region (C). If this occurs, read the directions again and repeat the test with a new test. If the result is still invalid, stop using the test kit immediately and contact your local distributor.
(see illustration on the reverse side)

QUALITY CONTROL

A procedural control is built inside the test device. A colored line appears in the control region (C) is considered an internal positive procedural control, and indicates a valid test result.
Specimen addition controls are not included along the kit, however, it is recommended to test positive and negative specimen controls as a good laboratory practice to confirm the right operation procedure and to verify proper test performance of the test device.

LIMITATION

1. The HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibody to HCV in serum or plasma or whole blood specimen.
2. The HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) will only indicate the presence of antibody to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is non-reactive and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A non-reactive result at any time does not preclude the possibility of Hepatitis C Virus infection.
5. Intravenous ascorbic acid (IAA) therapy may cause a false reactive result. Ascorbic acid concentrations up to 0.2mg/mL in serum or plasma or whole blood did not impact the results.
6. For HCV negative samples of multiple blood transfusion recipients, there is the risk of a weak reactive result for some individual specimens.

EXPECTED VALUES

The HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) has been compared with leading commercial HCV product. The correlation between these two systems is 99.95% (95%CI:99.73%-99.99%).

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity & Specificity

A total of 520 HCV positive serum/plasma/whole blood specimens and 1600 negative serum/plasma/whole blood specimens were tested using the HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma) and other commercial available reference tests. The results gave diagnostic sensitivity of 99.81 % (95%CI: 98.92%-99.97%) and diagnostic specificity of 100% (95%CI:99.76%-100%).

			HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma)		Total results
			Reactive	Non-reactive	
Reference assay	Reactive	Serum/plasma	419*	1	520*
		Whole Blood	100*	0	
		Finger stick whole blood	100	0	
	Non-reactive	Serum/plasma	0	1000	1600
		Whole Blood	0	500	
		Finger stick whole blood	0	100	
Diagnostic Sensitivity (95 %CI)			519/520 99.81% (95%CI: 98.92%-99.97%)		
Diagnostic Specificity (95 %CI)			1600/1600 100% (95%CI:99.76%-100%)		

Note: "*" 100 positive paired whole blood and plasma samples were evaluated, but calculated only once for the diagnostic sensitivity.

Whole Blood vs. Serum vs. Plasma

1. Serum/Plasma equivalence
   25 negative for Anti-HCV Ab serum samples, sodium heparin plasma samples, Lithium heparin plasma samples, EDTA-K_2 plasma samples, EDTA-K_3 plasma samples, sodium citrate plasma samples and 25 Anti-HCV Ab positive serum samples, sodium heparin plasma samples, Lithium heparin plasma samples, EDTA-K_2 plasma samples, EDTA-K_3 plasma samples, sodium citrate plasma samples were tested in parallel with the HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma).

Sample type	No. of reactive/No. of positive sample	No. of non-reactive/No. of negative sample
Serum	25/25	25/25
Sodium heparin plasma	25/25	25/25
Lithium heparin plasma	25/25	25/25
EDTA-K_2 plasma	25/25	25/25
EDTA-K_3 plasma	25/25	25/25
Sodium citrate plasma	25/25	25/25

Paired serum, plasma specimens show the equivalent results with the HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma).
2. Whole blood / plasma equivalence
   From 100 HCV infected patients whole blood samples (matrix EDTA-K_2) as well as an EDTA-K_3 plasma samples were collected at the same time and were tested by the HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma). All samples obtained reactive test results.

Tested	EDTA-K_2 Whole blood	EDTA-K_3 plasma
	100	100
Non-reactive test results	0	0
Reactive test results	100	100

Paired whole blood, plasma specimens show the equivalent results with the HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma).

Precision

Precision of the HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) has been demonstrated by day-to-day, inter-assay, intra-assay using in-house reference samples. All values were identical to acceptable criteria.

