WHO Prequalification of Diagnostics Programme
PUBLIC REPORT
Product: ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device
WHO reference Number: PQDx 0141-051-00

Digitally signed by Bolea Petru
Date: 2023.03.06 13:01:06 EET
Reason: MoldSign Signature
Location: Moldova

ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device with product codes IHI-T402WA, IHI-T402WG, IHI-T402WB, IHI-T402WD, IHI-T402WE, IHI-T402WF and IHI-T402WI manufactured by **ABON Biopharm Hangzhou Co., Ltd.**, **Rest of World regulatory version**, was accepted for the WHO list of prequalified diagnostics and was listed on 25 August 2014.

Summary of WHO prequalification assessment for ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device

	Date	Outcome
Status on PQ list	25 August 2014	listed
Dossier review	14 July 2014	MR
Site inspection(s) of the quality management system	13 August 2014	MR
Product performance evaluation	7 November 2013	MR

MR: Meets Requirements

Report amendments and product changes

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

Version	Summary of amendment	Date of report amendment
Version 1.0 to 6.0	Addition of one new packaging configuration with code **IHI-T402WG** and change the existing code IHI-T402W to **IHI-T0402WA**. Another amendment was to address a typographical error.	3 May 2017
Version 7.0	Alcohol swab labelling changed by revising the symbol and mailbox. Physical move of whole blood testing on the semi-finished and finished product, including product performance evaluation on whole blood specimens to a different location.	1 March 2019

	Created SET configuration with accessories (and assigned Product Code). Created a new kit size (and assigned Product Code)	
8.0	1. For IHI-T402WA: Change the package style of pouch/box/carton/buffer/ Package Insert (PI) from ABON to Abbott. 2. Created three new product codes to backup the specimen dropper for fingerstick whole blood and lancet (assign product code IHI-T402WE/IHI-T402WF/IHI-T402WI). 3. For IHI-T402WB/IHI-T402WD/IHI-T402WG: a) Changed the package style, b) Changed specimen dropper and lancet, c) Updated PI due to updating the specimen dropper and lancet information. 4. Changed label for the sterile lancet due to a change of supplier's manufacturing site and EU AR address. 5. Created a new kit size (with product code: IHI-T402WD) 6. Removal of IHI-T402WC.	20 December 2022

Intended use:

According to the claim of intended use from ABON Biopharm Hangzhou Co., Ltd, "*HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device is an in vitro diagnostic rapid immunochromatographic assay for the qualitative detection of antibodies to HIV-1, including subtype O, and HIV-2 in venous and capillary whole blood, serum and plasma specimens. The product may be used as an aid in the diagnosis of HIV infection. A reactive result should be confirmed by supplemental testing as part of a validated HIV testing algorithm. This product has not been evaluated on paediatric and neonatal specimens."*

Test principle:

According to the claim from ABON Biopharm Hangzhou Co., Ltd, *"the HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device test strip is pre-coated with HIV-1 and subtype O antigens on T1 test line and HIV-2 antigen on T2 test line. Firstly, specimen and then buffer is added to the specimen well, thus starting the migration of the specimen/buffer. The specimen/buffer passes the conjugate pad which contains a mixture of HIV-1 envelope and capsid antigens and HIV-2 envelope antigen. These detection antigens are conjugated to latex particles. If present, the HIV-1 of HIV-2 antibodies react and bind to the detection antigen-conjugate. The antibody/antigen-conjugate mixture then migrates further and binds to antigens present on the test lines. If the specimen contains antibodies to HIV-1, the specimen will bind to the T1 test line and produce a line, if specimen contains antibodies to HIV-2, the specimen will bind to the T2 test line. As liquid continues to migrate down the test strip, the control line will appear. If the control line is present, in addition to either or both test lines, then the test is reactive for HIV1/2 antibodies. If the specimen does not contain HIV-1 or HIV-2 antibodies, no colored lines will appear for either of the test lines region indicating a non-reactive result. Please note that the appearance of coloured lines at T1 and T2 is highly unlikely to be indicative of co-infection with HIV-1 and HIV-2 but rather is a result of cross-reactivity between antigens. A*

colored line will appear in the control line region if the migration of liquid has been successful and must be present for the test to be valid. Its presence does not confirm sufficient specimen addition.

If used as a first-line (screening) assay, any reactive specimens should be referred for additional testing using another method to confirm reactivity. Depending on the prevalence of the disease, this may require one or two additional reactive results on at least two other assays."

Product test kit contents:

Component	40 tests (product code IHI-T402WA)	40 tests (product code IHI-T402WG)	40 tests (product code IHI-T402WB)	10 tests (product code IHI-T402WD)	40 tests (product code IHI-T402WE	10 tests (product code HI-T402WF	10 tests (product code IHI-T402WI
Pouched test devices with desiccant	40	40	40	10	40	10	40
Sterile safety lancets, single-use	N/A	40	40	10	40	10	40
Capillary tubes (For Fingerstick Whole Blood)	N/A	40	40	10	40	10	40
Alcohol swabs, 70% ethanol	N/A	40	N/A	10	40	10	N/A
Specimen dropper (For Serum/Plasma/Venipuncture Whole Blood)	40	40	40	10	40	10	40
3 ml Buffer	2	2	2	1	2	1	2
Instructions for use	1	1	1	1	1	1	1

Items required but not provided:

Item
Consumables: Biosafety waste containers, sharps and non-sharps Specimen collection equipment for venous whole blood if serum/plasma/venipuncture whole blood specimens are used.
Equipment: Timer Centrifuge, if serum/plasma

Storage:
The test kit must be stored at 2-30 °C.

Shelf-life upon manufacture:
24 months[1]

Warnings/limitations:
Please refer to the attached instructions for use.

[1] Shelf-life stated at time of original prequalification public report was 24 months.

Prioritization for prequalification

Based on the established eligibility criteria, ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device was given priority for WHO prequalification assessment.

Product dossier assessment

ABON Biopharm Hangzhou Co., Ltd. submitted a product dossier for ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device as per the "Instructions for compilation of a product dossier" (PQDx_018 v1). The information submitted in the product dossier was reviewed by WHO staff and external experts (assessors).
The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 14 July 2014.

Manufacturing site inspection

Two comprehensive inspections were performed at the site of manufacture (Hangzhou, China) of the ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device in September 2012 and in November 2013 as per the "Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics" (PQDx_014 v1). The second inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality. The manufacturer's responses to the nonconformities found at the time of the inspection were accepted on 16 April 2014.

Product performance evaluation

ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device was evaluated by WHO at the Institute of Tropical Medicine, Antwerp, Belgium - a WHO Collaborating Centre for HIV/AIDS Diagnostics and Laboratory Support. The laboratory evaluation was conducted according to the "WHO protocol for the laboratory evaluation of HIV serology assays" (PQDx_030 v1.0) and drew the following conclusions:

ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device is an immunochromatographic rapid diagnostic test for the discriminatory detection of HIV-1 and HIV-2 antibodies in human serum, plasma, capillary and venous whole blood. A volume of 25µl of serum/plasma or 50µl of whole blood is required to perform the assay. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities and non-laboratory settings. Reading of the results can be done visually.

In this limited evaluation on a panel of 1118 serum/plasma specimens, we observed an initial sensitivity (95% CI) of 100% (99.2% - 100%) and an initial specificity (95% CI) of 99.7% (98.9% - 100%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.2 % - 100%), and the final specificity (95% CI) was 99.7% (98.9% - 100%) compared to the reference assays. In this study, 0% of the results

were recorded as indeterminate. Results were interpreted independently by three technicians; the overall inter-reader variability was 3.9% (0.1% for the HIV-1 band, 3.8% for the HIV-2 band). The invalid rate was 0.9%. Lot-to-lot variation was acceptable for all but one dilution series (WHO3-0690). False reactivity was observed for the HIV-2 test line for the first 4 dilutions when tested with lot HIV 2090089. No false reactivity was observed for the HIV-2 line when the same dilution series was tested with lot HIV 2090023.

ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device was unable to discriminate between HIV-1 and HIV-2 infection for 150 of the 1118 specimens (2 HIV-2 positives and 148 HIV-1 positives).

For eight seroconversion panels, ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid

Test Device detected on average 0.5 (95% CI -0.3 – 1.0) specimens later than the benchmark assay; Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics). For the mixed titer panel, ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device correctly classified all specimens. F or the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device correctly classified all subtypes tested (HIV-1 A, H IV-1 B, HIV-C, HIV-1 CRF01_AE, HIV-1 O and HIV-2).

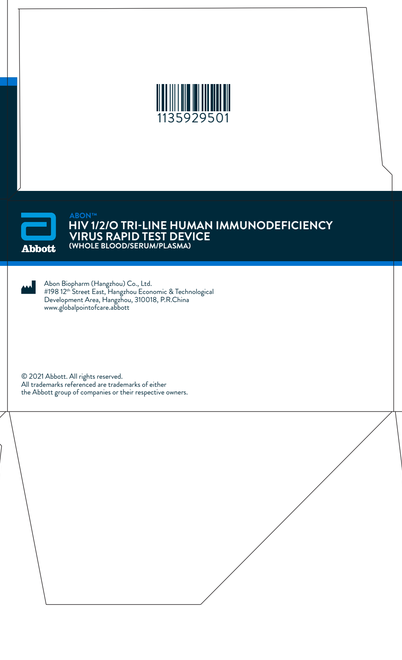
Labelling

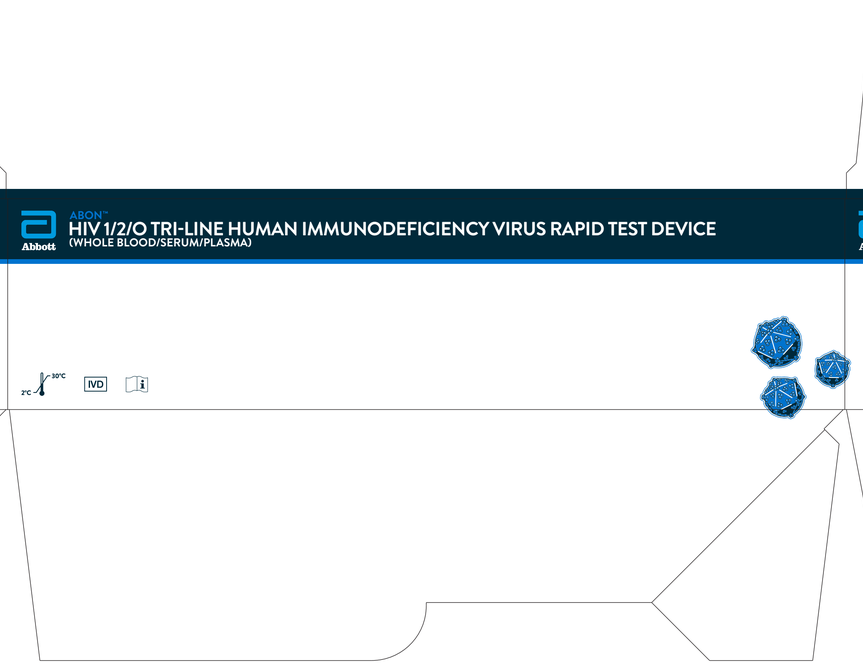
1. **Labels**
2. **Instructions for use**

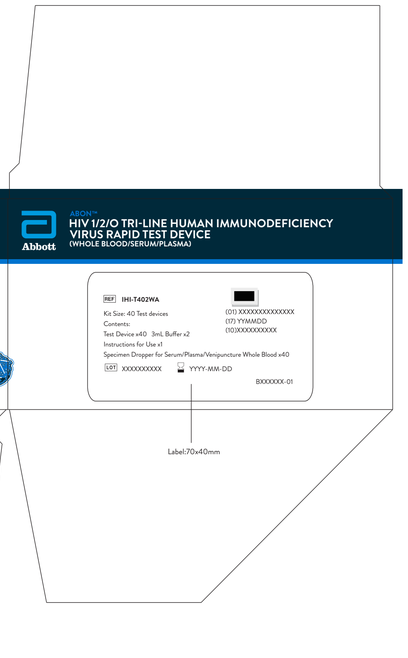
1. Labels

1.1.1 Kit box artwork for product codes IHI-T402WA, IHI-T402WG, IHI-T402WB, IHI-T402WE, and IHI-T402WI.

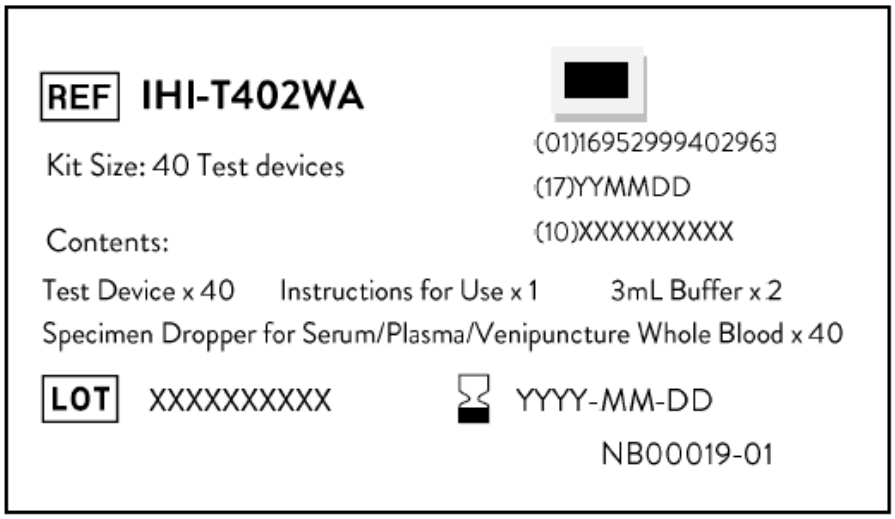

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)
Abbott
ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)
2°C 30°C
IVD

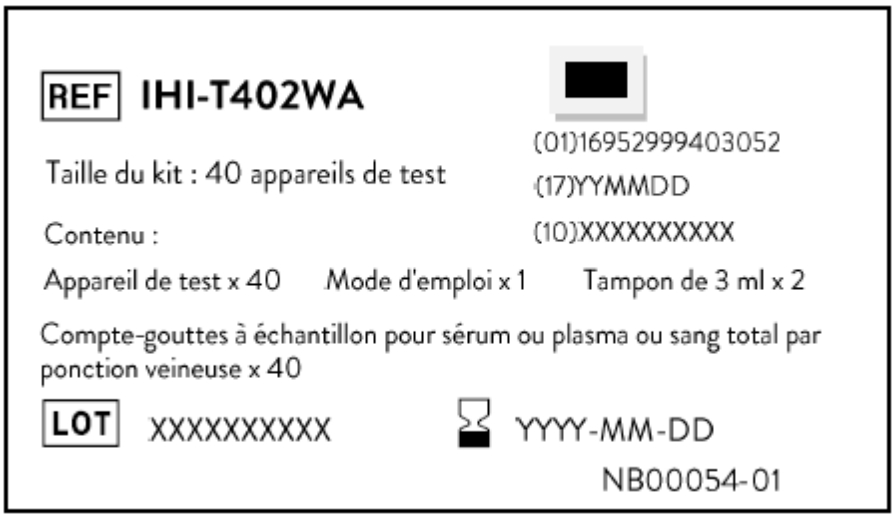

1135929501
ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)
Abbott
Abon Biopharm (Hangzhou) Co., Ltd.
#198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R.China
www.globalpointofcare.abbott
© 2021 Abbott. All rights reserved.
All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.


ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)
Abbott
2°C 30°C
IVD

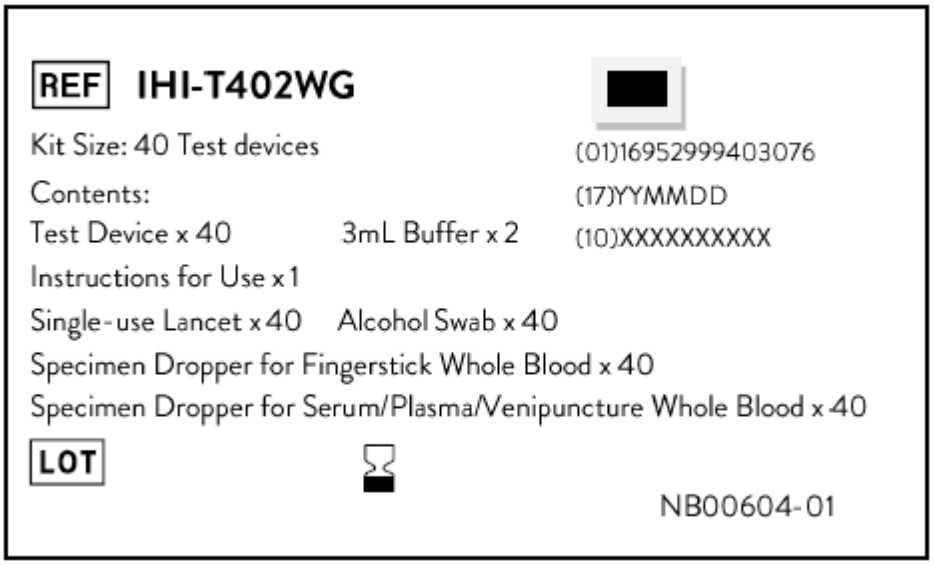

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)
Abbott
REF IHI-T402WA
Kit Size: 40 Test devices
Contents:
Test Device x40 3mL Buffer x2
Instructions for Use x1
Specimen Dropper for Serum/Plasma/Venipuncture Whole Blood x40
LOT XXXXXXXXX
YYYY-MM-DD
(01) XXXXXXXXXXXXX
(17) YYMMDD
(10)XXXXXXXXXX
BXXXXXX-01
Label:70x40mm

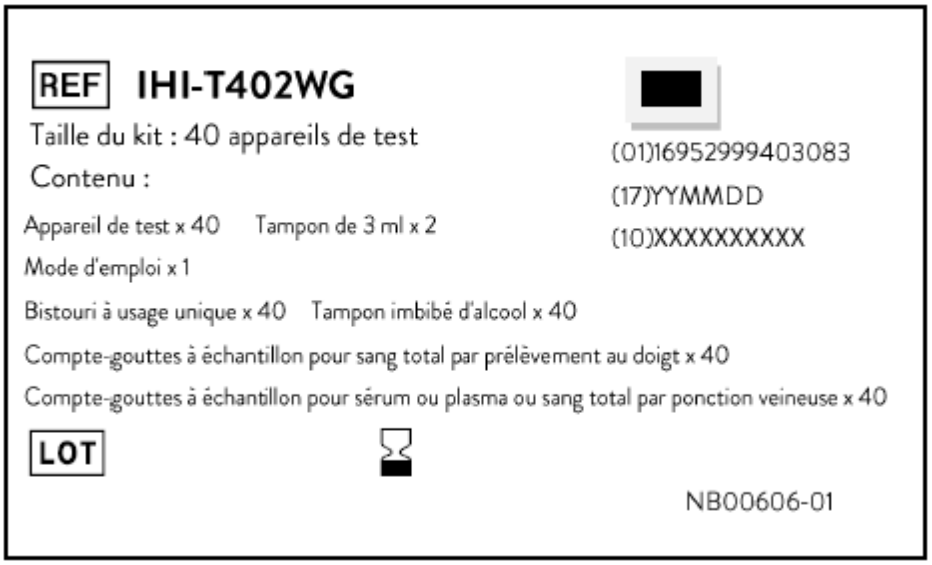
1.1.2 Label for product IHI-T402WA



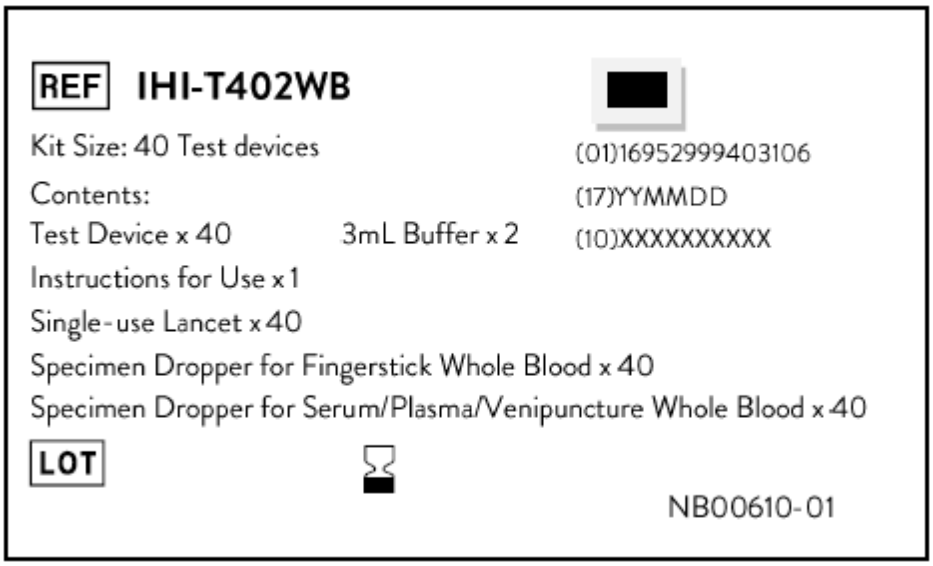


1.1.3 Label for product code IHI-T402WG

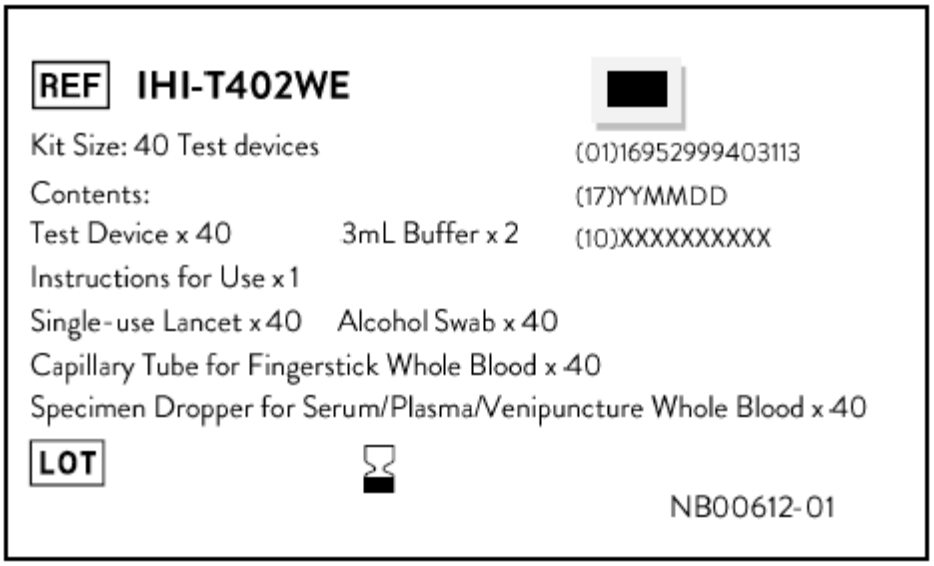


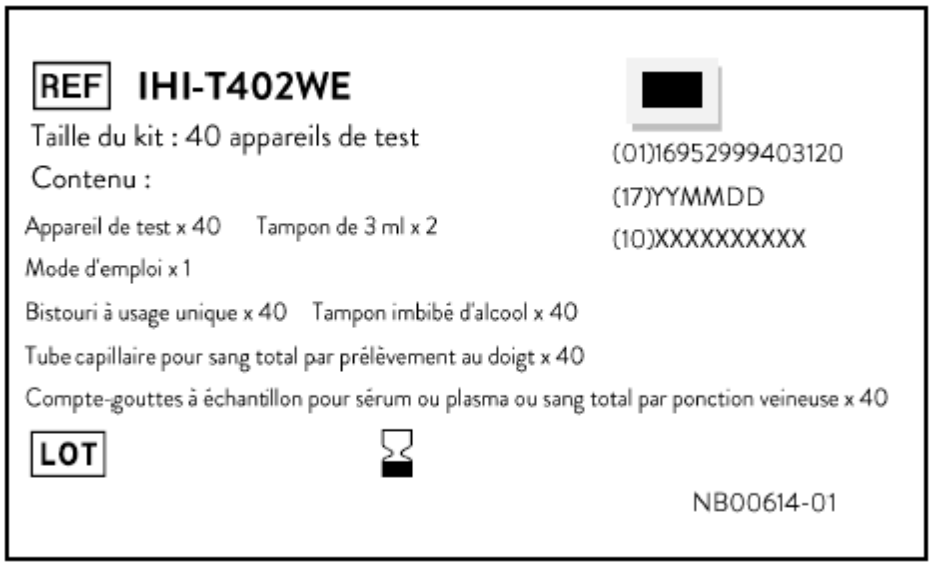


1.1.4 Box label for product code IHI-T402WB

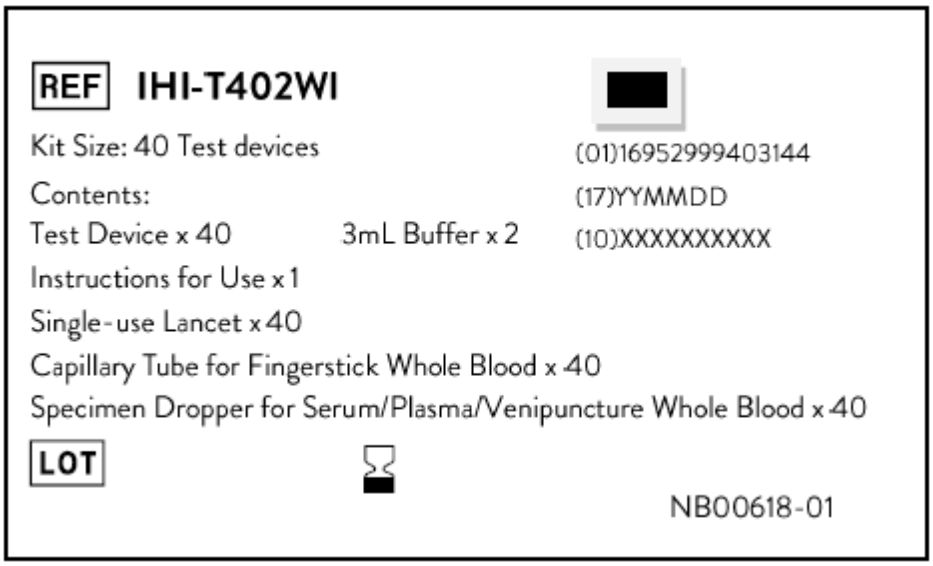


1.1.5 Box label for product code IHI-T402WE





1.1.6 Box label for product code IHI-T402WI



1.2 Box Artwork for product codes IHI-T402WD and IHI-T402WF

Abbott

ABON™

HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE

(WHOLE BLOOD/SERUM/PLASMA)

2°C 30°C IVD

1135929401

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

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

© 2021 Abbott. All rights reserved.
All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.

2°C 30°C IVD

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

REF IHI-T402WD

Kit Size: 10 Test devices
Contents:
Test Device x10 3mL Buffer x1
Instructions for Use x1
Single-use Lancet x10 Alcohol Swab x10
Specimen Dropper for Fingerstick Whole Blood x10
Specimen Dropper for Serum/Plasma/Venipuncture Whole Blood x10

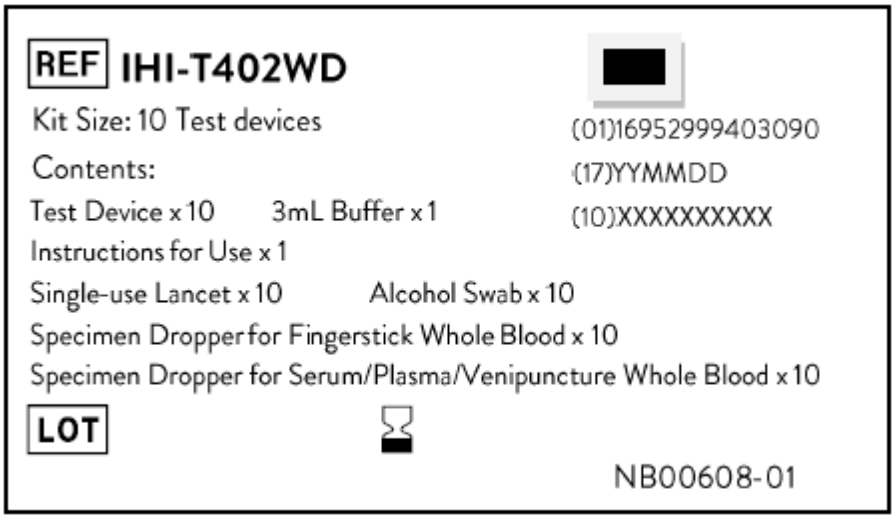
(01) xxxxxxxxxxxx
(17) YYMMDD
(10)XXXXXXXXXX

LOT XXXXXXXXXX YYYY-MM-DD

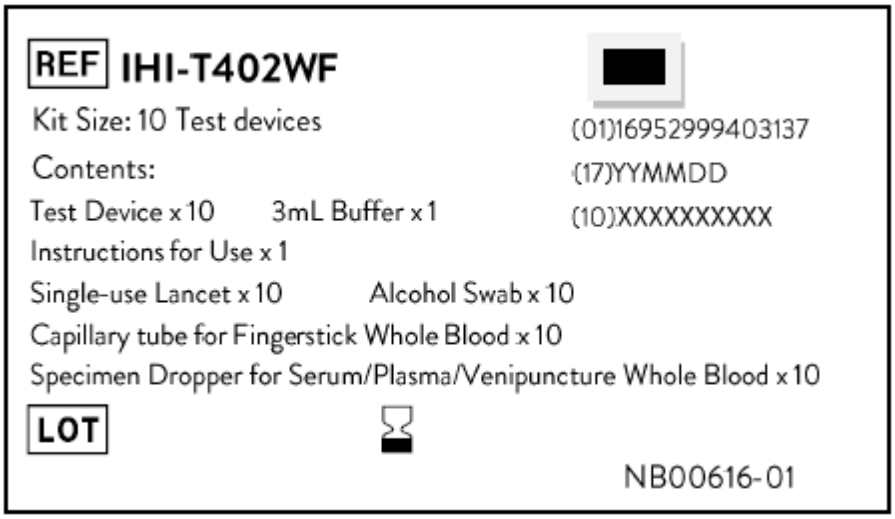
Bxxxxxx-01

Label:70x40mm

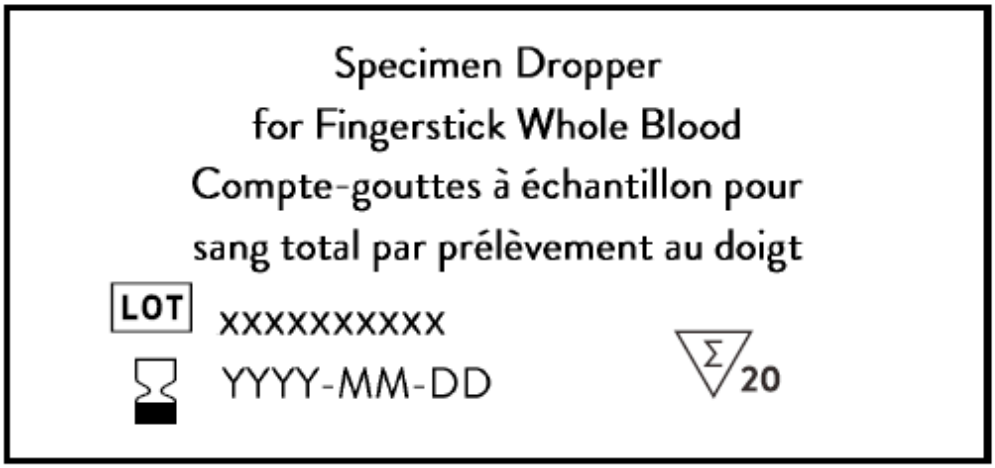
1.2.1 Box label for product code IHI-T402WD

