**WHO Prequalification of In Vitro Diagnostics**

# PUBLIC ASSESSMENT 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 the 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 |
| **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 summarised in the following table, and details of each amendment are provided below.

| Version | Summary of the amendments | Date of report amendment |
|---|---|---|
| 2.0 | Closure of dossier commitment to prequalification. The manufacturer submitted the validation report, which was acceptable. | 14 March 2024 |
| 3.0 | 1. Labelling change for the lancet (PQC-IVD-2025-0036).<br>2. Add customized box artwork and IFU in Ukrainian for Ukraine:<br>i. Box for IHC-402WC: Add info on accessories and Ukraine authorized representative.<br>ii. Box label for IHC-402WA and IHC-402WC: (1) create standard box label for Ukraine based on English version, but update the UDI info; (2) add an additional customized box label in Ukrainian to include LM information and | 27 April 2026 |

| | | |
|---|---|---|
| | Ukraine authorized representative information.<br>iii. IFU for IHC-402WA and IHC-402WC translated to Ukrainian based on English version and add the Ukraine authorized representative information (PQC-IVD-2025-0115). | |

**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."*

**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 must be stored between 2 and 30 °C.

**Shelf-life upon manufacture**[1]

24 months.

## 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 March 2023.

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.

[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.

## 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

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 %<br>(N=163) | 100% (95% CI: 97.7% - 100%) |
| Specificity %<br>(N= 320) | 100% (95% CI: 98.8% - 100%) |
| Invalid rate %<br>(N= 483) | 0% |
| 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 (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<br>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 review

The labelling submitted for the HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) 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**

IHC-402WA

| Document Type | Document Title | Version / Revision | Date Approved | Controlled Document No. |
|---|---|---|---|---|
| Outer box artwork | (WHO)ABT ABON HCV 40T box(25T big) | 01 | 2024/1/17 | 1135929801 |
| Box label | (WHO)ABT ABON Non-CE IHC-402WA (40T) box label ink printing (GS1 2D barcode) | 01 | 2024/1/17 | NB00025-01 |
| Pouch artwork | (WHO)ABT ABON ID device pouch | 01 | 2023/6/2 | 1125907001 |
| Pouch label | (WHO)ABT ABON IHC-402WP pouch ink jetting | 01 | 2024/1/17 | NP00006-01 |
| Buffer label | (WHO)ABT ABON HCV Buffer label ink printing | 01 | 2024/1/17 | NB00026-01 |
| Sterile safety lancets, single-use | N/A | N/A | N/A | N/A |
| Specimen Dropper for Fingerstick Whole Blood | N/A | N/A | N/A | N/A |
| Specimen dropper (For Serum/Plasma/Venipuncture | Packaging Specification of | N/A | N/A | TC-0930 |

| | | | | |
|---|---|---|---|---|
| Whole Blood) | Pouched Dropper | | | |
| Instructions for Use (IFU) | ABT WHO ABON IHC-402WA&WB English PI | 04 | 2024/1/17 | 1156214401 |

IHC-402WB

| **Document Type** | **Document Title** | **Version / Revision** | **Date Approved** | **Controlled Document No.** |
|---|---|---|---|---|
| Outer box artwork | (WHO)ABT ABON HCV 25T box | 01 | 2024/1/17 | 1135929701 |
| Box label | (WHO)ABT ABON Non-CE IHC-402WB (25T) box label ink printing | 01 | 2024/1/17 | NB00028-01 |
| Pouch artwork | (WHO)ABT ABON ID device pouch | 01 | 2023/6/2 | 1125907001 |
| Pouch label | (WHO)ABT ABON IHC-402WP pouch ink jetting | 01 | 2024/1/17 | NP00006-01 |
| Buffer label | (WHO)ABT ABON HCV Buffer label ink printing | 01 | 2024/1/17 | NB00026-01 |
| Sterile safety lancets, single-use | N/A | N/A | N/A | N/A |
| Specimen Dropper for Fingerstick Whole Blood | N/A | N/A | N/A | N/A |
| Specimen dropper (For Serum/Plasma/Venipuncture Whole Blood) | Packaging Specification of Pouched Dropper | N/A | N/A | TC-0930 |
| IFU | ABT WHO ABON IHC-402WA&WB English PI | 04 | 2024/1/17 | 1156214401 |

IHC-402WC

| Document Type | Document Title | Version / Revision | Date Approved | Controlled Document No. |
|---|---|---|---|---|
| Outer box artwork | (WHO)ABT ABON HCV 40T box(big) | 01 | 2024/1/17 | 1135929901 |
| Box label | (WHO)ABT ABON Non-CE IHC-402WC (40T) box label ink printing | 01 | 2024/1/17 | NB00030-01 |
| Pouch artwork | (WHO)ABT ABON ID device pouch | 01 | 2023/6/2 | 1125907001 |
| Pouch label | (WHO)ABT ABON IHC-402WP pouch ink jetting | 01 | 2024/1/17 | NP00006-01 |
| Buffer label | (WHO)ABT ABON HCV Buffer label ink printing | 01 | 2024/1/17 | NB00026-01 |
| Sterile safety lancets, single-use | Specification of Single-use Lancet | N/A | N/A | TC-0884 |
| Specimen Dropper for Fingerstick Whole Blood | Specification of Plastic Wrapped Glass Capillary Tube | N/A | N/A | TC-0944 |
| Specimen dropper (For Serum/Plasma/Venipuncture Whole Blood) | Packaging Specification of Pouched Dropper | N/A | N/A | TC-0930 |
| IFU | ABT WHO ABON IHC-402WC&WD English PI | 03 | 2024/1/17 | 1156214501 |

IHC-402WD

| Document Type | Document Title | Version / Revision | Date Approved | Controlled Document No. |
|---|---|---|---|---|
| Outer box artwork | (WHO)ABT ABON HCV 40T box(25T big) | 01 | 2024/1/17 | 1135929801 |
| Box label | (WHO)ABT ABON Non-CE IHC-402WD (25T) box label ink printing | 01 | 2024/1/17 | NB00032-01 |
| Pouch artwork | (WHO)ABT ABON ID device pouch | 01 | 2023/6/2 | 1125907001 |
| Pouch label | (WHO)ABT ABON IHC-402WP pouch ink jetting | 01 | 2024/1/17 | NP00006-01 |
| Buffer label | (WHO)ABT ABON HCV Buffer label ink printing | 01 | 2024/1/17 | NB00026-01 |
| Sterile safety lancets, single-use | Specification of Single-use Lancet | N/A | N/A | TC-0884 |
| Specimen Dropper (10T) for Fingerstick Whole Blood | Specification of Plastic Wrapped Glass Capillary Tube | N/A | N/A | TC-0944 |
| Specimen Dropper (5T) for Fingerstick Whole Blood | Specification of Plastic Wrapped Glass Capillary Tube | N/A | N/A | TC-0944 |
| Specimen dropper (For Serum/Plasma/Venipuncture Whole Blood) | Packaging Specification of Pouched Dropper | N/A | N/A | TC-0930 |
| IFU | ABT WHO ABON IHC-402WC&WD English PI | 03 | 2024/1/17 | 1156214501 |