Cross reactivity

No cross-reactivity was observed in potentially cross reactive samples including: HIV antibody positive specimens, HTLV I/II antibody positive specimens, Syphilis antibody positive specimens, Hepatitis A antibody positive specimens, Hepatitis B surface antigen positive specimens, Hepatitis B surface antibody positive specimens, Hepatitis B e antigen positive specimens, Hepatitis B e antibody positive specimens, Hepatitis B core antibody positive specimens, Hepatitis E antibody positive specimens, Jaundice specimens, ALT positive specimens, Human anti-mouse antibody (HAMA) positive specimens, Anti-nuclear antibody (ANA) positive specimens, Rheumatoid factor positive specimens, Hyperlipidemia specimens, HCG positive specimens, Haemolytic panel specimens, H. pylori antibody positive specimens, TB antibody positive specimens, Cytomegalovirus antibody positive specimens, Epstein-Barr virus antibody positive specimens, Herpes simplex virus 1 antibody positive specimens, Varicella zoster virus antibody positive specimens, Toxo antibody positive specimens, Chlamydia trachomatis positive specimens, Leishmaniasis antibody positive specimens, Malaria antibody positive specimens, Trypanosomiasis antibody (Human African trypanosomiasis) positive specimens, Anti-Influenza A or anti-Influenza B antibody positive specimens, Anti-Escherichia coli antibody positive specimens, Elevated Immunoglobulin G (IgG) specimens, Elevated immunoglobulin M (IgM) specimens, AFP positive specimens, Carcinoembryonic (CEA) positive specimens, Post-immunization measle specimens , Influenza vaccine recipient specimens, Yellow fever virus post-immunization antibody specimens, Systemic Lupus Erythematosus (SLE) antibody specimens, Sickle-cell disease specimens, Rubella antibody positive specimens.

Interfering Substances

No interference was observed in samples with high concentrations of 0.2mg/mL Ascorbic acid, 0.2mg/mL Gentistic acid, 0.6mg/mL Oxalic acid, 0.6mg/mL Uric acid, 0.6mg/mL Salicylic acid, 0.2mg/mL Acetoacetic acid, 0.65mg/mL Acetylsalicylic acid (aspirin), 0.2mg/mL Caffeine, 1mg/mL Creatine, 1mg/mL Acetaminophen, 0.25mg/mL Cyclobenzaprine, 0.12mg/mL Metronidazole, 10mg/mL Hemoglobin, 50mg/mL Triglyceride, 0.25mg/mL Ibuprofen, 0.5mg/mL Naproxen, 60mg/mL Albumin, 0.6mg/mL Bilirubin, 1% Ethyl alcohol, 2% Methanol.

BIBLIOGRAPHY

1. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. *An assay for circulating antibodies to a major etiologic Virus of human non-A, non-B hepatitis.* Science 1989; 244:362-364.
2. Choo, Q.L., G. Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley, and M. Houghton. *Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome.* Science 1989; 244:359-362.
3. Van der Poel, C. L., H.T.M. Cuypers, H.W. Reesink, and P.N.Lelie. *Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunoblot assay.* Lancet 1991; 337:317-319.

Index of Symbols

	Consult instructions for use	Σ	Contains sufficient for <n> tests	REF	Catalogue number
LOT	Batch code		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C		Manufacturer	IVD	*In vitro* diagnostic medical device

Technical Support

Middle East
+965 2202 2828
EME.TechSupport@abbott.com

APAC (Asia-Pacific)
+61 7 3363 7711
AP.TechSupport@abbott.com

Africa
+27 10 500 9700 Option 3
arcis.techsupport@abbott.com

LATAM (Latin-America)
+57-601-4824033
LA.TechSupport@Abbott.com

Russia, and Commonwealth of Independent States (RCIS)
+7 499 403 9512
arcis.techsupport@abbott.com

Abon Biopharm (Hangzhou) Co., Ltd.
#198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R.China
www.globalpointofcare.abbott

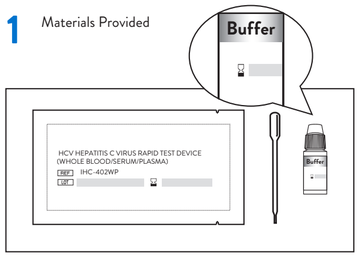
Abbott

ABON™

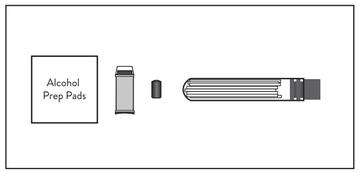
HCV HEPATITIS C VIRUS RAPID TEST DEVICE (WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

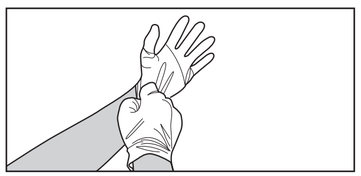
1 Materials Provided



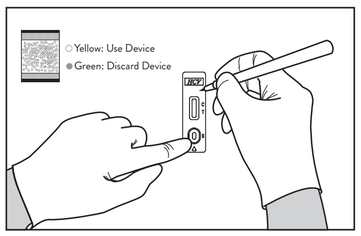
Materials Required But Not Provided



2 Wear gloves

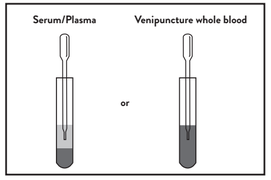


3 Open the pouch, do not use the test device if the desiccant shows green when the pouch is opened. Label with specimen ID. Use it as soon as possible (within one hour).