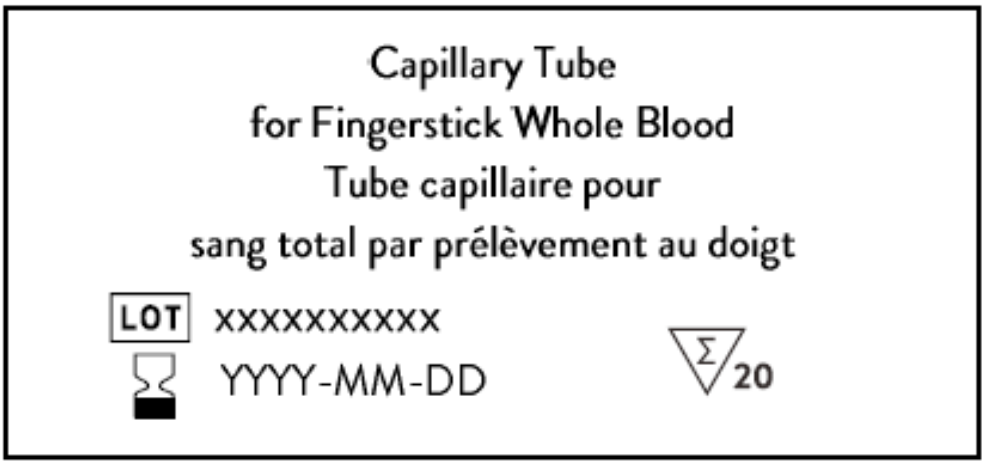


1.2.2 Box label for product code IHI-T402WF.

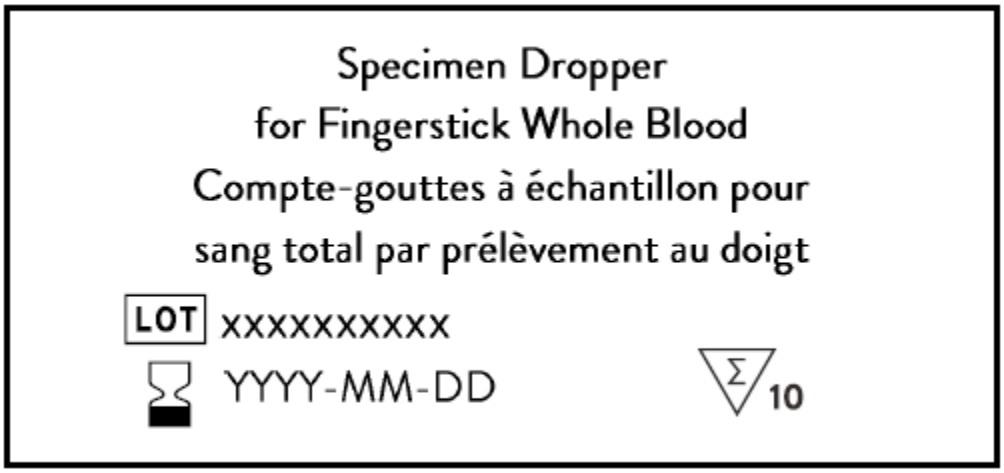


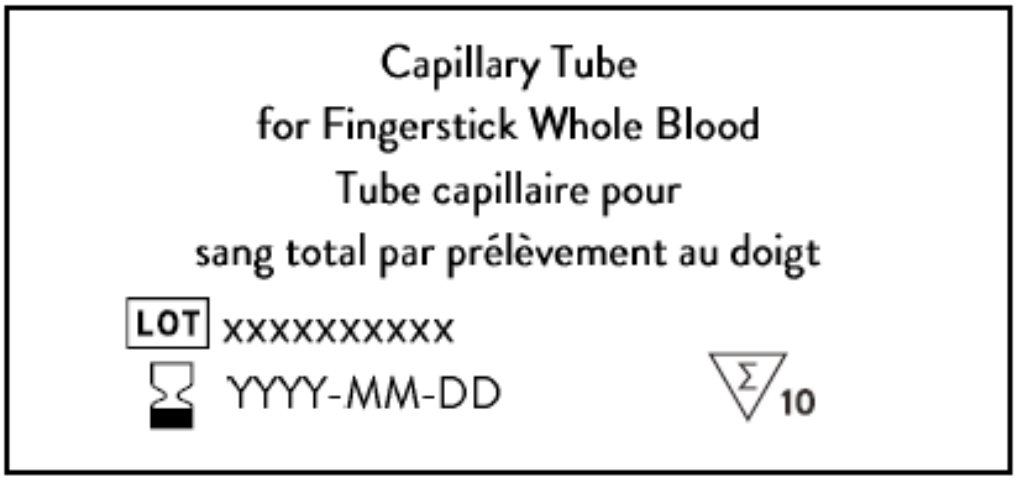
1.3 Specimen dropper labels (pack of 20)



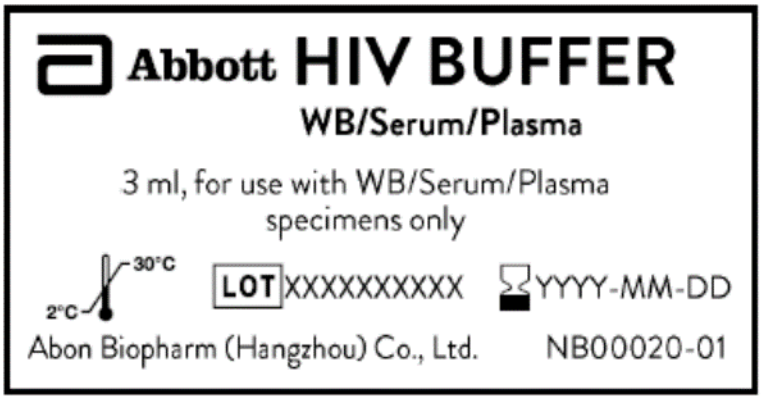


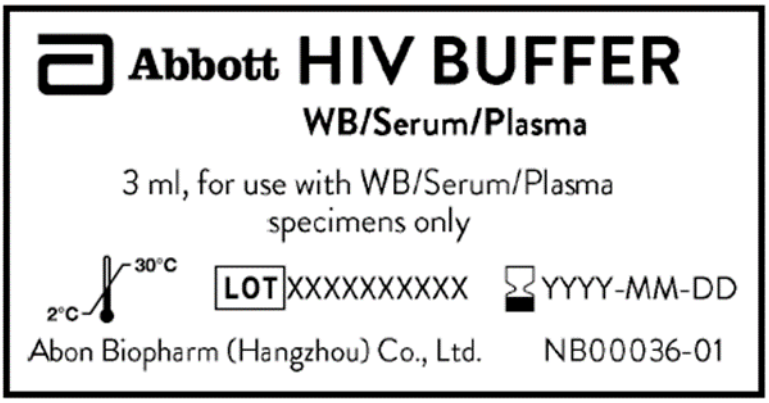
Specimen dropper label (pack of 10)





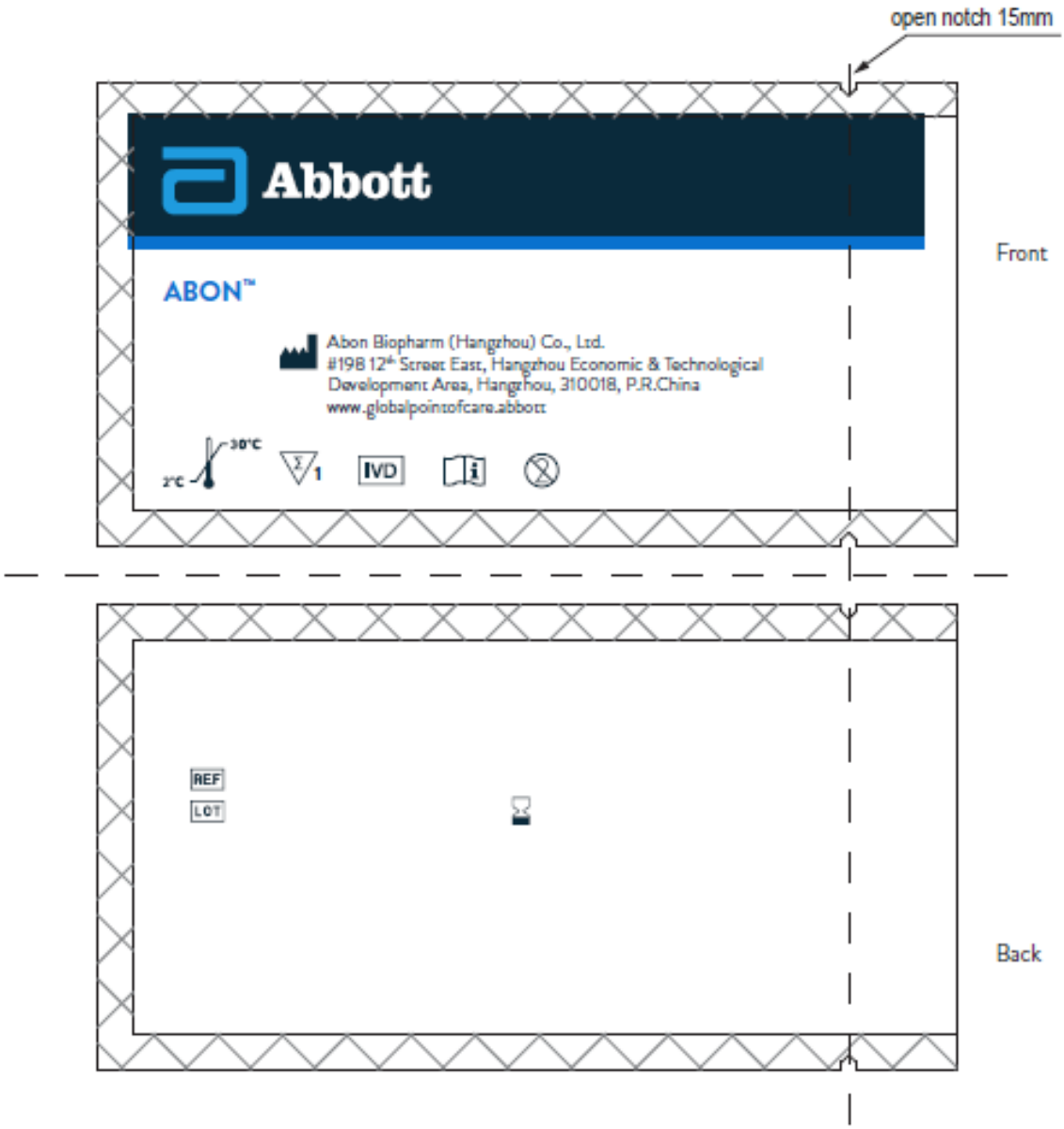
1.4 Buffer label (English)





Buffer label (French)