## Labelling

1.1 box artwork

IHC-402WA and IHC-402WD (code: 1135929801)

2°C 30°C



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

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Development Area, Hangzhou, 310018, P.R.China
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2°C 30°C IVD

2°C 30°C IVD

IHC-402WB (code: 1135929701)

Pantone 2925 C

Pantone 303 C

Pantone 285 C

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# HCV HEPATITIS C VIRUS RAPID TEST DEVICE

(WHOLE BLOOD/SERUM/PLASMA)

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## HCV HEPATITIS C VIRUS RAPID TEST DEVICE

(WHOLE BLOOD/SERUM/PLASMA)

2°C 30°C IVD

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HCV HEPATITIS C VIRUS RAPID TEST DEVICE

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2°C 30°C IVD

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(WHOLE BLOOD/SERUM/PLASMA)

IHC-402WC (code: 1135929901)

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

Pantone 2925 C
Pantone 303 C
Pantone 285 C

| | | | |
|---|---|---|---|
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| | | | |
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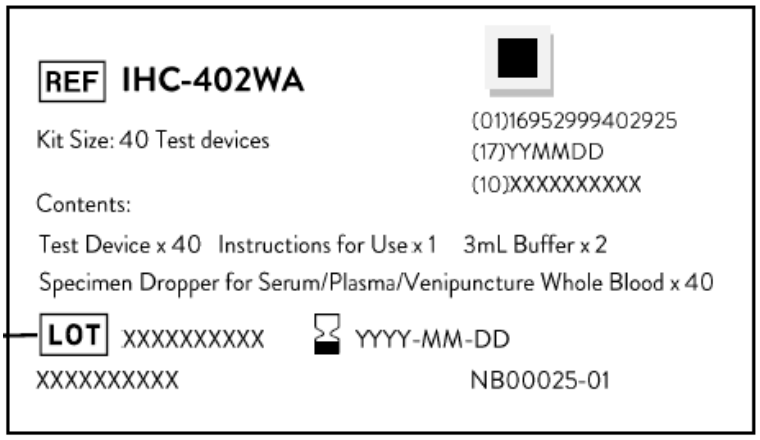
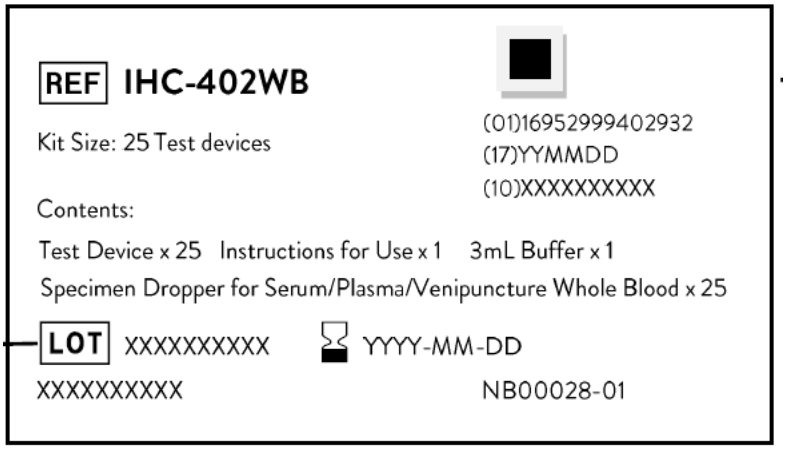
| | | | |