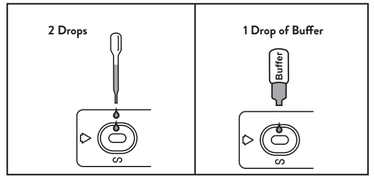


SERUM OR PLASMA OR VENIPUNCTURE WHOLE BLOOD SPECIMENS

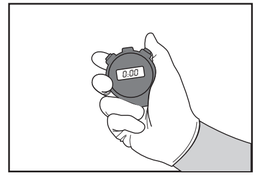
4 Draw the specimen from the specimen tube with a dropper.



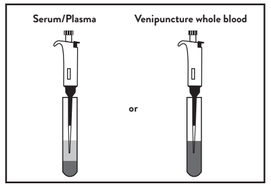
5 Transfer 2 drops of serum or plasma or venipuncture whole blood with specimen dropper vertically (approximately 50 µL), then add 1 drop of buffer vertically (approximately 30 µL).



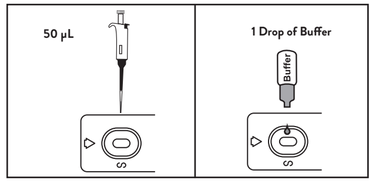
6 Start the timer.



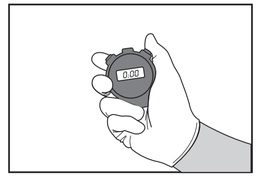
4 Draw the specimen from the specimen tube with a pipette.



5 Transfer 50 µL serum or plasma or venipuncture whole blood with specimen pipette, then add 1 drop of buffer vertically (approximately 30 µL).

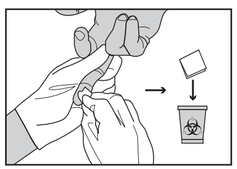


6 Start the timer.

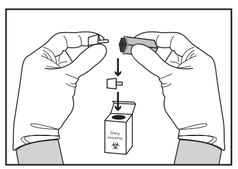


FINGERSTICK WHOLE BLOOD SPECIMENS

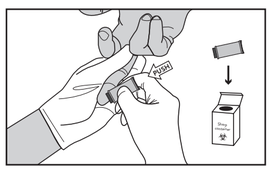
4 Clean entire fingertip (prefer middle or ring finger from non-dominant hand) with alcohol prep pads. Dispose the alcohol prep pads.



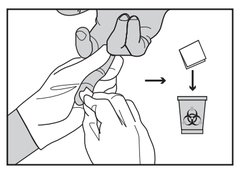
5 Take off the cap of the lancet and dispose the cap in sharps container.



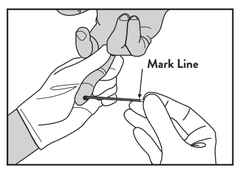
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



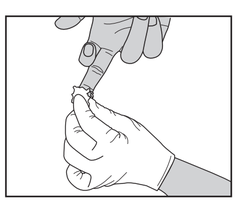
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



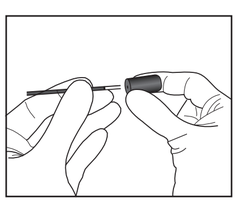
8 Immerse the open end of the capillary tube into the blood drop and allow for the blood to draw into the capillary tube up to mark line.



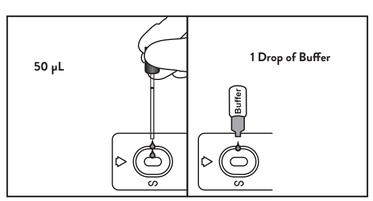
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



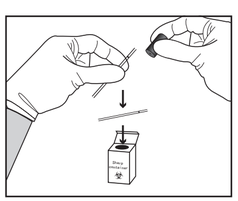
10 Place the bulb onto the top end of the capillary tube.



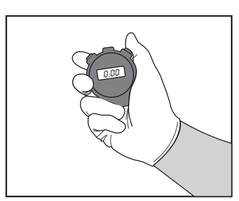
11 Squeeze the bulb to dispense all whole blood on the specimen well (approximately 50 µL) , then add 1 drop of buffer vertically (approximately 30 µL).



12 Dispose the capillary tube in sharps container after testing.

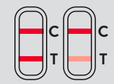


13 Start the timer.



READ RESULTS

Wait for the colored line(s) to appear.
Read results at **10-20 minutes**.



REACTIVE: Two distinct colored lines appear*. One line should be in the control region (C) and another line should be in the test region (T).

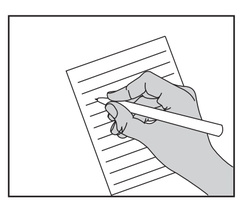
***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of HCV antibody present in the specimen. Therefore, any shade of color in the test region should be considered reactive.