1.5 Device pouch (IHI-T402WA, IHI-T402WG, IHI-T402WB, IHI-T402WD, IHI-T402WE, IHI-T402WF and IHI-T402WI)

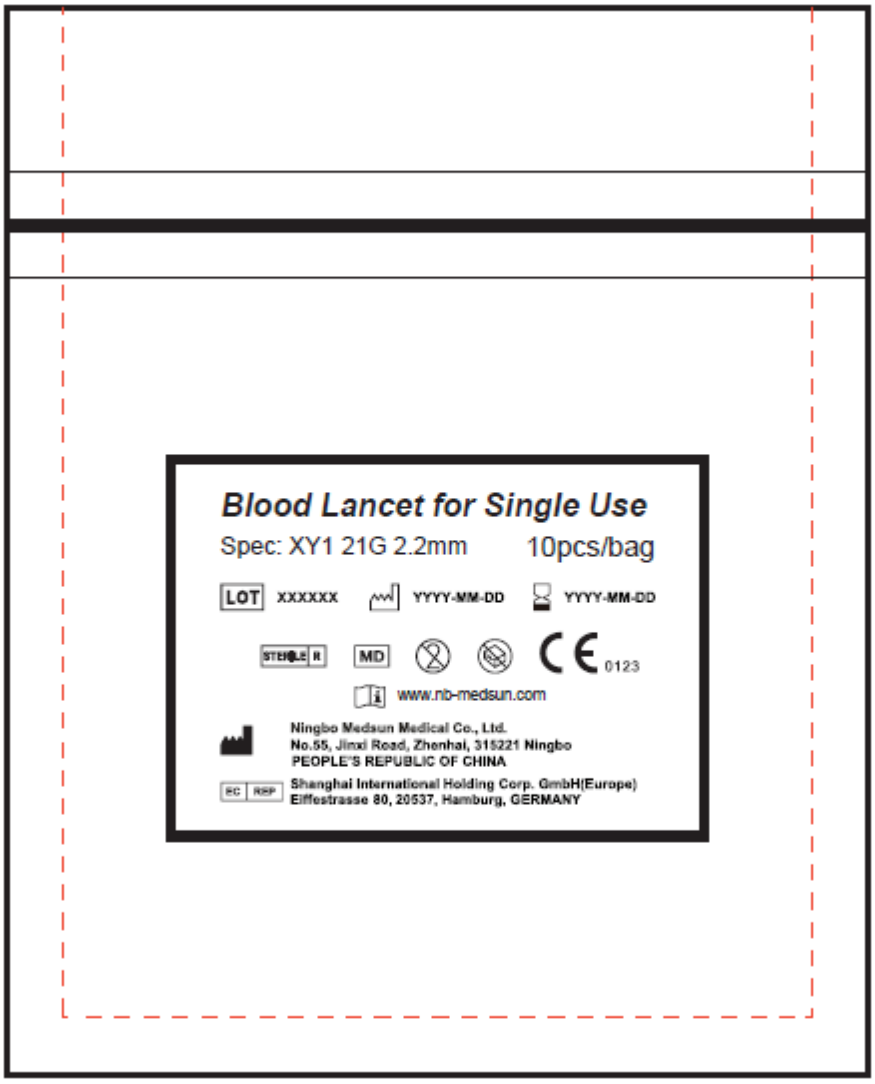


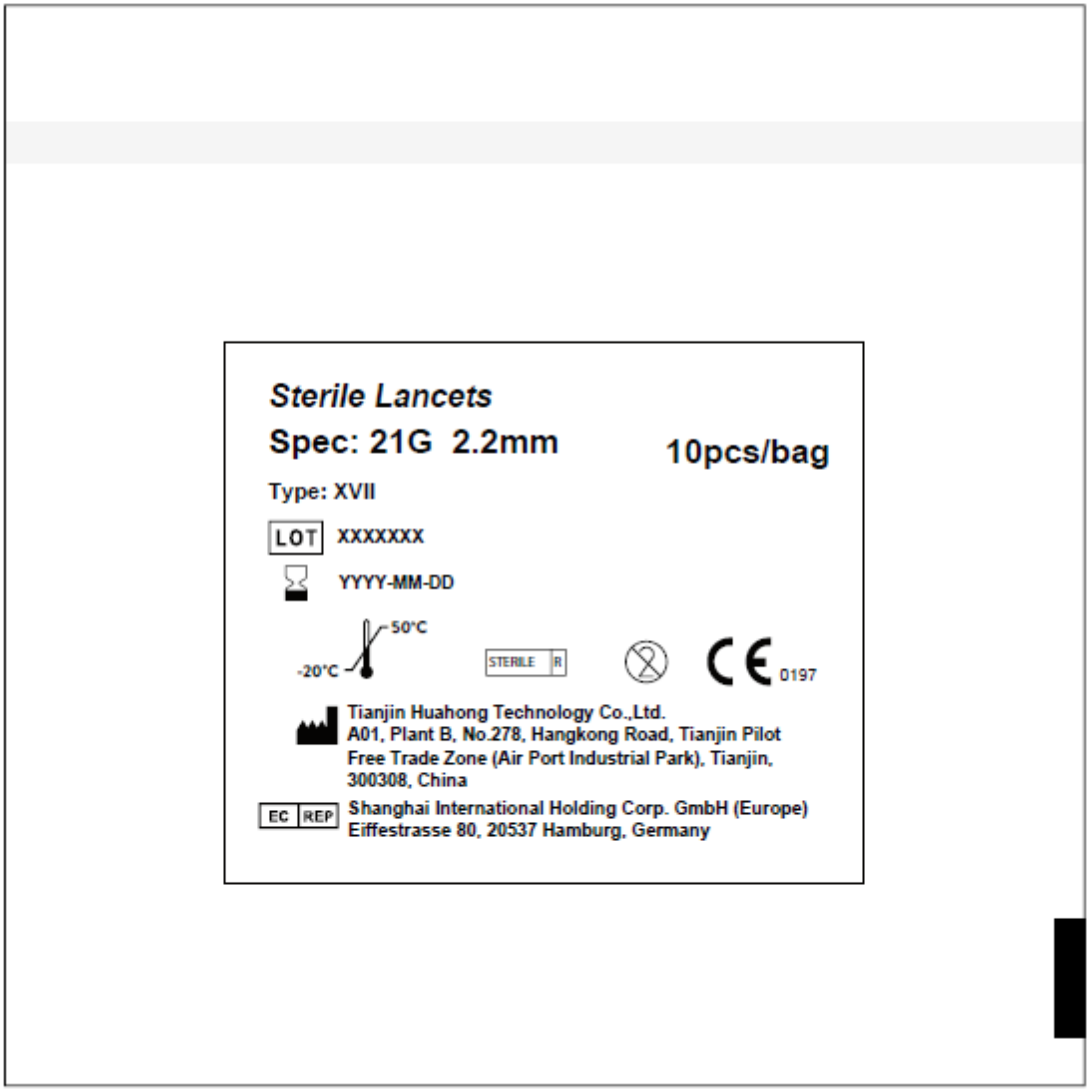
1.6 Alcohol swab (IHI-T402WG,IHI-T402WD, IHI-T402WE, and IHI-T402WF)

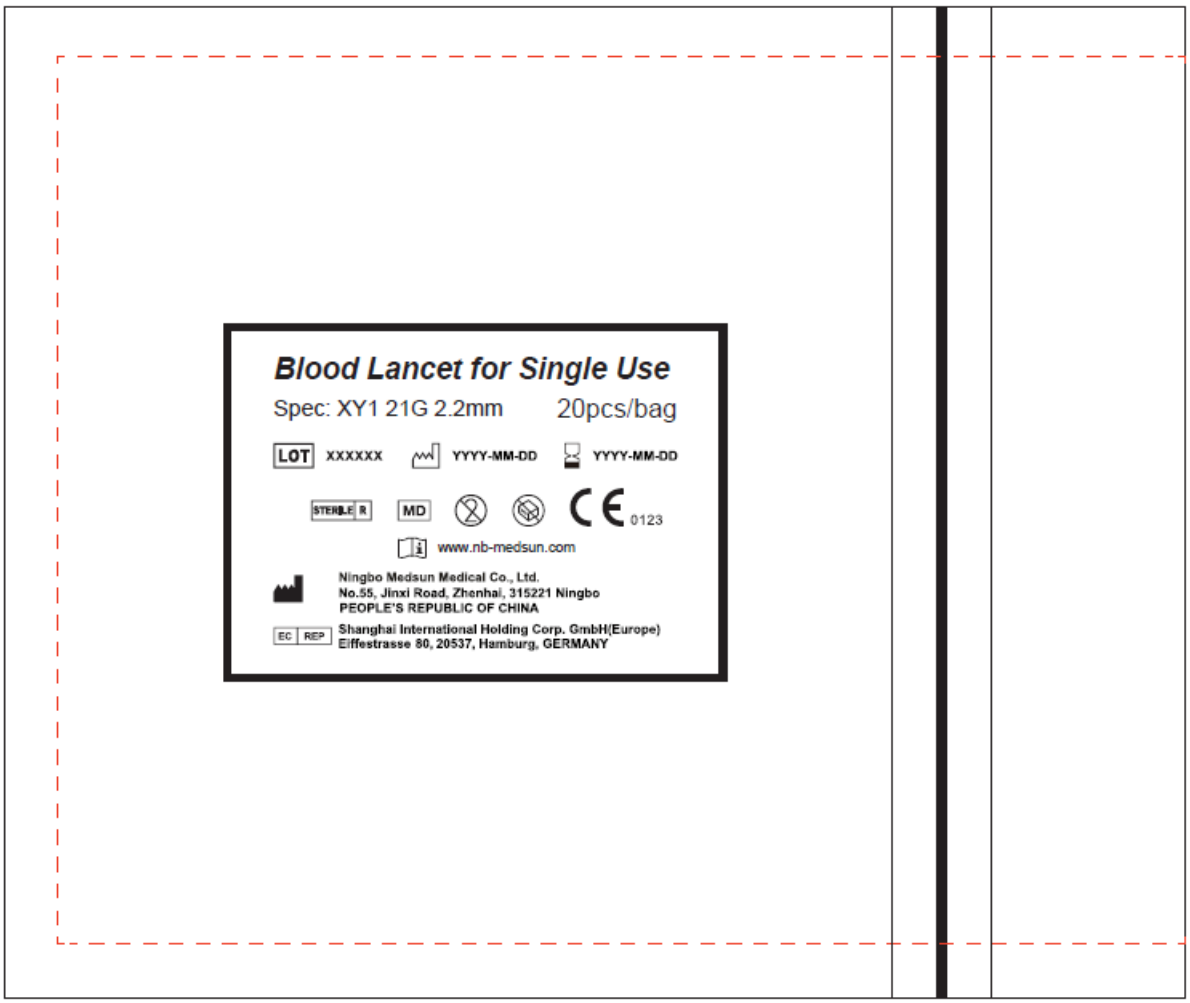
Front

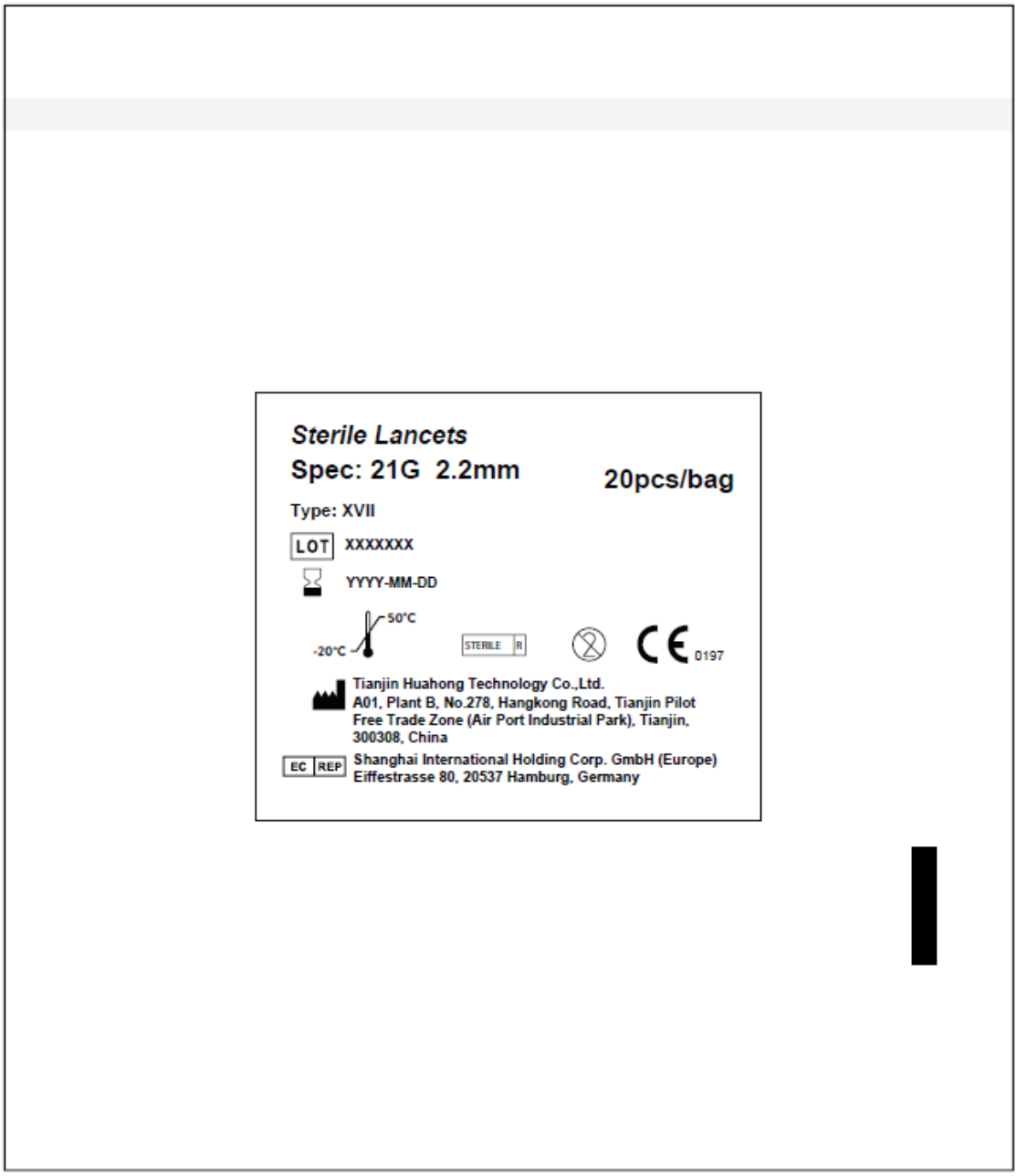
Back

1.7 Lancet Labels (for product codes IHI-T402WG, IHI-T402WB, IHI-T402WD, IHI-T402WE, IHI-T402WF and IHI-T402WI)




Sterile Lancets
Spec: 21G 2.2mm
10pcs/bag
Type: XVII
LOT XXXXXXX
YYYY-MM-DD
-20°C
50°C
STERILE R
CE 0197
Tianjin Huahong Technology Co.,Ltd.
A01, Plant B, No.278, Hangkong Road, Tianjin Pilot Free Trade Zone (Air Port Industrial Park), Tianjin, 300308, China
EC REP
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany


Blood Lancet for Single Use
Spec: XY1 21G 2.2mm
20pcs/bag
LOT XXXXXX
YYYY-MM-DD
YYYY-MM-DD
STERILE R
MD
0123
www.nb-medsun.com
Ningbo Medsun Medical Co., Ltd.
No.55, Jinxi Road, Zhenhai, 315221 Ningbo
PEOPLE'S REPUBLIC OF CHINA
EC REP
Shanghai International Holding Corp. GmbH(Europe)
Eiffestrasse 80, 20537, Hamburg, GERMANY


Sterile Lancets
Spec: 21G 2.2mm
20pcs/bag
Type: XVII
LOT XXXXXXX
YYYY-MM-DD
-20°C
50°C
STERILE R
CE 0197
Tianjin Huahong Technology Co.,Ltd.
A01, Plant B, No.278, Hangkong Road, Tianjin Pilot Free Trade Zone (Air Port Industrial Park), Tianjin, 300308, China
EC REP
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

2. Instructions for use[2]

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

Abbott

1156212601

Revision date: 2021-05-18
IFU version 07

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

REF IHI-T402WA IVD

Instructions for Use

English

A rapid diagnostic test for the qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) type 1, including subtype O, and type 2 in whole blood, serum or plasma.
For professional use only.

INTENDED USE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is an *in vitro* diagnostic rapid immunochromatographic assay for the qualitative detection of antibodies to HIV-1, including subtype O, and HIV-2 in venous and capillary whole blood, serum and plasma specimens. The product may be used as an aid in the diagnosis of HIV infection. A reactive result should be confirmed by supplemental testing as part of a validated HIV testing algorithm. This product has not been evaluated on paediatric and neonatal specimens.

PRINCIPLE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) test strip is pre-coated with HIV-1 and subtype O antigens on T1 test line and HIV-2 antigen on T2 test line. Firstly, specimen and then buffer is added to the specimen well, thus starting the migration of the specimen/buffer. The specimen/buffer passes the conjugate pad which contains a mixture of HIV-1 envelope and capsid antigen and HIV-2 envelope antigen. These detection antigens are conjugated to latex particles. If present, the HIV-1 of HIV-2 antibodies react and bind to the detection antigen-conjugate. The antibody/antigen-conjugate mixture then migrates further and binds to antigens present on the test lines. If the specimen contains antibodies to HIV-1, the specimen will bind to the T1 test line and produce a line, if specimen contains antibodies to HIV-2, the specimen will bind to the T2 test line. As liquid continues to migrate down the test strip, the control line will appear. If the control line is present, in addition to either or both test lines, then the test is reactive for HIV1/2 antibodies. If the specimen does not contain HIV-1 or HIV-2 antibodies, no colored lines will appear for either of the test lines region indicating a non-reactive result. Please note that the appearance of colored lines at T1 and T2 is highly unlikely to be indicative of co-infection with HIV-1 and HIV-2 but rather is a result of cross-reactivity between antigens. A colored line will appear in the control line region if the migration of liquid has been successful, and must be present for the test to be valid. If the control line does not appear, the test result is not valid.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (storage in refrigerator is permitted). **Do not store in the freezer**. Protect the test kit from humidly. The test device is stable until the expiration date printed on the test kit and/or sealed test device pouch. Do not use beyond the expiration date. The test device must remain in the sealed pouch until use.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Read the instruction carefully before performing the test.
- Apply standard biosafety precautions when handling and disposing of potentially infectious material.
- Handle all specimens as potentially infectious.
- Wear protective clothing such as gloves, laboratory coats, and eye protection when specimens are being tested.
- The test device and accessory should be disposed in a proper biohazard waste container after testing.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Avoid splashes and clean up spills immediately with appropriate disinfectant.
- The buffer contains 0.02% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities of water.
- Do not use the test kit beyond the expiration date.
- Do not use if the packaging is damaged.
- Do not use the heparinized capillary tube, dispensing bulb, single-use lancet and alcohol pad if it is already damaged.
- Dispose the heparinized capillary tube, single-use lancet in the sharps container if it is already damaged before use.
- Do not set the lancet down before discarding it.
- Do not reuse the lancet.
- In case of Post-exposure prophylaxis for HIV, operators should familiarize themselves with PPE policy prior to conducting the testing.
- Humidity and temperature can adversely affect results.
- The optimal number of specimens to be tested at one time is 10.
- Do not use any other specimen than those specified. For plasma/venipuncture whole blood, EDTA-K_2/sodium heparin/sodium citrate/lithium heparin can be used as anticoagulant. Other anticoagulants have not been tested and may give incorrect results.
- Do not form air bubbles during addition of specimen. Bubble formation may lead to insufficient specimen volume added and a false non-reactive result may arise accordingly.