1.2 box label

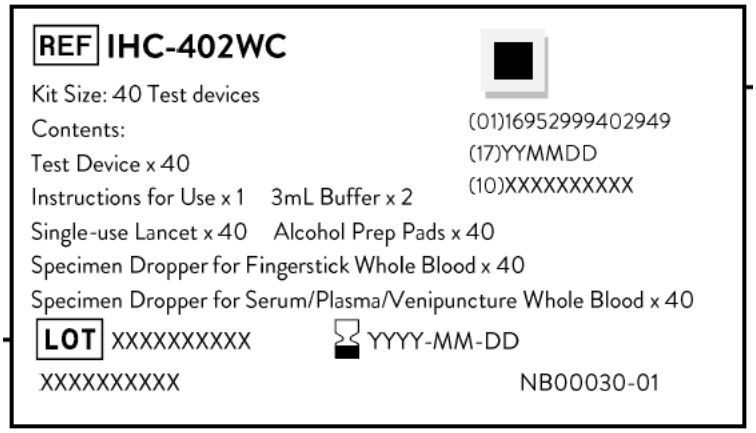
IHC-402WA



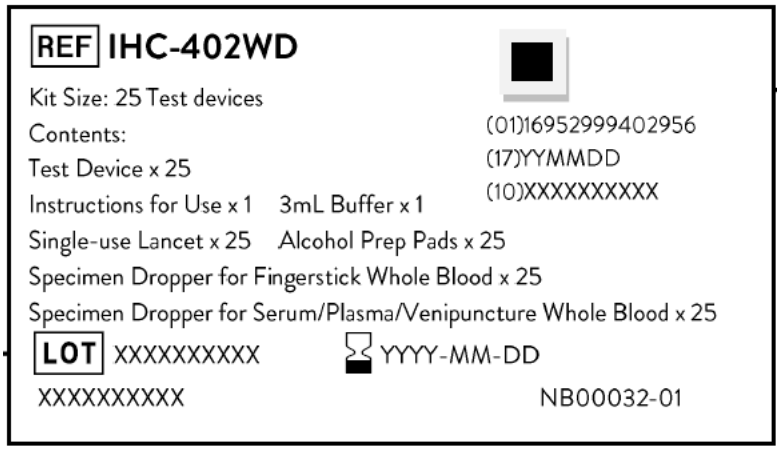

IHC-402WB




IHC-402WC

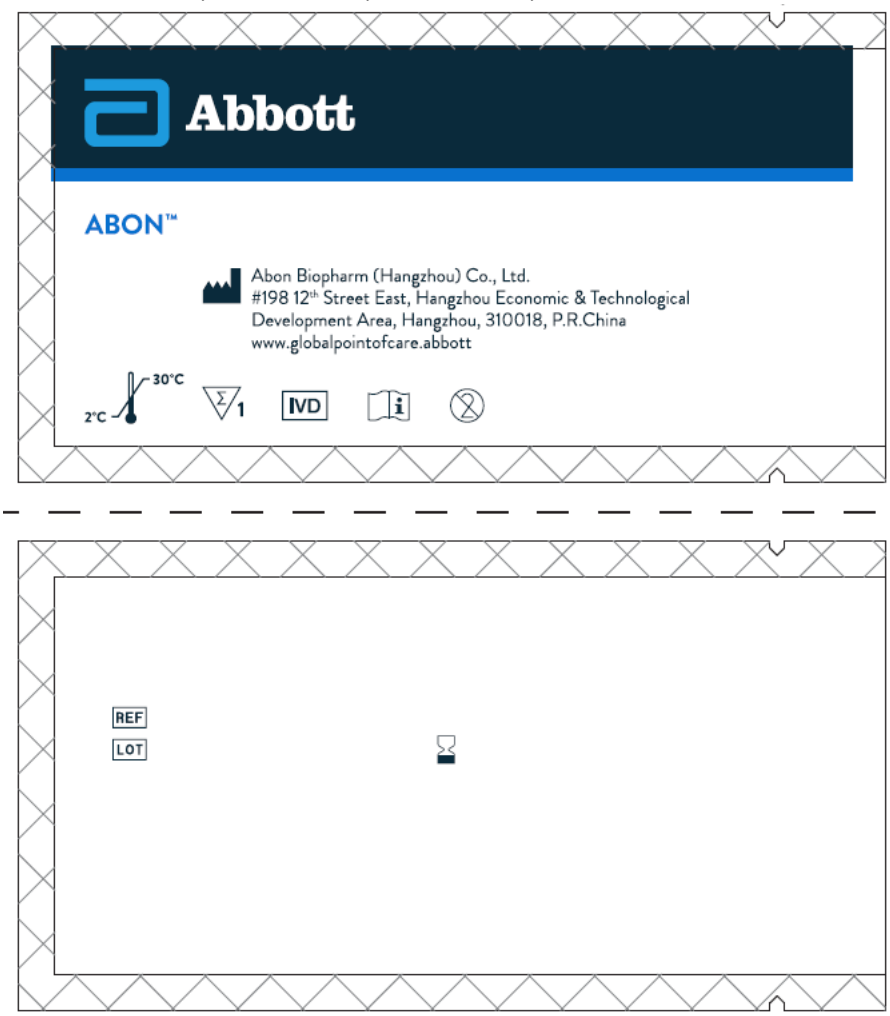


IHC-402WD



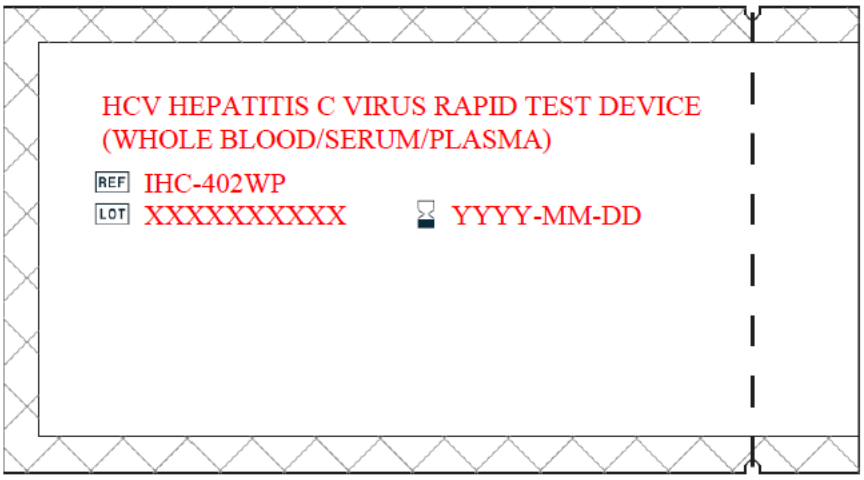

1.3 Pouch artwork

IHC-402WA, IHC-402WB, IHC-402WC, IHC-402WD

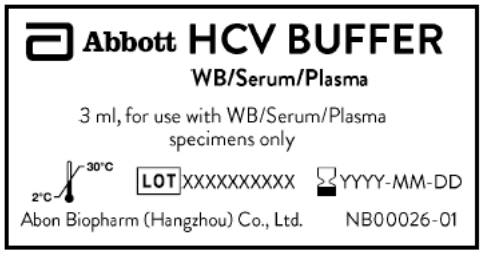


1.4 Pouch label

IHC-402WA, IHC-402WB, IHC-402WC, IHC-402WD

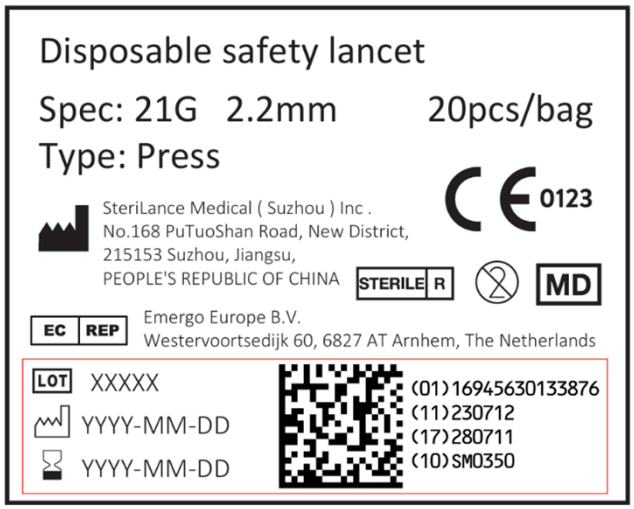



1.5 Buffer label

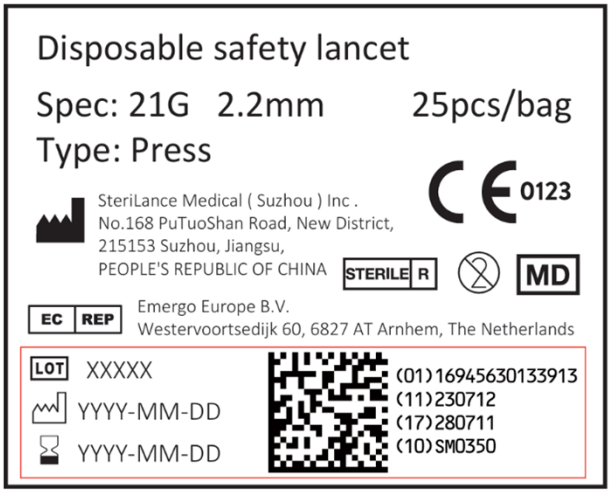



1.6 Lancet

IHC-402WC (code: 40007468)

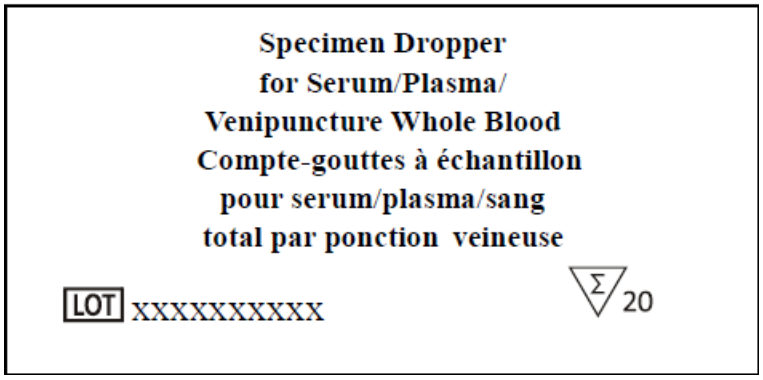


IHC-402WD (code: 40007469)