NON-REACTIVE: One colored line appears in the control region (C). No colored line appears in the test region (T).

INVALID: No line appears in the control line region (C). If this occurs, read the directions again and repeat the test with a new test. If the result is still invalid, stop using the test kit immediately and contact your local distributor.

CLEAN UP/RECORD

Dispose devices and gloves in a proper biohazard waste container.



Record the test results.

Abbott

1156214501

Revision date: 2023-10-08
IFU version 03

ABON™
HCV HEPATITIS C VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

REF IHC-402WC REF IHC-402WD IVD

Instructions for Use

English

INTENDED USE

The HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma) is a single use, visually read, rapid chromatographic immunoassay for the qualitative detection of antibodies to Hepatitis C Virus in human venous and capillary whole blood, serum or plasma. The test is intended to be used as an aid in the diagnosis of individuals at risk of Hepatitis C infection.
The test provides preliminary results. Negative or positive results do not preclude Hepatitis C infection and may need to be confirmed using other methods according to current guidelines.
The HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma) is not automated and is intended for professional use in a laboratory or near patient environment. This test device is not intended for self-testing or testing in infants younger than 18 months of age and must not be used for blood donation screening.

SUMMARY

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in most of patients with well-documented non-A, non-B hepatitis[1].
Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens[2]. Compared to the first generation HCV EIA using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests[3].
The HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a serum or plasma or whole blood specimen. The test utilizes a combination of recombinant HCV antigen coated particles and recombinant HCV proteins to selectively detect antibody to HCV in serum or plasma or whole blood. The recombinant HCV antigens used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

PRINCIPLE

The HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma or whole blood. The membrane is coated with recombinant HCV antigen on the test line region of the device. During testing, the serum or plasma or whole blood specimen reacts with the recombinant HCV antigen coated particles. The mixture migrates upward on the membrane by capillary action to react with recombinant HCV antigen on the membrane and generates a colored line. Presence of this colored line indicates a reactive result, while its absence indicates a non-reactive result. To serve as a procedural control, a colored line will always appear in the control line region. If the control line does not appear, the test result is invalid.

REAGENTS

The test device contains recombinant HCV antigen coated particles and another recombinant HCV antigen coated on the membrane.

PRECAUTIONS

- Proper storage condition is critical to product performance, the kit should be stored at 2-30°C.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection before the test. Handle all specimens and controls as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing. Standard personal hygiene measures should be taken in the case of ingestion or direct eye contact with the buffer. If the buffer comes into contact with the eyes or skin, wash affected area immediately, and seek medical attention if necessary.
- Bystanders may be contaminated with the biological material and sample in the testing process, so stay away from bystanders.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- For professional *in vitro* diagnostic use only, do not use the test device if the expiration date on the foil pouch has passed, and do not use the buffer if the expiration date on the buffer bottle has passed.
- Do not use the test if pouch is damaged. Do not use the test device if the desiccant shows green when the pouch is opened.
- Do not eat the desiccant from the foil pouch. Do not drink the buffer which contains phosphate and 0.09% sodium azide. Dispose the used buffer according to standard procedures and local regulations. If unused assay buffer is discarded in a sink, it must be well rinsed with a copious quantity of water.
- Avoid touching a finger directly to the specimen pad, membrane or result window of the test as this can cause incorrect results.
- Each device is for single use only. Do not reuse the device.
- Humidity and temperature can adversely affect results. Test the product in the prescribed environmental condition (15-30°C). Once the foil pouch is opened, use the product as soon as possible.
- Do not mix or interchange components among different lots or those for other product.
- It is essential to use correct anticoagulant. Use EDTA-K_2/EDTA-K_3/Sodium citrate/Sodium heparin/Lithium heparin as anticoagulant to collect plasma for testing, while whole blood samples should only use EDTA-K_2/EDTA-K_3/Sodium citrate as anticoagulant.
- The instruction must be followed exactly to achieve accurate results. Read the results in the required time (10-20 min).
- Follow standard procedures and local regulations for proper disposal of specimens, controls, used test, buffer, dropper, foil pouch and desiccant.
- Repeat the test or use plasma sample if the whole blood sample doesn't migrate well. If the plasma sample still doesn't migrate well, stop using the test kit immediately and contact your local distributor.