SPECIMEN COLLECTION AND PREPARATION

- HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **fingerstick whole blood** specimens:
  - Wear gloves.
  - Clean entire fingertip (preferable 3rd or 4th finger from non-dominant hand) with alcohol swab. Allow to dry (30 seconds).
  - Puncture the side of the finger with a new lancet each time. Disposed the lancet in sharps container immediately after using it. Do not use the lancet if the cap is already pulled off. Wipe away the first blood drop with a sterile gauze pad or cotton wool.
- To collect a fingerstick whole blood specimen by using a capillary tube:
  - 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. Avoid air bubbles.
  - After collecting the sample, place a gauze pad or cotton ball on the finger until the bleeding stops.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense all whole blood on the specimen well (S) of the test device for testing.
  - Dispose the capillary tube in sharps container after testing.
- To collect **serum or plasma or venipuncture whole blood** specimens:
  - Collect according to safe phlebotomy procedures, using vacuum technique into 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.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature (15-30°C) for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be stored at -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing.
- No qualitative performance difference were observed between experimental controls and 20 nonreactive or 20 reactive specimens subjected to 6 freeze/thaw cycles; however, multiple freeze/thaw cycles should be avoided.

MATERIALS

Materials Provided

Components	IHI-T402WA
Test Device	x40
3mL Buffer	x2
Specimen Dropper (For Serum/plasma/Venipuncture Whole Blood)	x40
Instructions for Use	x1

Materials Required But Not Provided

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

TEST PROCEDURE

Allow the test device, buffer and specimen to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible (within one hour).
2. Place the test device on a clean and level surface. Label with specimen ID. And start to add specimen and buffer. Avoid bubbles formation during addition of specimen and buffer.
   For **serum or plasma** specimens: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µL) and start the timer.
   For **venipuncture whole blood** specimens: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
   For **fingerstick whole blood** specimens: Take whole blood specimen with a 50 µL capillary tube until marked line. And **add specimen** (about 50 µL) on the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes. Do not read results after 20 minutes.**

INTERPRETATION OF RESULTS

REACTIVE:* Two or three distinct colored lines appear. One line should always appear in the control line region (C), and another one or two apparent colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
Note: The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).
INVALID: No line appears in the control line region (C). If this occurs, read the test procedure again and repeat the test with a new test device. If the result is still invalid, stop using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A control line is included in the test as an internal control. The test must absorb liquid and allow it to migrate along the membrane for the control line to appear. A colored line appearing in the control region (C) is the internal procedural control.
Quality control specimens are not supplied with this kit; however, it is recommended that quality control specimens be tested as a good laboratory practice.

LIMITATION

1. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HIV-1/2 in human whole blood, serum or plasma. The concentration of antibodies to HIV-1/2 can not be determined by this qualitative test.
2. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HIV-1/2 in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1, HIV-2, and/or HIV-1 subtype O infection.
3. For confirmation of reactive test results, specimens should undergo further testing using different assays, such as rapid diagnostic tests, EIA and/or Western blotting in accordance with a validated HIV testing algorithm.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Results should not be used to determine the genotype of HIV infections.
6. Due to possible antibody cross reactivity, the appearance of lines in both T1 and T2 does not necessarily indicate co-infection from HIV-1 and HIV-2.
7. False reactive results may arise due to rheumatoid factors, antinuclear antibodies, other viral infections (i.e. hepatitis B or hepatitis C), parasitic infections (i.e. schistosomiasis and trypanosomiasis), damage to test components by heat or humidity, other test kit components (e.g. buffer or droppers) substituted between test kits.
8. False non-reactive results may arise when titers of antibodies to HIV1/2 are very low, titers of antibodies to HIV1/2 are very high (high-hook effect), insufficient specimen volume added, excess of buffer added, damage to test components by heat or humidity.
9. False-negative results may be observed in individuals who are receiving effective antiretroviral therapy. [1,2,3]
10. The estimated rate of Cross-reactivity between HIV-1 and HIV-2 positive samples was 32.6% using HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)[4]. Although dual infection of HIV-1 and HIV-2 is uncommon, it is reported that 9% of individuals with HIV-2 infection are coinfected with HIV-1 in Spain[5,6].

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) was evaluated with 1,640 specimens from different countries in an unpublished multi-center field study, 1,000 specimens from a blood donation center and 3,430 specimens from an in-house clinical study. Of the 6,070 total specimens (which included whole blood, serum and plasma specimens), 1,602 were found HIV seropositive and 4,468 specimens were found HIV seronegative by a characterization testing algorithm comprising of EIA and/or Western blot. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) showed 99.9% relative sensitivity, and 99.8% relative specificity compared to EIA and/or Western blot.

HIV 1/2/O Tri-line Rapid Test Device vs. EIA and/or Western blot

		EIA and/or Western blot		Total Results
HIV 1/2/O Tri-line Rapid Test Device	Results	Positive	Negative	
	Reactive	1,601	10	1,611
	Non-reactive	1	4,458	4,459
Total Results		1,602	4,468	6,070

Relative Sensitivity: 99.9% (99.7-100.0%)*
Relative Specificity: 99.8% (99.6-99.9%)*
Relative Accuracy: 99.8% (99.7-100.0%)*
* 95% Confidence Interval

Specimen Types Consistency

50 HIV seropositive whole blood and paired plasma specimens, 26 HIV seropositive whole blood, paired plasma and serum specimens, 50 negative whole blood, paired plasma and serum specimens were tested with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

EIA and/or Western blot	Specimen type	No. tested	HIV 1/2/O Tri-line Rapid Test Device	
			Non-reactive	Reactive
Negative	Plasma	50	50	0
	Serum	50	50	0
	Whole blood	50	50	0
Positive	Serum	26	0	26
	Plasma	76	0	76
	Whole blood	76	0	76

Paired whole blood, plasma, serum specimens show the consistent results with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

Precision

Intra-Assay (same lot)

Within-run precision has been determined by using 10 replicates of five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 **(subtype O)** positive, a medium titer HIV-1 positive and a HIV-2 positive. All above values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 (subtype O) positive, a medium titer HIV-1 positive and a HIV-2 positive. Three different lots of the HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using above specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. Delaney KP, Branson BM, Uniyal A, et al. *Evaluation of the Performance Characteristics of 6 Rapid HIV Antibody Tests.* Clinical Infectious Diseases. 2011; 52(2): 257-263.
2. O'Connell RJ, Merritt TM, Malia JA, et al. *Performance of the OraQuick Rapid Antibody Test for Diagnosis of Human Immunodeficiency Virus Type 1 Infection in Patients with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2003; 41(5):2153-2155
3. O'Connell RJ, Agan BK, Anderson SA, et al. *Sensitivity of the Multispot HIV-1/HIV-2 Rapid Test Using Samples from Human Immunodeficiency Virus Type 1-Positive Individuals with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2006; 44(5): 1831-1833
4. WHO HIV ASSAY REPORT 18: *Laboratory performance and other operational characteristics rapid diagnostic test.*
5. Requena S, Caballero E, Lozano AB, Ríos-Villegas MJ, Benito R, Rojo S, Cabezas T, Macià MD, Nieto MDC, Soriano V, de Mendoza C; *Spanish HIV-2 Study Group. Treatment outcome in dually HIV-1 and HIV-2 coinfected patients living in Spain.* AIDS. 2019 Nov 15;33(14):2167-2172.
6. Zbinden A, Dürig R, Shah C, Böni J, Schüpbach J. *Importance of an Early HIV Antibody Differentiation Immunoassay for Detection of Dual Infection with HIV-1 and HIV-2.* PLoS One. 2016 Jun 16;11(6):e0157690.

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

Technical Support

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

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

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

Asia-Pacific
+61 7 3363 7100
AP.TechSupport@abbott.com

Latin America
57 1 4824033
LA.TechSupport@abbott.com

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

© 2021 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.

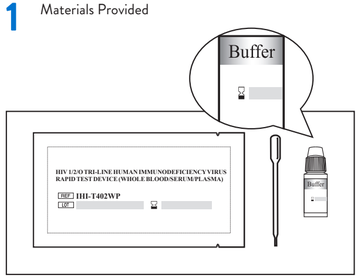
Abbott

ABON™

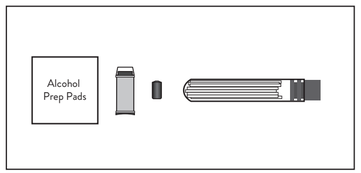
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE (WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

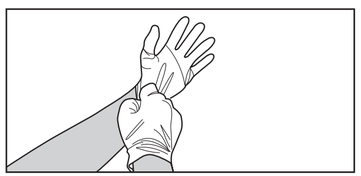
1 Materials Provided



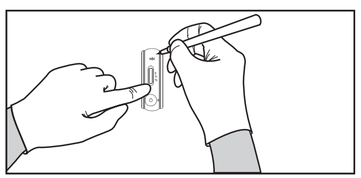
Materials Required But Not Provided



2 Wear gloves

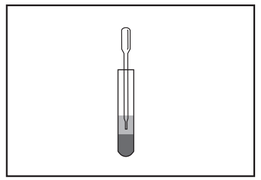


3 Open the pouch, Label with specimen ID.
Use it as soon as possible (within one hour).

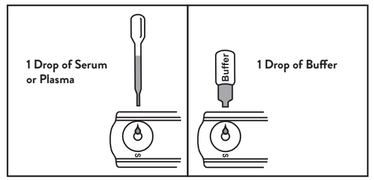


SERUM OR PLASMA SPECIMENS

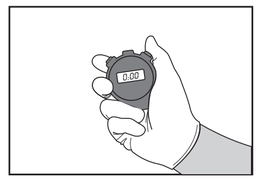
4 Draw the specimen from the specimen tube with a dropper.



5 Transfer 1 drop of serum or plasma (approximately 25 µL), then add 1 drop of buffer (approximately 40 µL).

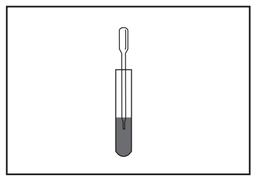


6 Start the timer.

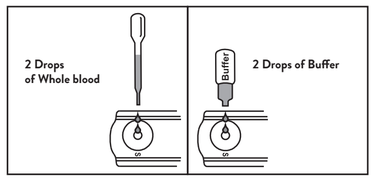


VENIPUNCTURE WHOLE BLOOD SPECIMENS

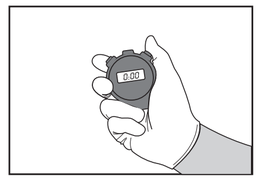
4 Draw the specimen from the specimen tube with a dropper.



5 Transfer 2 drops of whole blood (approximately 50 µL), then add 2 drops of buffer (approximately 80 µL).

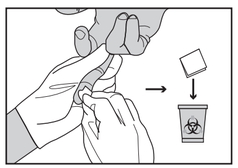


6 Start the timer.

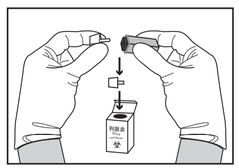


FINGERSTICK WHOLE BLOOD SPECIMENS

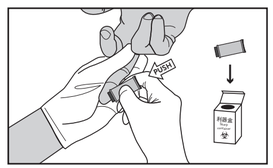
4 Clean entire fingertip (preferable 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



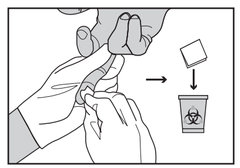
5 Take off the cap of the lancet and dispose the cap in sharps container.



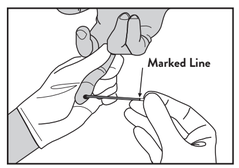
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



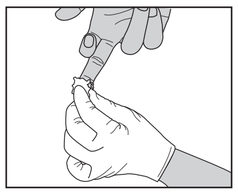
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



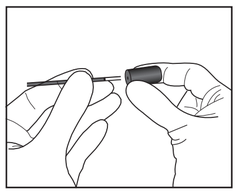
8 Immerse the open end of the capillary tube into the blood drop and allow for the blood to draw into the capillary tube up to marked line.



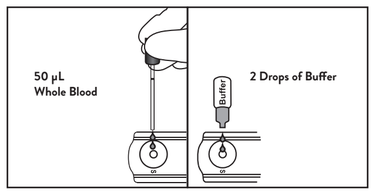
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



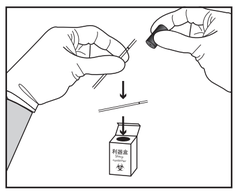
10 Place the bulb onto the top end of the capillary tube.



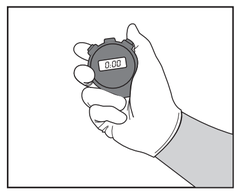
11 Squeeze the bulb to dispense all whole blood on the specimen well (approximately 50 µL) , then add 2 drops of buffer (approximately 80 µL).



12 Dispose the capillary tube in sharps container after testing.

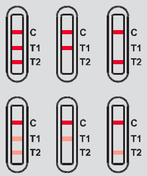


13 Start the timer.



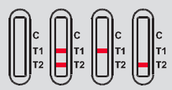
READ RESULTS

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



REACTIVE:* **Two or three distinct colored lines appear. One line should always appear in the control line region (C), and another one or two apparent colored line(s) should appear in the test line region(s) (T1 and/or T2).**
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
Note: The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.

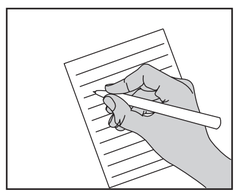
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).



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

CLEAR UP/RECORD

Dispose devices, gloves in a proper biohazard waste container.



Record the test results.

Abbott

1156213401

Date de révision: 2021-05-12
Mode d'emploi version 05

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

REF IHI-T402WA IVD

Mode d'emploi

Français

Un test de diagnostic rapide pour la détection qualitative des anticorps dirigés contre le virus de l'immunodéficience humaine (VIH) de type 1, y compris le sous-type O et le type 2, dans le sang total, le sérum ou le plasma.
Réservé exclusivement à un usage professionnel.

UTILISATION PRÉVUE

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) est un dosage immunochromatographique rapide de diagnostic *in vitro* pour la détection qualitative des anticorps dirigés contre le VIH-1, y compris le sous-type O et le VIH-2, dans les échantillons de sang total veineux et capillaire, de sérum et de plasma. Le produit peut être utilisé pour faciliter le diagnostic d'une infection par le VIH. Un résultat réactif doit être confirmé par des tests complémentaires dans le cadre d'un algorithme de dépistage du VIH validé. Ce produit n'a pas été évalué sur des échantillons pédiatriques et néonatals.