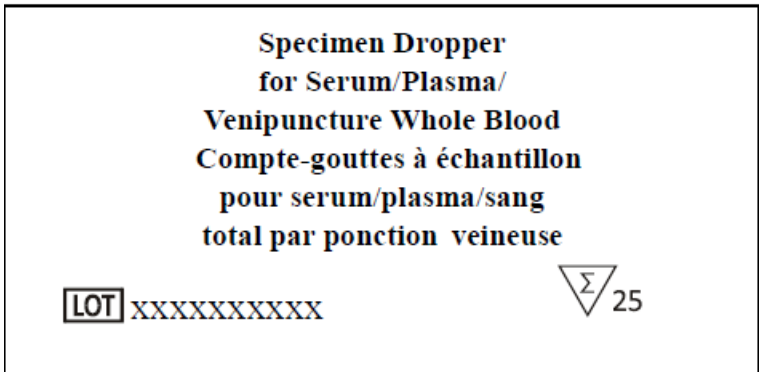



1.7 Specimen dropper (For Serum/Plasma/Venipuncture Whole Blood)

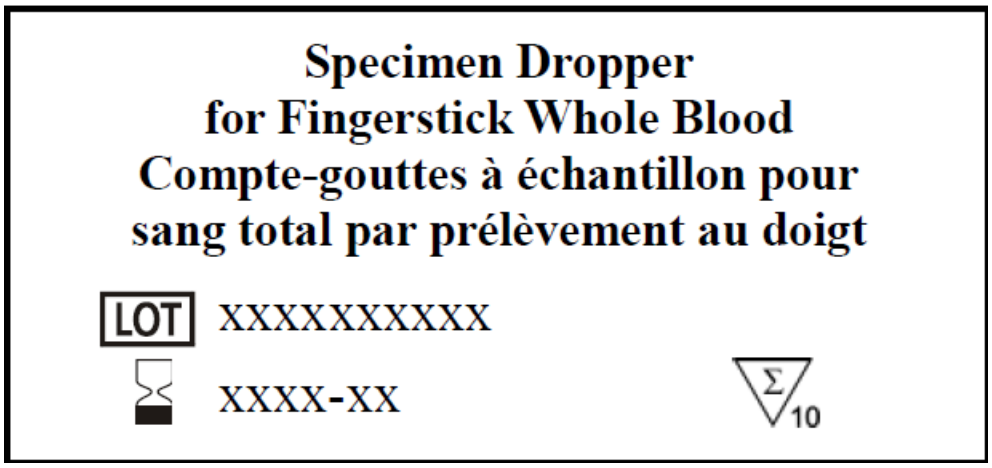
IHC-402WA, IHC-402WC (code: 1115809601)



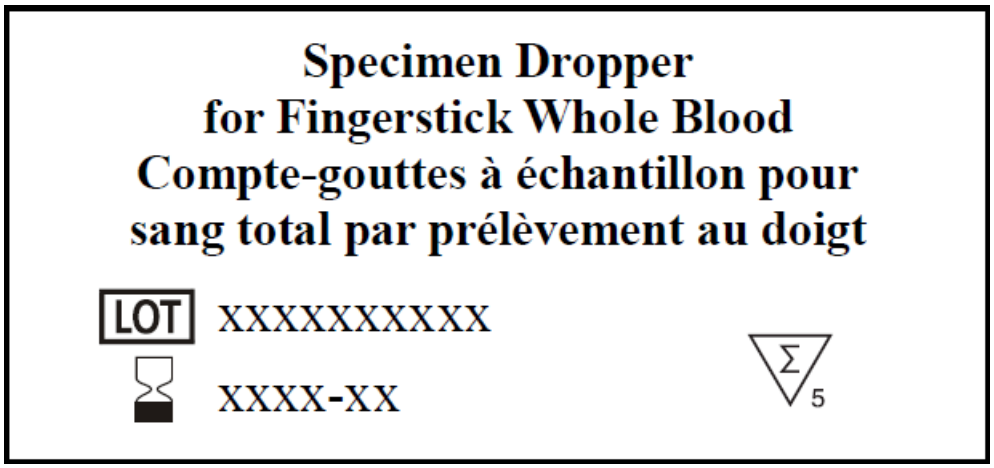

IHC-402WB, IHC-402WD (code: 1115809701)



1.8 Specimen Dropper for Fingerstick Whole Blood
IHC-402WC, IHC-402WD (code: 1115807302)




IHC-402WD (code: 1115809501)




**2.0 Instructions for Use[2]**

[2] 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.

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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 | | 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 |

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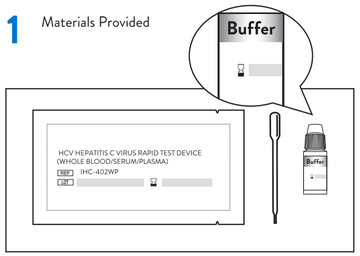
Abbott

ABON™

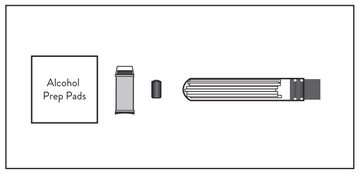
# HCV HEPATITIS C VIRUS RAPID TEST DEVICE (WHOLE BLOOD/SERUM/PLASMA)

## PREPARATION

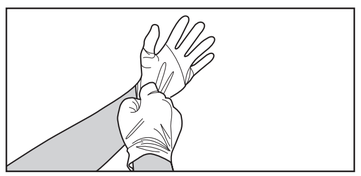
**1** Materials Provided



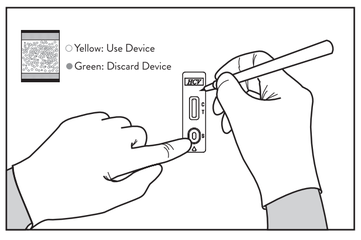

Materials Required But Not Provided




**2** Wear gloves

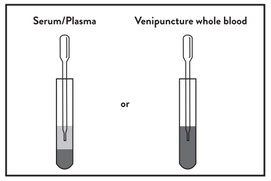


**3** Open the pouch, do not use the test device if the desiccant shows green when the pouch is opened. Label with specimen ID. Use it as soon as possible (within one hour).

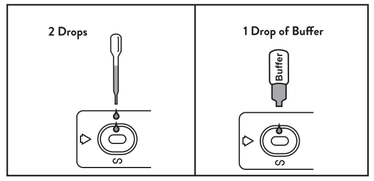



## SERUM OR PLASMA OR VENIPUNCTURE WHOLE BLOOD SPECIMENS

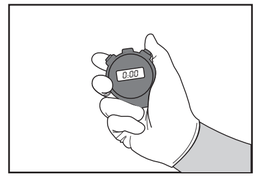
**4** Draw the specimen from the specimen tube with a dropper.