STORAGE AND STABILITY

The kit can be stored at 2-30°C. The test device is stable before the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) can be performed using either serum or plasma or whole blood (for venipuncture or fingerstick).
- To collect **Serum or Plasma or Venipuncture Whole Blood** specimens:
  - Collect according to safe phlebotomy procedures, using vacuum tubes for serum or plasma or venipuncture whole blood preparation.
  - Prepare serum or plasma from whole blood as soon as possible to avoid hemolysis. Don't use turbid or haemolysed specimens.
- To collect **Fingerstick Whole Blood** specimens (see illustration on the reverse side):
  - Clean entire fingertip (prefer middle or ring finger) with alcohol prep pads. Allow to dry (30 seconds).
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood at the puncture site.
  - Add the fingerstick whole blood specimen to the test device by using a specimen dropper for Fingerstick Whole Blood:
    - Hold the specimen dropper for Fingerstick Whole Blood. DO NOT TOUCH OR SQUEEZE BULB.
    - Immerse the open end of the specimen dropper into the blood drop and allow for the blood to draw into the specimen dropper up to marked line. Avoid air bubbles.
    - Squeeze bulb by covering the 2 air holes on it to dispense all whole blood onto the specimen well (S) of the test device for testing. Keep pressure on bulb while moving dropper away (avoid back suction). Then add 1 drop of buffer vertically (approximately 30µL) into the specimen well (S) and start the timer.
- Separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum or plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept at -30 ~ -10°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 1 day of collection. Whole blood collected by fingerstick should be tested immediately. Do not freeze whole blood specimens.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing.
- No qualitative performance difference was observed between 11 non-reactive and 11 reactive specimens subjected to 3 freeze/thaw cycles; however, multiple freeze/thaw cycles should be avoided.
- If specimens are to be shipped, they should be packed in compliance with federal/country regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

Components	IHC-402WC	IHC-402WD
1. Test Device	x40	x25
2. Specimen Dropper for Serum/Plasma/Venipuncture Whole Blood	x40	x25
3. 3mL Buffer (Phosphate buffer 0.2M pH7.4 and sodium azide 0.09%)	x2	x1
4. Alcohol Prep Pads	x40	x25
5. Single-use Lancet	x40	x25
6. Specimen Dropper for Fingerstick Whole Blood	x40	x25
7. Instructions for Use	x1	x1

Materials Required But Not Provided

- Specimen collection equipment and containers
- Cotton wool or gauze pad (for fingerstick whole blood only)
- Biohazard waste containers for sharps and non sharps
- Centrifuge (for plasma only)
- Timer

DIRECTIONS FOR USE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Transfer the specimen to the sample well.
   For **Serum/Plasma/Venipuncture Whole Blood** sample
   Transfer the specimen by a pipette or a dropper for Serum/Plasma/Venipuncture Whole Blood:
   - To use a **Pipette**: Transfer 50 µL of serum or plasma or venipuncture whole blood to the specimen well (S) of the test device, then add 1 full drop of buffer vertically (approximately 30 µL) and start the timer. Avoid trapping air bubbles in the specimen well (S).
   - To use a **Disposable Specimen Dropper for Serum/Plasma/Venipuncture Whole Blood**: Hold the dropper vertically, draw serum or plasma or venipuncture whole blood specimen. Transfer 2 full drops of the specimen vertically (approximately 50 µL) to the specimen well (S) of the test device, then add 1 full drop of buffer vertically (approximately 30 µL) and start the timer. Avoid trapping air bubbles in the specimen well (S).

   For **Fingerstick Whole Blood** sample
   - To use a **Specimen dropper for Fingerstick Whole Blood:** Fill the specimen dropper for Fingerstick Whole Blood , transfer approximately 50µL of fingerstick whole blood specimen to the specimen well (S) of the test device, then add 1 drop of buffer vertically (approximately 30µL) into the specimen well (S) and start the timer.
3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

REACTIVE: Two distinct colored lines appear*. One line should be in the control region (C) and another line should be in the test region (T).
***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of HCV antibody present in the specimen. Therefore, any shade of color in the test region should be considered reactive.
NON-REACTIVE: One colored line appears in the control region (C). No colored line appears in the test region (T).
INVALID: No line appears in the control line region (C). If this occurs, read the directions again and repeat the test with a new test. If the result is still invalid, stop using the test kit immediately and contact your local distributor.
(see illustration on the reverse side)

QUALITY CONTROL

A procedural control is built inside the test device. A colored line appears in the control region (C) is considered an internal positive procedural control, and indicates a valid test result.
Specimen addition controls are not included along the kit, however, it is recommended to test positive and negative specimen controls as a good laboratory practice to confirm the right operation procedure and to verify proper test performance of the test device.

LIMITATION

1. The HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibody to HCV in serum or plasma or whole blood specimen.
2. The HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) will only indicate the presence of antibody to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is non-reactive and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A non-reactive result at any time does not preclude the possibility of Hepatitis C Virus infection.
5. Intravenous ascorbic acid (IAA) therapy may cause a false reactive result. Ascorbic acid concentrations up to 0.2mg/mL in serum or plasma or whole blood did not impact the results.
6. For HCV negative samples of multiple blood transfusion recipients, there is the risk of a weak reactive result for some individual specimens.