PRINCIPE

La bandelette de test de HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) est pré-enduite d'antigènes du VIH-1 et du sous-type O sur la ligne de test T1 et d'antigène du VIH-2 sur la ligne de test T2. Tout d'abord, l'échantillon puis le tampon sont ajoutés au puits d'échantillonnage, ce qui initie la migration de l'échantillon/du tampon. L'échantillon/le tampon passe par le tampon de conjugué qui contient un mélange d'antigènes de l'enveloppe du VIH-1, de la capside et de l'enveloppe du VIH-2. Ces antigènes de détection sont conjugués à des particules de latex. S'ils sont présents, les anticorps dirigés contre le VIH-1 ou le VIH-2 réagissent et se lient à l'antigène-conjugué de détection. Le mélange anticorps/antigène-conjugué migre ensuite plus loin et se lie aux antigènes présents sur les lignes de test. Si l'échantillon contient des anticorps au VIH-1, l'échantillon se liera à la ligne de test T1 et produira une ligne. Si l'échantillon contient des anticorps au VIH-2, l'échantillon se liera à la ligne de test T2. À mesure que le liquide migre vers le bas de la bandelette de test, la ligne de contrôle apparaît. Si la ligne de contrôle est présente, en plus d'une ou des deux lignes de test, alors le test est réactif pour les anticorps au VIH1/2. Si l'échantillon ne contient pas d'anticorps au VIH-1 ou au VIH-2, aucune ligne colorée ne s'affiche sur l'une ou l'autre zone de ligne de test, indiquant ainsi un résultat non réactif. Veuillez noter que l'apparition de lignes colorées sur les lignes de test T1 et T2 est peu probablement le signe d'une co-infection par le VIH-1 et le VIH-2, mais plutôt le résultat d'une réactivité croisée entre les antigènes. Une ligne colorée apparaît dans la zone de la ligne de contrôle si la migration du liquide est réussie. Elle doit être présente pour que le test soit valide. Si la ligne de contrôle n'apparaît pas, le résultat du test n'est pas valide.

CONSERVATION ET STABILITÉ

Conservez le produit conditionné dans la pochette scellée entre 2 et 30 °C (la conservation dans un réfrigérateur est autorisée). **Ne conservez pas le produit dans le congélateur**. Conservez le kit de test à l'abri de l'humidité. L'appareil de test est stable jusqu'à la date d'expiration imprimée sur le kit de test et/ou sur la pochette scellée de l'appareil de test. Ne l'utilisez pas au-delà de la date d'expiration. L'appareil de test doit rester dans sa pochette scellée jusqu'à son utilisation.

MISES EN GARDE ET PRÉCAUTIONS

- Pour une utilisation de diagnostic *in vitro* uniquement.
- Lisez attentivement les instructions avant de réaliser le test.
- Appliquez les précautions standard en matière de biosécurité lors de la manipulation et de l'élimination des matériels potentiellement infectieux.
- Manipulez tous les échantillons comme des échantillons potentiellement infectieux.
- Lors des tests, portez des vêtements de protection tels que des gants, des blouses de laboratoire et des lunettes de protection.
- L'appareil de test et ses accessoires doivent être mis au rebut dans une poubelle pour déchets présentant un risque biologique après le test.
- Ne mangez pas, ne buvez pas ou ne fumez pas dans la pièce où les échantillons et les kits sont manipulés.
- Évitez les éclaboussures et nettoyez-les immédiatement avec un désinfectant adapté.
- Le tampon contient 0,02 % d'azoture de sodium comme agent conservateur qui peut être toxique si ingéré. Lorsque vous le mettez au rebut dans l'évier, rincez avec de grandes quantités d'eau.
- N'utilisez pas le kit de test au-delà de la date d'expiration.
- Ne l'utilisez pas si l'emballage est endommagé.
- N'utilisez pas le tube capillaire héparinié, l'ampoule de distribution, le bistouri à usage unique et le tampon imbibé d'alcool s'ils sont déjà endommagés.
- Jetez le tube capillaire héparinié et le bistouri à usage unique dans la poubelle pour objets tranchants s'ils sont déjà endommagés avant utilisation.
- Ne posez pas le bistouri avant de le mettre au rebut.
- Ne réutilisez pas le bistouri.
- En cas de prophylaxie post-exposition au VIH, les opérateurs doivent se familiariser avec la politique de la PPE avant de réaliser les tests.
- L'humidité et la température peuvent affecter négativement les résultats.
- Le nombre optimal d'échantillons à tester en une seule fois est de 10.
- N'utilisez pas d'autres échantillons que ceux spécifiés. Pour le sang total par ponction veineuse/le plasma, l'EDTA-K$_2$/l'héparine de sodium/le citrate de sodium/l'héparine de lithium peuvent être utilisés comme anticoagulants. D'autres anticoagulants n'ont pas été testés et peuvent donner des résultats incorrects.
- Ne pas former de bulles d'air pendant l'ajout de l'échantillon. La formation de bulles peut entraîner l'ajout d'un volume d'échantillon insuffisant et par conséquent un faux résultat non réactif.

PRÉLÈVEMENT D'ÉCHANTILLONS ET PRÉPARATION

- HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) peut être utilisé avec du sang total (par ponction veineuse ou prélèvement au doigt), du sérum ou du plasma.
- Pour prélever des échantillons de **sang total par prélèvement au doigt :**
  - Portez des gants.
  - Nettoyez le bout du doigt (de préférence le 3e ou 4e doigt de lamain non dominante) avec un tampon imbibé d'alcool. Laissez sécher (30 secondes).
  - Effectuez une ponction sur le côté du doigt avec un nouveau bistouri à chaque fois. Mettez le bistouri au rebut dans la poubelle pour objets tranchants immédiatement après son utilisation. N'utilisez pas le bistouri si le capuchon a déjà été retiré. Essuyez la première goutte de sang avec un tampon de gaze ou un morceau de coton stérile.
- Pour recueillir un échantillon de sang total par prélèvement au doigt à l'aide d'un tube capillaire :
  - Plongez l'extrémité ouverte du tube capillaire dans la goutte de sang et laissez le sang remonter dans le tube capillaire jusqu'à la ligne de remplissage marquée. Évitez les bulles d'air.
  - Après le prélèvement de l'échantillon, placez un tampon de gaze ou un morceau de coton sur le doigt jusqu'à l'arrêt du saignement.
  - Placez l'ampoule sur l'extrémité supérieure du tube capillaire, puis appuyez sur l'ampoule pour distribuer tout le sang total sur le puits d'échantillonnage (S) de l'appareil de test pour les tests.
  - Jetez le tube capillaire dans la poubelle pour objets tranchants après les tests.
- Pour prélever des échantillons de **sérum, de plasma ou de sang total par ponction veineuse :**
  - Prélevez en respectant les procédures de phlébotomie sécurisées, en utilisant la technique du vide dans des tubes pour les préparations de sérum, de plasma ou de sang total par ponction veineuse.
  - Préparez le sérum ou le plasma à partir du sang total dès que possible pour éviter l'hémolyse. N'utilisez pas d'échantillons troubles ou hémolysés.
- Les tests doivent être effectués immédiatement après le prélèvement d'échantillon. Ne laissez pas les échantillons à température ambiante (entre 15 et 30 °C) pendant des périodes prolongées. Les échantillons de sérum et de plasma peuvent être conservés entre 2 et 8 °C jusqu'à 3 jours. Pour la conservation à long terme, les échantillons doivent être conservés à -20 °C. Le sang total prélevé par ponction veineuse doit être conservé entre 2 et 8 °C si le test doit être réalisé dans les 2 jours suivant le prélèvement. Ne congelez pas les échantillons de sang total. Le sang total prélevé par prélèvement au doigt doit être testé immédiatement.
- Laissez les échantillons s'équilibrer à température ambiante avant de réaliser les tests. Les échantillons congelés doivent être complètement décongelés et mélangés avant de commencer le test.
- Aucune différence de performance qualitative n'a été observée entre les contrôles expérimentaux et 20 échantillons non réactifs ou 20 échantillons réactifs soumis à 6 cycles de congélation/décongélation; cependant, plusieurs cycles de congélation/décongélation doivent être évités.

MATÉRIEL

Matériel fourni

Composants	IHI-T402WA
Appareil de test	x40
Tampon de 3 ml	x2
Compte-gouttes à échantillon (Pour sérum/plasma/sang total par ponction veineuse)	x40
Mode d'emploi	x1

Matériel requis mais non fourni

- Équipement de prélèvement d'échantillons et conteneurs
- Bistouris à usage unique, tampons imbibés d'alcool, coton ou tampon de gaze (pour sang total par prélèvement au doigt uniquement)
- Centrifugeuse
- Chronomètre
- Tubes capillaires héparinés avec une ligne de remplissage marquée à 50 µl et ampoule de distribution (pour sang total par prélèvement au doigt uniquement)
- Poubelles pour déchets présentant un risque biologique pour objets tranchants et non tranchants

PROCÉDURE DE TEST

Laissez l'appareil de test, le tampon et l'échantillon s'équilibrer à température ambiante (entre 15 et 30 °C) avant le test.

1. Retirez l'appareil de test de la pochette en aluminium et utilisez-le dès que possible (dans l'heure).
2. Placez l'appareil de test sur une surface propre et plane. Étiquetez avec l'ID de l'échantillon. Commencer ensuite à ajouter l'échantillon et le tampon. Éviter la formation de bulles lors de l'ajout de l'échantillon et du tampon.
   Pour les échantillons de **sérum ou de plasma :** Tenez le compte-gouttes à la verticale et **transférez 1 goutte de sérum ou de plasma** (environ 25 µl) dans le puits d'échantillonnage (S) de l'appareil de test, puis **ajoutez 1 goutte de tampon** (environ 40 µl) et lancez le chronomètre.
   Pour les échantillons de **sang total par ponction veineuse :** Tenez le compte-gouttes à la verticale et **transférez 2 gouttes de sang total** (environ 50 µl) dans le puits d'échantillonnage (S) de l'appareil de test, puis **ajoutez 2 gouttes de tampon** (environ 80 µl) et lancez le chronomètre.
   Pour les échantillons de **sang par prélèvement au doigt :** Prélevez un échantillon de sang total avec un tube capillaire de 50 µl jusqu'à la ligne de remplissage marquée. **Ajoutez l'échantillon** (50 µl) sur le puits d'échantillonnage (S) de l'appareil de test, puis **ajoutez 2 gouttes de tampon** (environ 80 µl) et lancez le chronomètre.
3. Attendez qu'une ou plusieurs lignes colorées apparaissent. **Lisez les résultats au bout de 10 minutes. Ne lisez pas les résultats après 20 minutes.**

INTERPRÉTATION DES RÉSULTATS

RÉACTIF :* Deux ou trois lignes colorées différentes apparaissent. Une ligne doit toujours apparaître dans la zone de ligne de contrôle (C) et une ou deux lignes colorées apparentes devraient apparaître dans les zones de lignes de test (T1 et/ou T2).
RÉACTIF AU VIH-1 : Si la ligne de contrôle (C) et la ligne de test T1 apparaissent, cela indique un résultat réactif à l'infection par le VIH-1.
RÉACTIF AU VIH-2 : Si la ligne de contrôle (C) et la ligne de test T2 apparaissent, cela indique un résultat réactif à l'infection par le VIH-2.
Si la ligne de contrôle (C) et les lignes de test T1 et T2 apparaissent, cela est plus susceptible d'être causé par une réactivité croisée, due à une certaine similarité des séquences d'acides aminés du VIH-1 et du VIH-2. Il peut s'agir d'une seule infection par le VIH-1/VIH-2 ou d'une double infection par le VIH-1 et le VIH-2. Dans ce cas, il est impossible d'établir un résultat discriminant et un test supplémentaire de différenciation des anticorps est nécessaire. Veuillez vous reporter à la section Limitation pour connaître le taux estimé de réactivité croisée entre le VIH-1 et le VIH-2 pour ce produit et les cas de double infection signalés.
Remarque : L'intensité de la couleur dans la zone de ligne de test (T1 et/ou T2) peut varier, mais n'importe quelle nuance de couleur dans la zone de ligne de test (T1 et/ou T2) doit être considérée comme réactive.
NON RÉACTIF : Une ligne colorée apparaît dans la zone de contrôle (C). Aucune ligne colorée n'apparaît dans les zones de lignes de test (T1 et/ou T2).
NON VALIDE : Aucune ligne n'apparaît dans la zone de ligne de contrôle (C). Si tel est le cas, lisez la procédure de test et répétez le test avec un nouvel appareil de test. Si le résultat n'est toujours pas valide, arrêtez immédiatement d'utiliser le kit de test et contactez votre distributeur local.

CONTRÔLE QUALITÉ

Une ligne de contrôle est incluse dans le test en tant que contrôle interne. Le test doit absorber le liquide et lui permettre de migrer le long de la membrane pour que la ligne de contrôle apparaisse. Le contrôle de procédure interne repose sur l'apparition d'une ligne colorée dans la zone de contrôle (C).
Les échantillons de contrôle qualité ne sont pas fournis avec ce kit. Cependant, il est recommandé que les échantillons de contrôle qualité soient testés en tant que bonnes pratiques de laboratoire.

LIMITATION

1. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) est conçu pour une utilisation de diagnostic *in vitro* uniquement. Ce test doit être utilisé pour la détection des anticorps dirigés contre le VIH-1/2 dans le sang total, le sérum ou le plasma humain. La concentration d'anticorps au VIH-1/2 ne peut pas être déterminée par ce test qualitatif.
2. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) indique uniquement la présence d'anticorps au VIH-1/2 dans l'échantillon et ne doit pas être utilisé comme seul critère dans le diagnostic d'une infection par le VIH-1, le VIH-2 et/ou le VIH-1 sous-type O.
3. Pour confirmer les résultats réactifs des tests, les échantillons doivent subir d'autres tests à l'aide de différents dosages, tels que les tests de diagnostic rapide, l'EIA et/ou le Western blot (technique des immuno-empreintes) conformément à un algorithme de dépistage du VIH validé.
4. Comme pour tous les tests de diagnostic, tous les résultats doivent être interprétés conjointement avec les autres informations cliniques à la disposition du médecin.
5. Les résultats ne doivent pas être utilisés pour déterminer le génotype des infections par le VIH.
6. En raison d'une possible réactivité croisée des anticorps, l'apparition de lignes dans les lignes T1 et T2 n'indique pas nécessairement une co-infection par le VIH-1 et le VIH-2.
7. De faux résultats réactifs peuvent survenir en raison de facteurs rhumatoïdes, d'anticorps antinucléaires, d'autres infections virales (par exemple, l'hépatite B ou l'hépatite C), d'infections parasitaires (par exemple, la schistosomiase et la trypanosomiase), de composants de test endommagés par la chaleur ou l'humidité, ou de la substitution d'autres composants du kit de test (p. ex. les compte-gouttes ou le tampon) entre plusieurs kits de test.
8. De faux résultats non réactifs peuvent survenir lorsque les titres des anticorps au VIH-1/2 sont très faibles, lorsque les titres des anticorps au VIH-1/2 sont très élevés (effet « High-hook »), lorsqu'un volume insuffisant d'échantillon est ajouté, lorsqu'un volume excessif de tampon est ajouté ou lorsque des composants de test sont endommagés par la chaleur ou l'humidité.
9. Des faux négatifs peuvent être observés chez les individus recevant un traitement antirétroviral efficace. [1,2,3]
10. Le taux estimé de réactivité croisée entre les échantillons positifs au VIH-1 et au VIH-2 était de 32,6 % en utilisant HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)[4]. Bien que la double infection par le VIH-1 et le VIH-2 soit peu courante, il a été signalé que 9 % des personnes présentant une infection par le VIH-2 sont co-infectées par le VIH-1 en Espagne[5,6].

CARACTÉRISTIQUES DE PERFORMANCE

Sensibilité clinique, spécificité et précision

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) a été évalué avec 1 640 échantillons provenant de différents pays dans une étude de terrain multicentrique non publiée, avec 1 000 échantillons dans un centre de don du sang et avec 3 430 échantillons dans une étude clinique en interne. Sur les 6 070 échantillons au total (qui comprennent du sang total, du sérum et du plasma), 1 602 se sont révélés séropositifs au VIH et 4 468 échantillons se sont révélés séronégatifs au VIH par un algorithme de test de caractérisation comprenant une EIA et/ou un Western blot (technique des immunoempreintes). HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) a montré une sensibilité relative de 99,9 % et une spécificité relative de 99,8 % par rapport à l'EIA et/ou au Western blot (technique des immuno-empreintes).