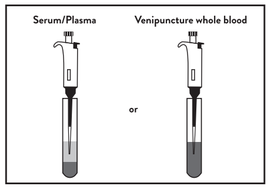

**5** Transfer 2 drops of serum or plasma or venipuncture whole blood with specimen dropper vertically (approximately 50 µL), then add 1 drop of buffer vertically (approximately 30 µL).



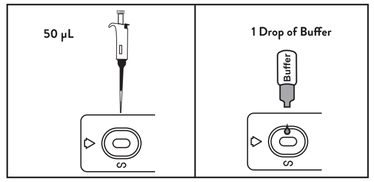

**6** Start the timer.



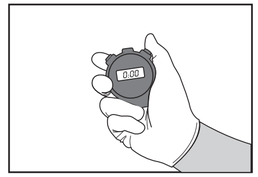

**4** Draw the specimen from the specimen tube with a pipette.




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

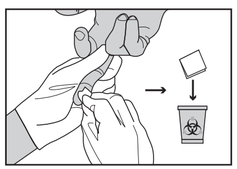



**6** Start the timer.

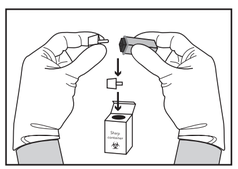



## FINGERSTICK WHOLE BLOOD SPECIMENS

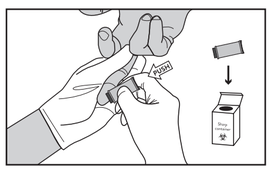
**4** Clean entire fingertip (prefer middle or ring finger from non-dominant hand) with alcohol prep pads. Dispose the alcohol prep pads.



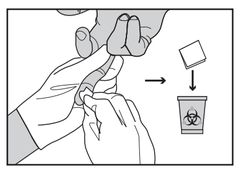
**5** Take off the cap of the lancet and dispose the cap in sharps container.



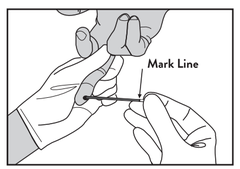
**6** Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



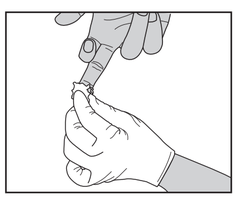

**7** Wipe away the first blood drop with a sterile gauze pad or cotton wool.



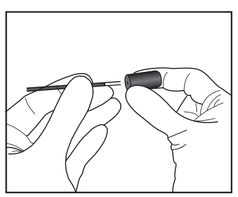
**8** Immerse the open end of the capillary tube into the blood drop and allow for the blood to draw into the capillary tube up to mark line.



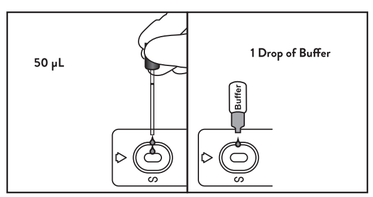

**9** After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



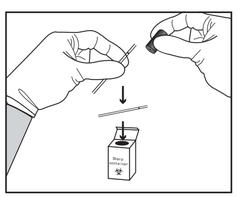
**10** Place the bulb onto the top end of the capillary tube.



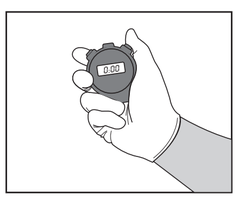
**11** Squeeze the bulb to dispense all whole blood on the specimen well (approximately 50 µL) , then add 1 drop of buffer vertically (approximately 30 µL).




**12** Dispose the capillary tube in sharps container after testing.

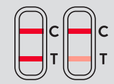


**13** Start the timer.




## 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).

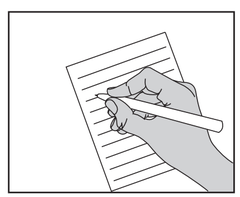
***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of HCV antibody present in the specimen. Therefore, any shade of color in the test region should be considered reactive.


**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.

Pantone 2925C

Pantone 285C

Pantone 285C 40%

Pantone 185C

Pantone 185C 50%

Black

Black 0-100%

美国以外的国际区域 OUS

美国 US

内销 China

| | | | |
|---|---|---|---|
| 描述<br>**Description** | ABT WHO ABON<br>IHC-402WA&WB English PI | 物料号<br>**Part Number** | 1156214401 |
| 打码号<br>**Ink jetting/ Ink printing No.** | N/A | 尺寸<br>**Size** | 580x360mm |
| 设计者/<br>日期/版本<br>**Designer/ Date/ Version** | Delia Xia<br>Oct. 08, 2023/H | 复核者/日期<br>**Reviewer/ Date** | Huiying Yi |
| 材质<br>**Material** | 70g双胶 | 折法<br>**Folding Method** | 折法32 |
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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 | | 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 |

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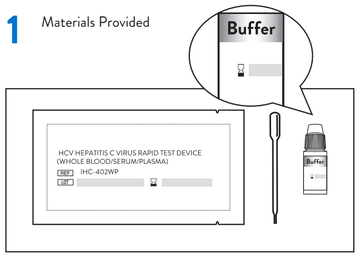
ABON™

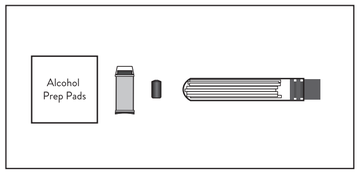
# HCV HEPATITIS C VIRUS RAPID TEST DEVICE (WHOLE BLOOD/SERUM/PLASMA)

## PREPARATION

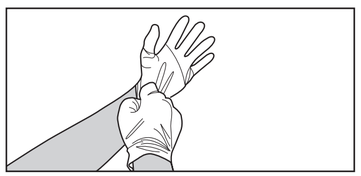
**1** Materials Provided



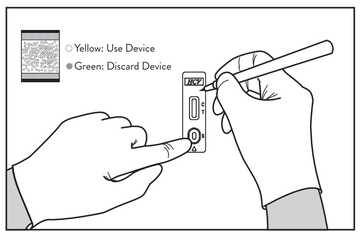

Materials Required But Not Provided




**2** Wear gloves

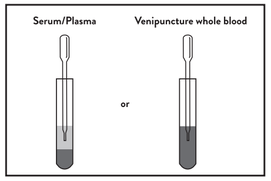


**3** Open the pouch, do not use the test device if the desiccant shows green when the pouch is opened. Label with specimen ID. Use it as soon as possible (within one hour).