EXPECTED VALUES

The HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) has been compared with leading commercial HCV product. The correlation between these two systems is 99.95% (95%CI:99.73%-99.99%).

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity & Specificity

A total of 520 HCV positive serum/plasma/whole blood specimens and 1600 negative serum/plasma/whole blood specimens were tested using the HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma) and other commercial available reference tests. The results gave diagnostic sensitivity of 99.81 % (95%CI: 98.92%-99.97%) and diagnostic specificity of 100% (95%CI:99.76%-100%).

			HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma)		Total results
			Reactive	Non-reactive	
Reference assay	Reactive	Serum/plasma	419*	1	520*
		Whole Blood	100*	0	
		Finger stick whole blood	100	0	
	Non-reactive	Serum/plasma	0	1000	1600
		Whole Blood	0	500	
		Finger stick whole blood	0	100	
Diagnostic Sensitivity (95 %CI)			519/520 99.81% (95%CI: 98.92%-99.97%)		
Diagnostic Specificity (95 %CI)			1600/1600 100% (95%CI:99.76%-100%)		

Note: "*" 100 positive paired whole blood and plasma samples were evaluated, but calculated only once for the diagnostic sensitivity.

Whole Blood vs. Serum vs. Plasma

1. Serum/Plasma equivalence
   25 negative for Anti-HCV Ab serum samples, sodium heparin plasma samples, Lithium heparin plasma samples, EDTA-K_2 plasma samples, EDTA-K_3 plasma samples, sodium citrate plasma samples and 25 Anti-HCV Ab positive serum samples, sodium heparin plasma samples, Lithium heparin plasma samples, EDTA-K_2 plasma samples, EDTA-K_3 plasma samples, sodium citrate plasma samples were tested in parallel with the HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma).

Sample type	No. of reactive/No. of positive sample	No. of non-reactive/No. of negative sample
Serum	25/25	25/25
Sodium heparin plasma	25/25	25/25
Lithium heparin plasma	25/25	25/25
EDTA-K_2 plasma	25/25	25/25
EDTA-K_3 plasma	25/25	25/25
Sodium citrate plasma	25/25	25/25

Paired serum, plasma specimens show the equivalent results with the HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma).

2. Whole blood / plasma equivalence
   From 100 HCV infected patients whole blood samples (matrix EDTA-K_2) as well as an EDTA-K_2 plasma samples were collected at the same time and were tested by the HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma). All samples obtained reactive test results.

Tested	EDTA-K_2 Whole blood	EDTA-K_2 plasma
	100	100
Non-reactive test results	0	0
Reactive test results	100	100

Paired whole blood, plasma specimens show the equivalent results with the HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma).

Precision

Precision of the HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) has been demonstrated by day-to-day, inter-assay, intra-assay using in-house reference samples. All values were identical to acceptable criteria.

Cross reactivity

No cross-reactivity was observed in potentially cross reactive samples including: HIV antibody positive specimens, HTLV I/II antibody positive specimens, Syphilis antibody positive specimens, Hepatitis A antibody positive specimens, Hepatitis B surface antigen positive specimens, Hepatitis B surface antibody positive specimens, Hepatitis B e antigen positive specimens, Hepatitis B e antibody positive specimens, Hepatitis B core antibody positive specimens, Hepatitis E antibody positive specimens, Jaundice specimens, ALT positive specimens, Human anti-mouse antibody (HAMA) positive specimens, Anti-nuclear antibody (ANA) positive specimens, Rheumatoid factor positive specimens, Hyperlipidemia specimens, HCG positive specimens, Haemolytic panel specimens, H. pylori antibody positive specimens, TB antibody positive specimens, Cytomegalovirus antibody positive specimens, Epstein-Barr virus antibody positive specimens, Herpes simplex virus 1 antibody positive specimens, Varicella zoster virus antibody positive specimens, Toxo antibody positive specimens, Chlamydia trachomatis positive specimens, Leishmaniasis antibody positive specimens, Malaria antibody positive specimens, Trypanosomiasis antibody (Human African trypanosomiasis) positive specimens, Anti-Influenza A or anti-Influenza B antibody positive specimens, Anti-Escherichia coli antibody positive specimens, Elevated Immunoglobulin G (IgG) specimens, Elevated immunoglobulin M (IgM) specimens, AFP positive specimens, Carcinoembryonic (CEA) positive specimens, Post-immunization measle specimens , Influenza vaccine recipient specimens, Yellow fever virus post-immunization antibody specimens, Systemic Lupus Erythematosus (SLE) antibody specimens, Sickle-cell disease specimens, Rubella antibody positive specimens.