Appareil de test rapide tri-ligne VIH 1/2/O contre EIA et/ou Western blot (technique des immuno-empreintes)

		EIA et/ou Western blot (technique des immuno-empreintes)		Résultats totaux
	Résultats	Positif	Negative	
Appareil de test rapide tri-ligne VIH 1/2/O	Réactif	1 601	10	1 611
	Non réactif	1	4 458	4 459
Résultats totaux		1 602	4 468	6 070

Sensibilité relative : 99,9 % (99,7-100,0 %)*
Spécificité relative : 99,8 % (99,6-99,9 %)*
Précision relative : 99,8 % (99,7-100,0 %)*
* Intervalle de confiance de 95 %

Homogénéité des types d'échantillons

50 échantillons appariés de plasma et de sang total séropositifs au VIH, 26 échantillons appariés de plasma, de sérum et de sang total séropositifs au VIH et 50 échantillons appariés de plasma, de sérum et de sang total négatifs ont été testés avec HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

EIA et/ou Western blot (technique des immuno-empreintes)	Type d'échantillon	Nombre testé	Appareil de test rapide tri-ligne VIH 1/2/O	
			Non réactif	Réactif
Négatif	Plasma	50	50	0
	Sérum	50	50	0
	Sang total	50	50	0
Positif	Sérum	26	0	26
	Plasma	76	0	76
	Sang total	76	0	76

Les échantillons appariés de sang total, de plasma et de sérum montrent des résultats cohérents avec HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

Précision

Intradosage (même lot)

La précision pendant un cycle a été déterminée à l'aide de 10 reproductions de cinq échantillons : un négatif, un positif au VIH-1 au titre faible, un positif au VIH-1 **(sous-type O)** au titre faible, un positif au VIH-1 au titre moyen et un positif au VIH-2. Toutes les valeurs ci-dessus ont été identifiées correctement >99 % du temps.

Intradosage

La précision pendant un cycle a été déterminée par 10 dosages indépendants sur les cinq mêmes échantillons: un négatif, un positif au VIH-1 au titre faible, un positif au VIH-1 (sous-type O) au titre faible, un positif au VIH-1 au titre moyen et un positif au VIH-2. Trois lots différents de HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) ont été testés à l'aide des échantillons ci-dessus. Les échantillons ont été identifiés correctement >99 % du temps.

BIBLIOGRAPHIE

1. K.P. Delaney, B.M. Branson, A. Uniyal, et al. *Evaluation of the Performance Characteristics of 6 Rapid HIV Antibody Tests.* Clinical Infectious Diseases. 2011 ; 52 (2) : 257-263.
2. R.J. O'Connell, T.M. Merritt, J.A. Malia, *et al. Performance of the OraQuick Rapid Antibody Test for Diagnosis of Human Immunodeficiency Virus Type 1 Infection in Patients with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2003 ; 41 (5) : 2153-2155
3. R.J. O'Connell, B.K. Agan, S.A. Anderson, *et al. Sensitivity of the Multispot HIV-1/HIV-2 Rapid Test Using Samples from Human Immunodeficiency Virus Type 1-Positive Individuals with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2006 ; 44 (5) : 1831-1833
4. WHO HIV ASSAY REPORT 18: *Laboratory performance and other operational characteristics rapid diagnostic test.*
5. Requena S, Caballero E, Lozano AB, Ríos-Villegas MJ, Benito R, Rojo S, Cabezas T, Macià MD, Nieto MDC, Soriano V, de Mendoza C; *Spanish HIV-2 Study Group. Treatment outcome in dually HIV-1 and HIV-2 coinfected patients living in Spain.* AIDS. 2019 Nov 15;33(14):2167-2172.
6. Zbinden A, Dürig R, Shah C, Böni J, Schüpbach J. *Importance of an Early HIV Antibody Differentiation Immunoassay for Detection of Dual Infection with HIV-1 and HIV-2.* PLoS One. 2016 Jun 16;11(6):e0157690.

Index des symboles

	Consulter les instructions d'utilisation		Contenu suffisant pour <n> tests	REF	Référence catalogue
LOT	Code de lot		Date d'expiration		Ne pas réutiliser
2°C 30°C	Conservation entre 2 et 30 °C		Fabricant	IVD	Dispositif médical de diagnostic in vitro

Support Technique

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

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

© 2021 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.

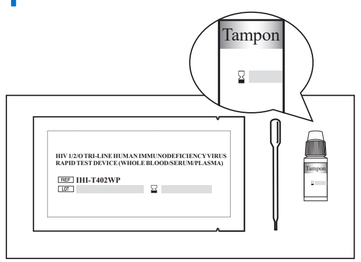
Abbott

ABON™

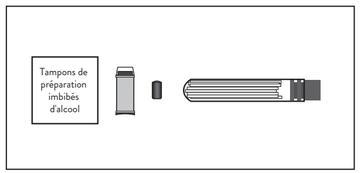
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PRÉPARATION

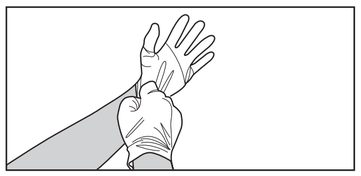
1 Matériel fourni



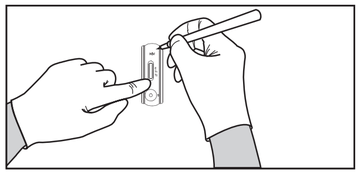
Matériel requis mais non fourni



2 Portez des gants.

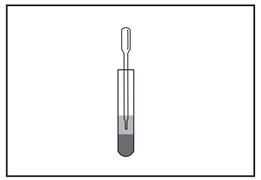


3 Ouvrez le sachet, étiquetez avec l'ID de l'échantillon. Utilisez-le dès que possible (dans l'heure).

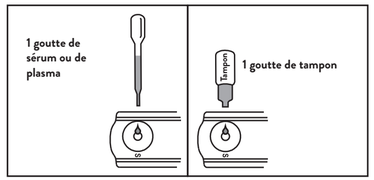


ÉCHANTILLONS DE SÉRUM OU DE PLASMA

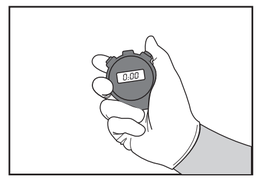
4 Prélevez l'échantillon du tube d'échantillon avec un compte-gouttes.



5 Transférez 1 goutte de sérum ou de plasma (environ 25 µl), puis ajoutez 1 goutte de tampon (environ 40 µl).

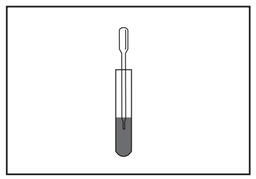


6 Lancez le chronomètre.

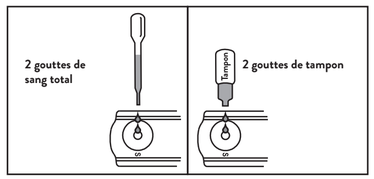


ÉCHANTILLONS DE SANG TOTAL PAR PONCTION VEINEUSE

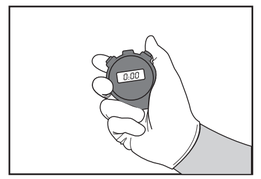
4 Prélevez l'échantillon du tube d'échantillon avec un compte-gouttes.



5 Transférez 2 gouttes de sang total (environ 50 µl), puis ajoutez 2 gouttes de tampon (environ 80 µl).

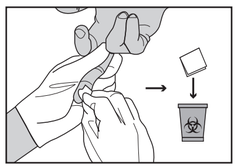


6 Lancez le chronomètre.

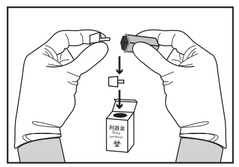


ÉCHANTILLONS DE SANG TOTAL PAR PRÉLÈVEMENT AU DOIGT

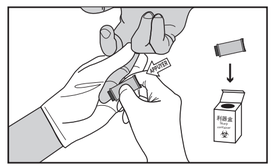
4 Nettoyez le bout du doigt (de préférence le 3e ou 4e doigt de la main non dominante) avec un tampon imbibé d'alcool. Jetez le tampon imbibé d'alcool.



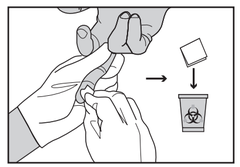
5 Retirez le capuchon du bistouri et jetez le capuchon dans une poubelle pour objets tranchants.



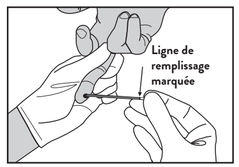
6 Effectuez une ponction sur le côté du doigt. Mettez le bistouri au rebut dans la poubelle pour objets tranchants immédiatement après son utilisation.



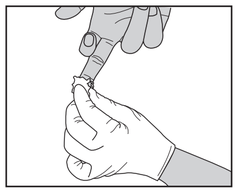
7 Essuyez la première goutte de sang avec un tampon de gaze ou un morceau de coton stérile.



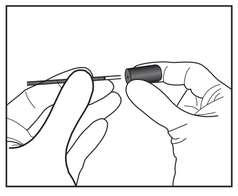
8 Plongez l'extrémité ouverte du tube capillaire dans la goutte de sang et laissez le sang remonter dans le tube capillaire jusqu'à la ligne de remplissage marquée.



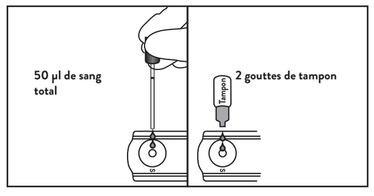
9 Après le prélèvement de l'échantillon, placez un tampon de gaze ou de coton sur le doigt jusqu'à l'arrêt du saignement.



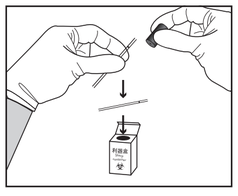
10 Placez l'ampoule sur l'extrémité supérieure du tube capillaire.



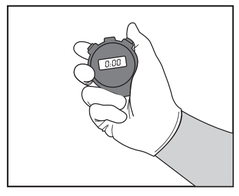
11 Appuyez sur l'ampoule pour distribuer tout le sang total sur le puits d'échantillonnage (environ 50 µl), puis ajoutez 2 gouttes de tampon (environ 80 µl).



12 Jetez le tube capillaire dans la poubelle pour objets tranchants après les tests.

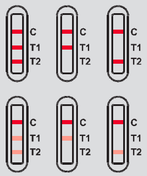


13 Lancez le chronomètre.



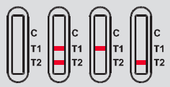
LECTURE DES RÉSULTATS

Attendez qu'une ou plusieurs lignes colorées apparaissent.
Lisez les résultats au bout de **10 à 20 minutes.**



RÉACTIF :* Deux ou trois lignes colorées différentes apparaissent. Une ligne doit toujours apparaître dans la zone de ligne de contrôle (C) et une ou deux lignes colorées apparentes devraient apparaître dans les zones de lignes de test (T1 et/ou T2).
RÉACTIF AU VIH-1 : Si la ligne de contrôle (C) et la ligne de test T1 apparaissent, cela indique un résultat réactif à l'infection par le VIH-1.
RÉACTIF AU VIH-2 : Si la ligne de contrôle (C) et la ligne de test T2 apparaissent, cela indique un résultat réactif à l'infection par le VIH-2.
Si la ligne de contrôle (C) et les lignes de test T1 et T2 apparaissent, cela est plus susceptible d'être causé par une réactivité croisée, due à une certaine similarité des séquences d'acides aminés du VIH-1 et du VIH-2. Il peut s'agir d'une seule infection par le VIH-1/VIH-2 ou d'une double infection par le VIH-1 et le VIH-2. Dans ce cas, il est impossible d'établir un résultat discriminant et un test supplémentaire de différenciation des anticorps est nécessaire. Veuillez vous reporter à la section Limitation pour connaître le taux estimé de réactivité croisée entre le VIH-1 et le VIH-2 pour ce produit et les cas de double infection signalés.
Remarque : L'intensité de la couleur dans la zone de ligne de test (T1 et/ou T2) peut varier, mais n'importe quelle nuance de couleur dans la zone de ligne de test (T1 et/ou T2) doit être considérée comme réactive.

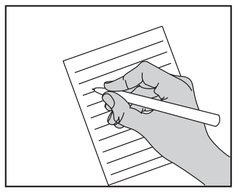
NON RÉACTIF : Une ligne colorée apparaît dans la zone de contrôle (C). Aucune ligne colorée n'apparaît dans les zones de lignes de test (T1 et/ou T2).



NON VALIDE : Aucune ligne n'apparaît dans la zone de ligne de contrôle (C). Si tel est le cas, lisez la procédure de test et répétez le test avec un nouvel appareil de test. Si le résultat n'est toujours pas valide, arrêtez immédiatement d'utiliser le kit de test et contactez votre distributeur local.

LECTURE DES RÉSULTATS

Mettez les appareils et les gants au rebut dans une poubelle pour les déchets présentant un risque biologique.



Enregistrez les résultats des tests.

Abbott

1156230801

Revision date: 2022-02-22
IFU version 01

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

REF IHI-T402WE IVD

Instructions for Use

English

A rapid diagnostic test for the qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) type 1, including subtype O, and type 2 in whole blood, serum or plasma.
For professional use only.

INTENDED USE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is an *in vitro* diagnostic rapid immunochromatographic assay for the qualitative detection of antibodies to HIV-1, including subtype O, and HIV-2 in venous and capillary whole blood, serum and plasma specimens. The product may be used as an aid in the diagnosis of HIV infection. A reactive result should be confirmed by supplemental testing as part of a validated HIV testing algorithm. This product has not been evaluated on paediatric and neonatal specimens.

PRINCIPLE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) test strip is pre-coated with HIV-1 and subtype O antigens on T1 test line and HIV-2 antigen on T2 test line. Firstly, specimen and then buffer is added to the specimen well, thus starting the migration of the specimen/buffer. The specimen/buffer passes the conjugate pad which contains a mixture of HIV-1 envelope and capsid antigen and HIV-2 envelope antigen. These detection antigens are conjugated to latex particles. If present, the HIV-1 or HIV-2 antibodies react and bind to the detection antigen-conjugate. The antibody/antigen-conjugate mixture then migrates further and binds to antigens present on the test lines. If the specimen contains antibodies to HIV-1, the specimen will bind to the T1 test line and produce a line, if specimen contains antibodies to HIV-2, the specimen will bind to the T2 test line. As liquid continues to migrate down the test strip, the control line will appear. If the control line is present, in addition to either or both test lines, then the test is reactive for HIV1/2 antibodies. If the specimen does not contain HIV-1 or HIV-2 antibodies, no colored lines will appear for either of the test lines region indicating a non-reactive result. Please note that the appearance of colored lines at T1 and T2 is highly unlikely to be indicative of co-infection with HIV-1 and HIV-2 but rather is a result of cross-reactivity between antigens. A colored line will appear in the control line region if the migration of liquid has been successful, and must be present for the test to be valid. If the control line does not appear, the test result is not valid.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (storage in refrigerator is permitted). **Do not store in the freezer**. Protect the test kit from humidity. The test device is stable until the expiration date printed on the test kit and/or sealed test device pouch. Do not use beyond the expiration date. The test device must remain in the sealed pouch until use.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Read the instruction carefully before performing the test.
- Apply standard biosafety precautions when handling and disposing of potentially infectious material.
- Handle all specimens as potentially infectious.
- Wear protective clothing such as gloves, laboratory coats, and eye protection when specimens are being tested.
- The test device and accessory should be disposed in a proper biohazard waste container after testing.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Avoid splashes and clean up spills immediately with appropriate disinfectant.
- The buffer contains 0.02% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities of water.
- Do not use the test kit beyond the expiration date.
- Do not use if the packaging is damaged.
- Do not use the capillary tube (for fingerstick whole blood), single-use lancet or alcohol pad if it is already damaged.
- Dispose the capillary tube (for fingerstick whole blood) and single-use lancet in the sharps container if it is already damaged before use.
- Do not set the lancet down before discarding it.
- Do not reuse the lancet.
- In case of Post-exposure prophylaxis for HIV, operators should familiarize themselves with PPE policy prior to conducting the testing.
- Humidity and temperature can adversely affect results.
- The optimal number of specimens to be tested at one time is 10.
- Do not use any other specimen than those specified. For plasma/venipuncture whole blood, EDTA-K_2/sodium heparin/sodium citrate/lithium heparin can be used as anticoagulant. Other anticoagulants have not been tested and may give incorrect results.
- Do not form air bubbles during addition of specimen. Bubble formation may lead to insufficient specimen volume added and a false non-reactive result may occur accordingly.