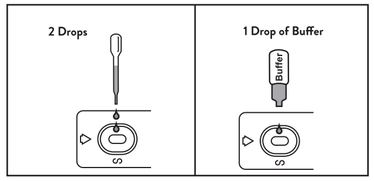



## SERUM OR PLASMA OR VENIPUNCTURE WHOLE BLOOD SPECIMENS

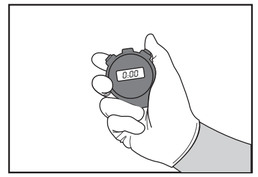
**4** Draw the specimen from the specimen tube with a dropper.



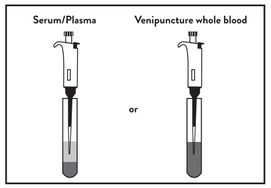

**5** Transfer 2 drops of serum or plasma or venipuncture whole blood with specimen dropper vertically (approximately 50 µL), then add 1 drop of buffer vertically (approximately 30 µL).



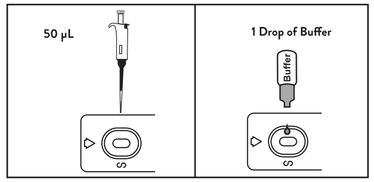

**6** Start the timer.



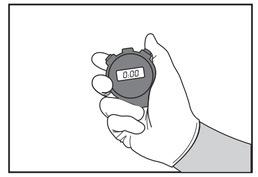

**4** Draw the specimen from the specimen tube with a pipette.




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

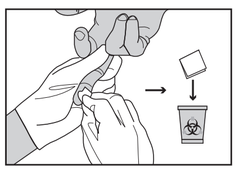



**6** Start the timer.

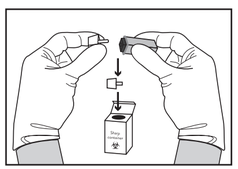



## FINGERSTICK WHOLE BLOOD SPECIMENS

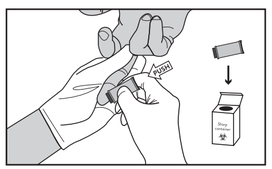
**4** Clean entire fingertip (prefer middle or ring finger from non-dominant hand) with alcohol prep pads. Dispose the alcohol prep pads.



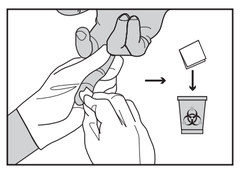
**5** Take off the cap of the lancet and dispose the cap in sharps container.



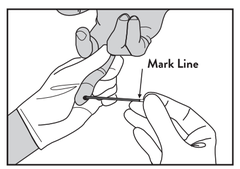
**6** Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



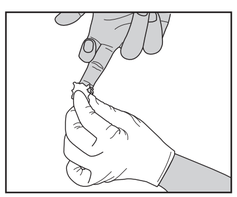

**7** Wipe away the first blood drop with a sterile gauze pad or cotton wool.



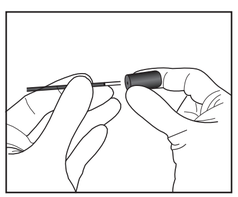
**8** Immerse the open end of the capillary tube into the blood drop and allow for the blood to draw into the capillary tube up to mark line.



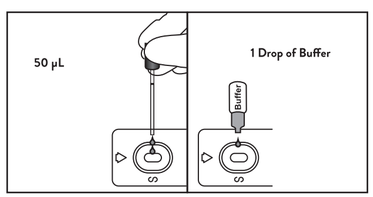

**9** After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



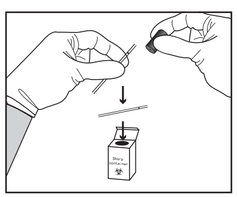
**10** Place the bulb onto the top end of the capillary tube.



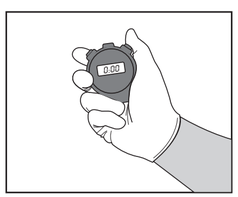
**11** Squeeze the bulb to dispense all whole blood on the specimen well (approximately 50 µL) , then add 1 drop of buffer vertically (approximately 30 µL).




**12** Dispose the capillary tube in sharps container after testing.

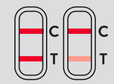


**13** Start the timer.




## 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).

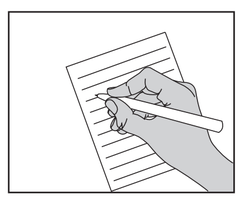
***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of HCV antibody present in the specimen. Therefore, any shade of color in the test region should be considered reactive.


**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.

Pantone 2925C

Pantone 285C

Pantone 285C 40%

Pantone 185C

Pantone 185C 50%

Black

Black 0-100%

美国以外的国际区域 OUS

美国 US

内销 China

| | | | |
|---|---|---|---|
| 描述<br>**Description** | ABT WHO ABON<br>IHC-402WA&WB English PI | 物料号<br>**Part Number** | 1156214401 |
| 打码号<br>**Ink jetting/ Ink printing No.** | N/A | 尺寸<br>**Size** | 580x360mm |
| 设计者/<br>日期/版本<br>**Designer/ Date/ Version** | Delia Xia<br>Oct. 08, 2023/H | 复核者/日期<br>**Reviewer/ Date** | Huiying Yi |
| 材质<br>**Material** | 70g双胶 | 折法<br>**Folding Method** | 折法32 |
| 模具号<br>**Mold Number** | N/A | 尺寸/材质/折法/模具号<br>审核/日期<br>**Size/Material/Folding Method/Mold Number checked by/ Date** | Robot Wang |

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<br>99.81% (95%CI: 98.92%-99.97%) | | |
| Diagnostic Specificity (95 %CI) | | | 1600/1600<br>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 |

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www.globalpointofcare.abbott

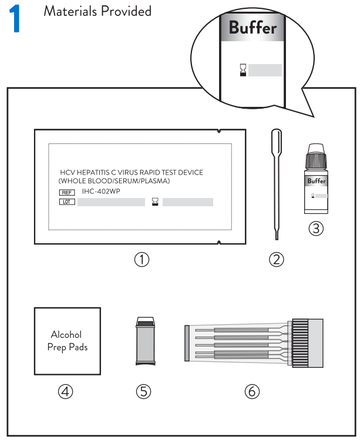
Abbott

ABON™

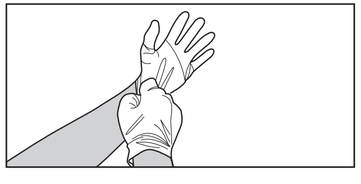
# HCV HEPATITIS C VIRUS RAPID TEST DEVICE (WHOLE BLOOD/SERUM/PLASMA)

## PREPARATION

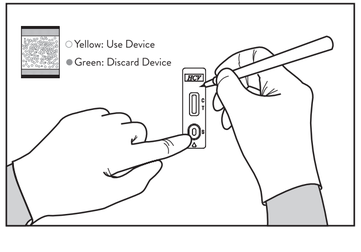
**1** Materials Provided




**2** Wear gloves

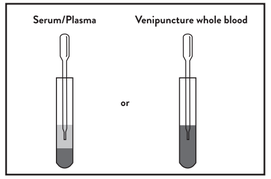


**3** Open the pouch, do not use the test device if the desiccant shows green when the pouch is opened. Label with specimen ID. Use it as soon as possible (within one hour).