Interfering Substances

No interference was observed in samples with high concentrations of 0.2mg/mL Ascorbic acid, 0.2mg/mL Gentistic acid, 0.6mg/mL Oxalic acid, 0.6mg/mL Uric acid, 0.6mg/mL Salicylic acid, 0.2mg/mL Acetoacetic acid, 0.65mg/mL Acetylsalicylic acid (aspirin), 0.2mg/mL Caffeine, 1mg/mL Creatine, 1mg/mL Acetaminophen, 0.25mg/mL Cyclobenzaprine, 0.12mg/mL Metronidazole, 10mg/mL Hemoglobin, 50mg/mL Triglyceride, 0.25mg/mL Ibuprofen, 0.5mg/mL Naproxen, 60mg/mL Albumin, 0.6mg/mL Bilirubin, 1% Ethyl alcohol, 2% Methanol.

BIBLIOGRAPHY

1. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. *An assay for circulating antibodies to a major etiologic Virus of human non-A, non-B hepatitis.* Science 1989; 244:362-364.
2. Choo, Q.L., G. Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley, and M. Houghton. *Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome.* Science 1989; 244:359-362.
3. Van der Poel, C. L., H.T.M. Cuypers, H.W. Reesink, and P.N.Lelie. *Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunoblot assay.* Lancet 1991; 337:317-319.

Index of Symbols

	Consult instructions for use	Σ	Contains sufficient for <n> tests	REF	Catalogue number
LOT	Batch code		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C		Manufacturer	IVD	*In vitro* diagnostic medical device

Technical Support

Middle East
+965 2202 2828
EME.TechSupport@abbott.com

APAC (Asia-Pacific)
+61 7 3363 7711
AP.TechSupport@abbott.com

Africa
+27 10 500 9700 Option 3
arcis.techsupport@abbott.com

LATAM (Latin-America)
+57-601-4824033
LA.TechSupport@Abbott.com

Russia, and Commonwealth of Independent States (RCIS)
+7 499 403 9512
arcis.techsupport@abbott.com

Abon Biopharm (Hangzhou) Co., Ltd.
#198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R.China
www.globalpointofcare.abbott

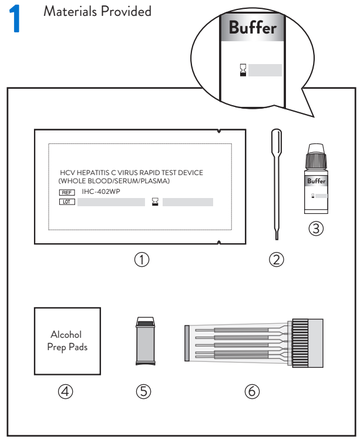
Abbott

ABON™

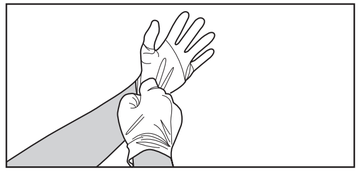
HCV HEPATITIS C VIRUS RAPID TEST DEVICE (WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

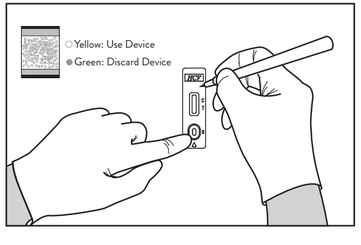
1 Materials Provided



2 Wear gloves

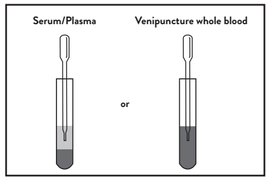


3 Open the pouch, do not use the test device if the desiccant shows green when the pouch is opened. Label with specimen ID. Use it as soon as possible (within one hour).

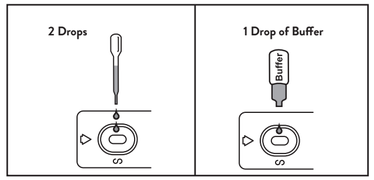


SERUM OR PLASMA OR VENIPUNCTURE WHOLE BLOOD SPECIMENS

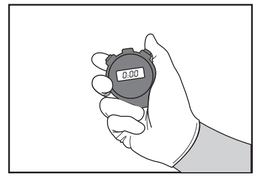
4 Draw the specimen from the tube with a specimen dropper for Serum/Plasma/Venipuncture Whole Blood.