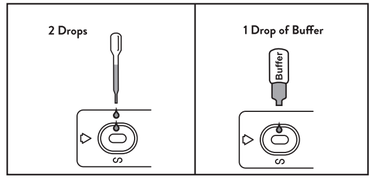



## SERUM OR PLASMA OR VENIPUNCTURE WHOLE BLOOD SPECIMENS

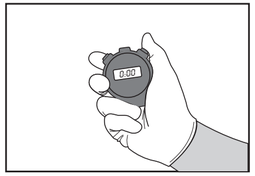
**4** Draw the specimen from the tube with a specimen dropper for Serum/Plasma/Venipuncture Whole Blood.



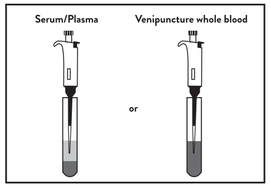

**5** Transfer 2 drops of serum or plasma or venipuncture whole blood with specimen dropper for Serum/Plasma/Venipuncture Whole Blood vertically (approximately 50 µL), then add 1 drop of buffer vertically (approximately 30 µL).



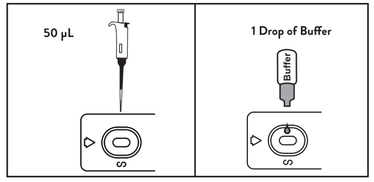

**6** Start the timer.



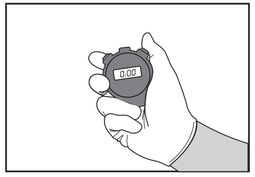

**4** Draw the specimen from the specimen tube with a pipette.




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

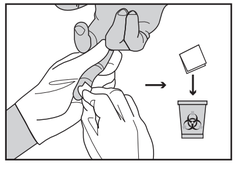



**6** Start the timer.

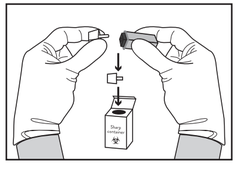



## FINGERSTICK WHOLE BLOOD SPECIMENS

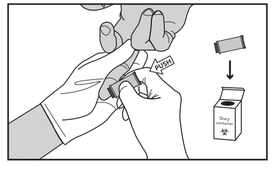
**4** Clean entire fingertip (prefer middle or ring finger from non-dominant hand) with alcohol prep pads.
Dispose the alcohol prep pads.



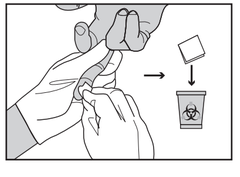
**5** Take off the cap of the lancet and dispose the cap in sharps container.



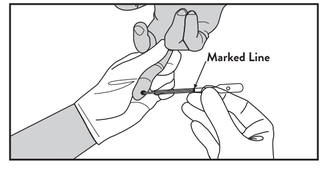

**6** Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



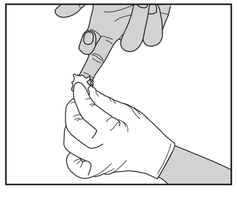

**7** Wipe away the first blood drop with a sterile gauze pad or cotton wool.



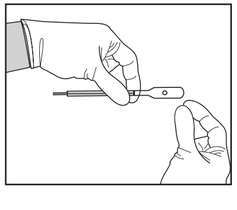

**8** Hold the specimen dropper for Fingerstick Whole Blood. DO NOT TOUCH OR SQUEEZE BULB. Immerse the open end of the specimen dropper into the blood drop and allow for the blood to draw into the specimen dropper up to marked line.



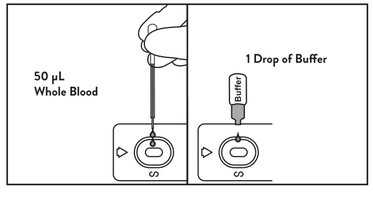

**9** After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



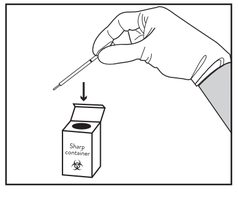
**10** Cover the 2 air holes.



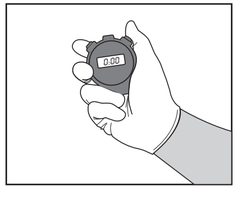
**11** Squeeze bulb to dispense all whole blood onto the specimen well (approximately 50 µL). Keep pressure on bulb while moving dropper away (avoids back suction). Then add 1 drop of buffer into the specimen well (approximately 30 µL).




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

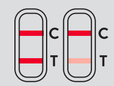



**13** Start the timer.




## 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).

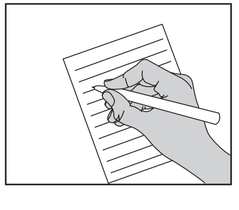
***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of HCV antibody present in the specimen. Therefore, any shade of color in the test region should be considered reactive.


**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.

Pantone 2925C

Pantone 285C

Pantone 285C 40%

Pantone 185C

Pantone 185C 50%

Black

Black 0-100%

美国以外的国际区域 OUS

美国 US

内销 China

| | | | |
|---|---|---|---|
| 描述<br>**Description** | ABT WHO ABON<br>IHC-402WC&WD English PI | 物料号<br>**Part Number** | 1156214501 |
| 打码号<br>**Ink jetting/ Ink printing No.** | N/A | 尺寸<br>**Size** | 580x360mm |
| 设计者/<br>日期/版本<br>**Designer/ Date/ Version** | Delia Xia<br>Oct. 08, 2023/H | 复核者/日期<br>**Reviewer/ Date** | Huiying Yi |
| 材质<br>**Material** | 70g双胶 | 折法<br>**Folding Method** | 折法32 |
| 模具号<br>**Mold Number** | N/A | 尺寸/材质/折法/模具号<br>审核/日期<br>**Size/Material/Folding Method/Mold Number checked by/ Date** | Robot Wang |

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<br>99.81% (95%CI: 98.92%-99.97%) | | |
| Diagnostic Specificity (95 %CI) | | | 1600/1600<br>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 |

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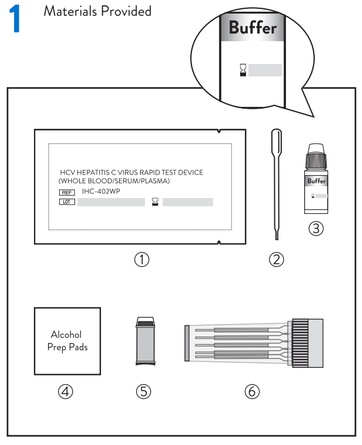
Abbott

ABON™

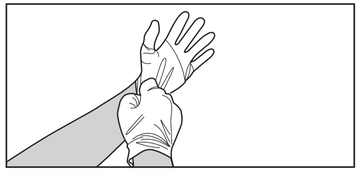
# HCV HEPATITIS C VIRUS RAPID TEST DEVICE (WHOLE BLOOD/SERUM/PLASMA)

## PREPARATION

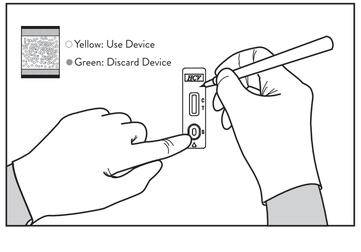
**1** Materials Provided




**2** Wear gloves

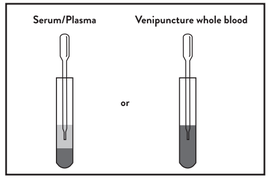


**3** Open the pouch, do not use the test device if the desiccant shows green when the pouch is opened. Label with specimen ID. Use it as soon as possible (within one hour).

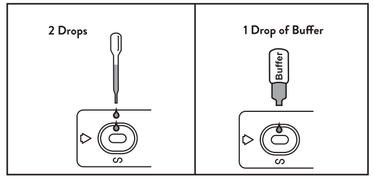



## SERUM OR PLASMA OR VENIPUNCTURE WHOLE BLOOD SPECIMENS

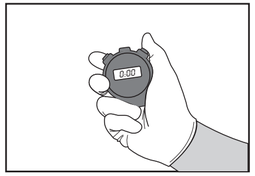
**4** Draw the specimen from the tube with a specimen dropper for Serum/Plasma/Venipuncture Whole Blood.



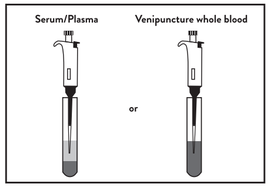

**5** Transfer 2 drops of serum or plasma or venipuncture whole blood with specimen dropper for Serum/Plasma/Venipuncture Whole Blood vertically (approximately 50 µL), then add 1 drop of buffer vertically (approximately 30 µL).



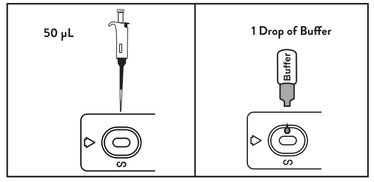

**6** Start the timer.



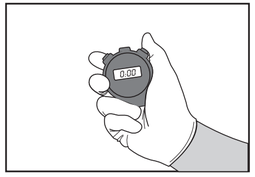

**4** Draw the specimen from the specimen tube with a pipette.




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

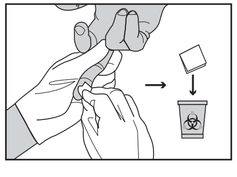



**6** Start the timer.

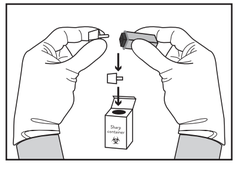



## FINGERSTICK WHOLE BLOOD SPECIMENS

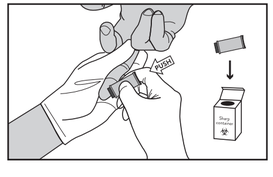
**4** Clean entire fingertip (prefer middle or ring finger from non-dominant hand) with alcohol prep pads.
Dispose the alcohol prep pads.



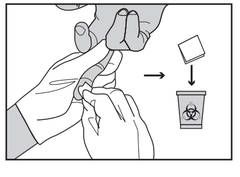
**5** Take off the cap of the lancet and dispose the cap in sharps container.



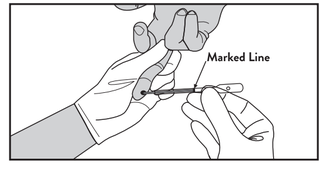

**6** Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



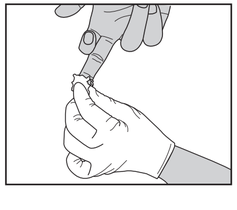

**7** Wipe away the first blood drop with a sterile gauze pad or cotton wool.



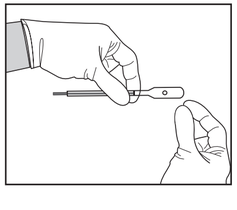

**8** Hold the specimen dropper for Fingerstick Whole Blood. DO NOT TOUCH OR SQUEEZE BULB. Immerse the open end of the specimen dropper into the blood drop and allow for the blood to draw into the specimen dropper up to marked line.



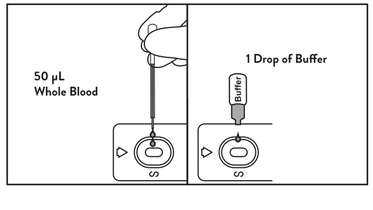

**9** After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



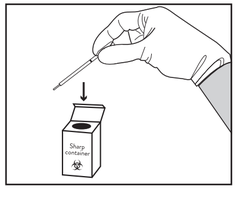
**10** Cover the 2 air holes.



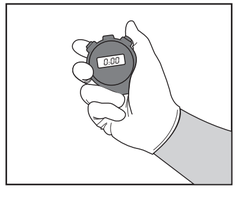
**11** Squeeze bulb to dispense all whole blood onto the specimen well (approximately 50 µL). Keep pressure on bulb while moving dropper away (avoids back suction). Then add 1 drop of buffer into the specimen well (approximately 30 µL).




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

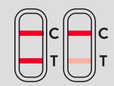



**13** Start the timer.




## 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).

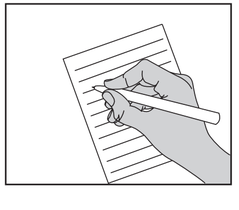
***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of HCV antibody present in the specimen. Therefore, any shade of color in the test region should be considered reactive.


**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.

Pantone 2925C

Pantone 285C

Pantone 285C 40%

Pantone 185C

Pantone 185C 50%

Black

Black 0-100%

美国以外的国际区域 OUS

美国 US

内销 China

| | | | |
|---|---|---|---|
| 描述<br>**Description** | ABT WHO ABON<br>IHC-402WC&WD English PI | 物料号<br>**Part Number** | 1156214501 |
| 打码号<br>**Ink jetting/ Ink printing No.** | N/A | 尺寸<br>**Size** | 580x360mm |
| 设计者/<br>日期/版本<br>**Designer/ Date/ Version** | Delia Xia<br>Oct. 08, 2023/H | 复核者/日期<br>**Reviewer/ Date** | Huiying Yi |
| 材质<br>**Material** | 70g双胶 | 折法<br>**Folding Method** | 折法32 |
| 模具号<br>**Mold Number** | N/A | 尺寸/材质/折法/模具号<br>审核/日期<br>**Size/Material/Folding Method/Mold Number checked by/ Date** | Robot Wang |