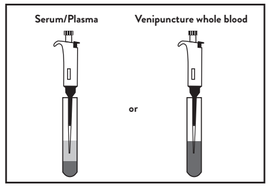
5 Transfer 2 drops of serum or plasma or venipuncture whole blood with specimen dropper for Serum/Plasma/Venipuncture Whole Blood vertically (approximately 50 µL), then add 1 drop of buffer vertically (approximately 30 µL).



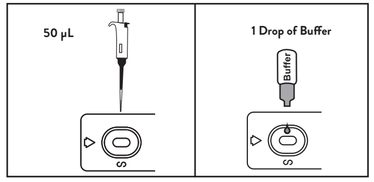
6 Start the timer.



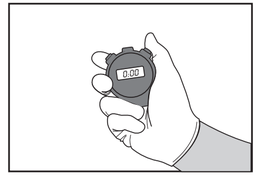
4 Draw the specimen from the specimen tube with a pipette.



5 Transfer 50 µL serum or plasma or venipuncture whole blood with specimen pipette, then add 1 drop of buffer vertically (approximately 30 µL).

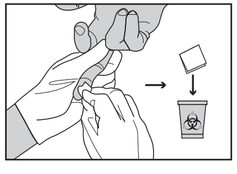


6 Start the timer.

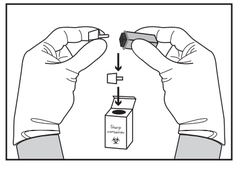


FINGERSTICK WHOLE BLOOD SPECIMENS

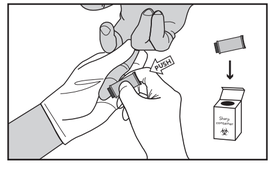
4 Clean entire fingertip (prefer middle or ring finger from non-dominant hand) with alcohol prep pads.
Dispose the alcohol prep pads.



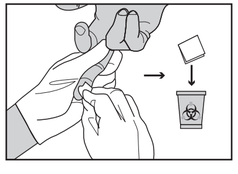
5 Take off the cap of the lancet and dispose the cap in sharps container.



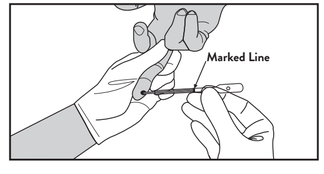
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



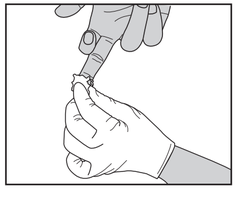
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



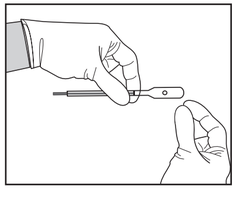
8 Hold the specimen dropper for Fingerstick Whole Blood. DO NOT TOUCH OR SQUEEZE BULB. Immerse the open end of the specimen dropper into the blood drop and allow for the blood to draw into the specimen dropper up to marked line.



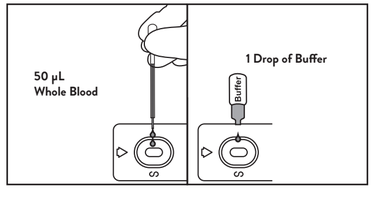
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



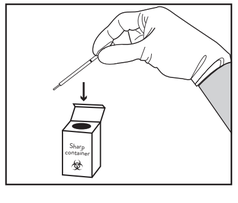
10 Cover the 2 air holes.



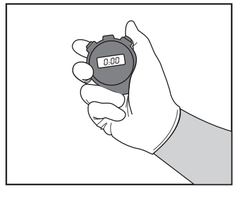
11 Squeeze bulb to dispense all whole blood onto the specimen well (approximately 50 µL). Keep pressure on bulb while moving dropper away (avoids back suction). Then add 1 drop of buffer into the specimen well (approximately 30 µL).



12 Dispose the specimen dropper for Fingerstick Whole Blood in sharps container after testing.

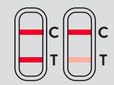


13 Start the timer.



READ RESULTS

Wait for the colored line(s) to appear.
Read results at **10-20 minutes**.



REACTIVE: Two distinct colored lines appear*. One line should be in the control region (C) and another line should be in the test region (T).

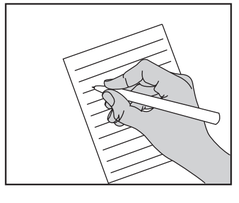
***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of HCV antibody present in the specimen. Therefore, any shade of color in the test region should be considered reactive.

NON-REACTIVE: One colored line appears in the control region (C). No colored line appears in the test region (T).

INVALID: No line appears in the control line region (C). If this occurs, read the directions again and repeat the test with a new test. If the result is still invalid, stop using the test kit immediately and contact your local distributor.

CLEAN UP/RECORD

Dispose devices and gloves in a proper biohazard waste container.



Record the test results.