SPECIMEN COLLECTION AND PREPARATION

- HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **fingerstick whole blood** specimens:
  - Wear gloves.
  - Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Allow to dry (30 seconds).
  - Puncture the side of the finger with a new lancet each time. Dispose the lancet in sharps container immediately after using it. Do not use the lancet if the cap is already pulled off. Wipe away the first blood drop with a sterile gauze pad or cotton wool.
  - Hold the provided capillary tube (for fingerstick whole blood) horizontally below the bulb. DO NOT TOUCH OR SQUEEZE BULB.
  - Immerse the open end of the capillary tube into the blood drop and let the blood rise by capillarity to the **joint** (volume position). Avoid air bubbles.
  - Squeeze the bulb and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).
- To collect **serum or plasma or venipuncture whole blood** specimens:
  - Collect according to safe phlebotomy procedures, using vacuum technique into 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.

SPECIMEN STORAGE

- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature (15-30°C) for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be stored at -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 experimental controls and 20 nonreactive or 20 reactive specimens subjected to 6 freeze/thaw cycles; however, multiple freeze/thaw cycles should be avoided.

MATERIALS

Materials Provided

Components	IHI-T402WE
1. Test Device	x40
2. Specimen Dropper (For Serum/Plasma/Venipuncture Whole Blood)	x40
3. 3mL Buffer	x2
4. Alcohol Swab	x40
5. Single-use Lancet	x40
6. Capillary Tube (For Fingerstick Whole Blood)	x40
7. Instructions for Use	x1

Materials Required But Not Provided

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

TEST PROCEDURE

Allow the test device, buffer and specimen to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible (within one hour).
2. Place the test device on a clean and level surface. Label with specimen ID. Add specimen and buffer. Avoid bubbles formation during addition of specimen and buffer.
   For **serum or plasma** specimens: Hold the specimen dropper (for serum/plasma/venipuncture whole blood) vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µL) and start the timer.
   For **venipuncture whole blood** specimens: Hold the specimen dropper (for serum/plasma/venipuncture whole blood) vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
   For **fingerstick whole blood** specimens: Take whole blood specimen with the 50 µL capillary tube (for fingerstick whole blood) until **joint** (volume position). And **add specimen** (approximately 50 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes. Do not read results after 20 minutes.**

INTERPRETATION OF RESULTS

REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
***Note:** The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).
INVALID: No line appears in the control line region (C). If this occurs, read the test procedure again and repeat the test with a new test device. If the result is still invalid, stop using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A control line is included in the test as an internal control. The test must absorb liquid and allow it to migrate along the membrane for the control line to appear. A colored line appearing in the control region (C) is the internal procedural control.
Quality control specimens are not supplied with this kit; however, it is recommended that quality control specimens be tested as a good laboratory practice.

LIMITATION

1. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HIV-1/2 in human whole blood, serum or plasma. The concentration of antibodies to HIV-1/2 can not be determined by this qualitative test.
2. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HIV-1/2 in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1, HIV-2, and/or HIV-1 subtype O infection.
3. For confirmation of reactive test results, specimens should undergo further testing using different assays, such as rapid diagnostic tests, EIA and/or Western blotting in accordance with a validated HIV testing algorithm.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Results should not be used to determine the genotype of HIV infections.
6. Due to possible antibody cross reactivity, the appearance of lines in both T1 and T2 does not necessarily indicate co-infection from HIV-1 and HIV-2.
7. False reactive results may arise due to rheumatoid factors, antinuclear antibodies, other viral infections (i.e. hepatitis B or hepatitis C), parasitic infections (i.e. schistosomiasis and trypanosomiasis), damage to test components by heat or humidity, or other test kit components (e.g. buffer or droppers) substituted between test kits.
8. False non-reactive results may arise when titers of antibodies to HIV1/2 are very low, titers of antibodies to HIV1/2 are very high (high-hook effect), insufficient specimen volume added, excess of buffer was added, or damage to test components by heat or humidity.
9. False-negative results may be observed in individuals who are receiving effective antiretroviral therapy. [1,2,3]
10. The estimated rate of Cross-reactivity between HIV-1 and HIV-2 positive samples was 32.6% using HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)[4]. Although dual infection of HIV-1 and HIV-2 is uncommon, it is reported that 9% of individuals with HIV-2 infection are coinfected with HIV-1 in Spain[5,6].

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) was evaluated with 1,640 specimens from different countries in an unpublished multi-center field study, 1,000 specimens from a blood donation center and 3,430 specimens from an in-house clinical study. Of the 6,070 total specimens (which included whole blood, serum and plasma specimens), 1,602 were found HIV seropositive and 4,468 specimens were found HIV seronegative by a characterization testing algorithm comprising of EIA and/or Western blot. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/ Serum/Plasma) showed 99.9% relative sensitivity, and 99.8% relative specificity compared to EIA and/or Western blot.

HIV 1/2/O Tri-line Rapid Test Device vs. EIA and/or Western blot

		EIA and/or Western blot		Total Results
	Results	Positive	Negative	
HIV 1/2/O Tri-line Rapid Test Device	Reactive	1,601	10	1,611
	Non-reactive	1	4,458	4,459
Total Results		1,602	4,468	6,070

Relative Sensitivity: 99.9% (99.7-100.0%)*
Relative Specificity: 99.8% (99.6-99.9%)*
Relative Accuracy: 99.8% (99.7-100.0%)*
* 95% Confidence Interval

Specimen Types Consistency

50 HIV seropositive whole blood and paired plasma specimens, 26 HIV seropositive whole blood, paired plasma and serum specimens, 50 negative whole blood, paired plasma and serum specimens were tested with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

EIA and/or Western blot	Specimen type	No. tested	HIV 1/2/O Tri-line Rapid Test Device	
			Non-reactive	Reactive
Negative	Plasma	50	50	0
	Serum	50	50	0
	Whole blood	50	50	0
Positive	Serum	26	0	26
	Plasma	76	0	76
	Whole blood	76	0	76

Paired whole blood, plasma, serum specimens show the consistent results with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

Precision

Intra-Assay (same lot)

Within-run precision has been determined by using 10 replicates of five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 **(subtype O)** positive, a medium titer HIV-1 positive and a HIV-2 positive. All above values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 (subtype O) positive, a medium titer HIV-1 positive and a HIV-2 positive. Three different lots of the HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/ Plasma) have been tested using above specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. Delaney KP, Branson BM, Uniyal A, et al. *Evaluation of the Performance Characteristics of 6 Rapid HIV Antibody Tests.* Clinical Infectious Diseases. 2011; 52(2): 257-263.
2. O'Connell RJ, Merritt TM, Malia JA, et al. *Performance of the OraQuick Rapid Antibody Test for Diagnosis of Human Immunodeficiency Virus Type 1 Infection in Patients with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2003; 41(5):2153-2155
3. O'Connell RJ, Agan BK, Anderson SA, et al. *Sensitivity of the Multispot HIV-1/HIV-2 Rapid Test Using Samples from Human Immunodeficiency Virus Type 1-Positive Individuals with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2006; 44(5): 1831-1833
4. WHO HIV ASSAY REPORT 18: *Laboratory performance and other operational characteristics rapid diagnostic test*.
5. Requena S, Caballero E, Lozano AB, Ríos-Villegas MJ, Benito R, Rojo S, Cabezas T, Macià MD, Nieto MDC, Soriano V, de Mendoza C; *Spanish HIV-2 Study Group. Treatment outcome in dually HIV-1 and HIV-2 coinfected patients living in Spain*. AIDS. 2019 Nov 15;33(14):2167-2172.
6. Zbinden A, Dürig R, Shah C, Böni J, Schüpbach J. *Importance of an Early HIV Antibody Differentiation Immunoassay for Detection of Dual Infection with HIV-1 and HIV-2*. PLoS One. 2016 Jun 16;11(6):e0157690.

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

Technical Support

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

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

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

Asia-Pacific
+61 7 3363 7100
AP.TechSupport@abbott.com

Latin America
57 1 4824033
LA.TechSupport@abbott.com

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

© 2022 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.

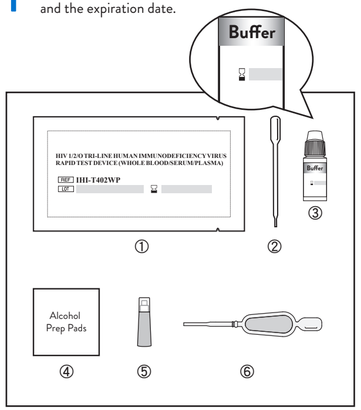
Abbott

ABON™

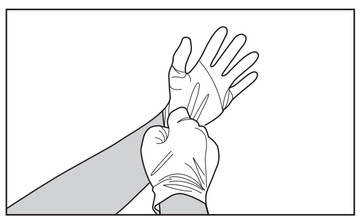
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

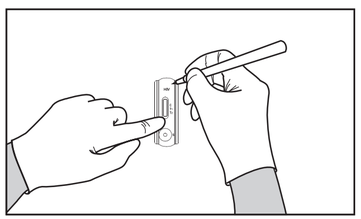
1 Open the package and check the content and the expiration date.



2 Wear gloves

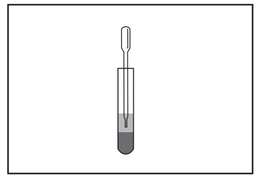


3 Open the pouch, Label with specimen ID. Use it as soon as possible (within one hour).

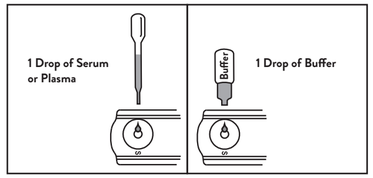


SERUM OR PLASMA SPECIMENS

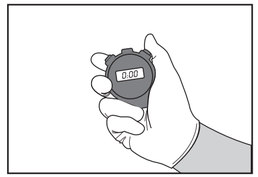
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



5 Transfer 1 drop of serum or plasma (approximately 25 µL), then add 1 drop of buffer (approximately 40 µL).

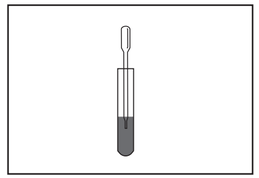


6 Start the timer.

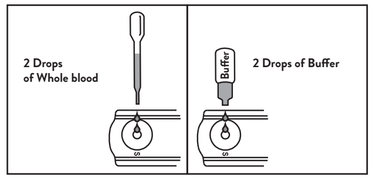


VENIPUNCTURE WHOLE BLOOD SPECIMENS

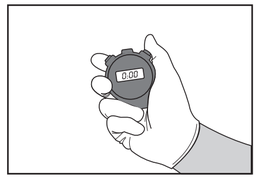
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



5 Transfer 2 drops of whole blood (approximately 50 µL), then add 2 drops of buffer (approximately 80 µL).

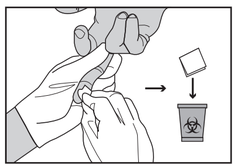


6 Start the timer.

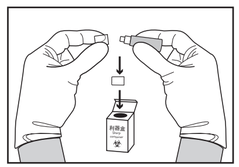


FINGERSTICK WHOLE BLOOD SPECIMENS

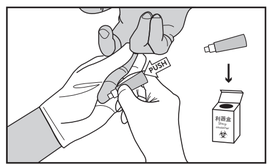
4 Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



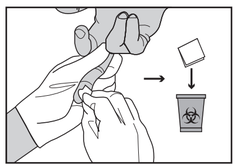
5 Take off the cap of the lancet and dispose the cap in sharps container.



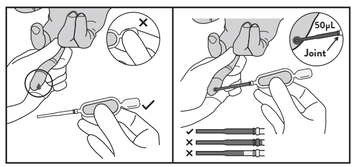
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



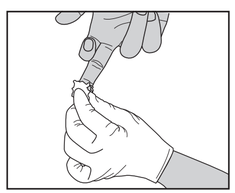
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



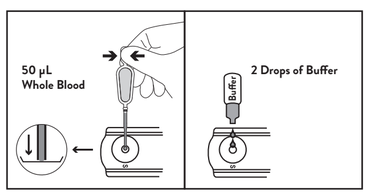
8 Hold the provided capillary tube (for fingerstick whole blood) horizontally below the bulb. DO NOT TOUCH OR SQUEEZE BULB. Immerse the open end of the capillary tube into the blood drop and let the blood rise by capillarity to the **joint** (volume position). Avoid air bubbles.



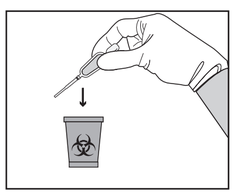
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



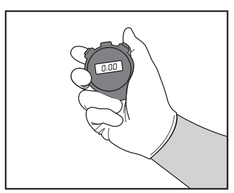
10 Squeeze the bulb and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).



11 Dispose the specimen dropper (for fingerstick whole blood) after testing.

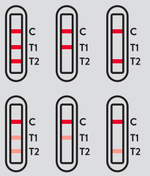


12 Start the timer.



READ RESULTS

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



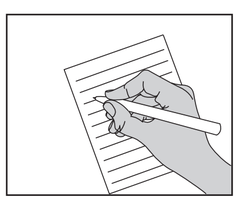
REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
***Note:** The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.

NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).

INVALID: No line appears in the control line region (C). If this occurs, read the test procedure again and repeat the test with a new test device. 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.

1156230901

Date de révision : 2022-01-21
Mode d'emploi version 01

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

REF IHI-T402WE IVD

Mode d'emploi

Français

Un test de diagnostic rapide pour la détection qualitative des anticorps dirigés contre le virus de l'immunodéficience humaine (VIH) de type 1, y compris le sous-type O et le type 2, dans le sang total, le sérum ou le plasma.
Réservé exclusivement à un usage professionnel.

UTILISATION PRÉVUE

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) est un dosage immunochromatographique rapide de diagnostic *in vitro* pour la détection qualitative des anticorps dirigés contre le VIH-1, y compris le sous-type O et le VIH-2, dans les échantillons de sang total veineux et capillaire, de sérum et de plasma. Le produit peut être utilisé pour faciliter le diagnostic d'une infection par le VIH. Un résultat réactif doit être confirmé par des tests complémentaires dans le cadre d'un algorithme de dépistage du VIH validé. Ce produit n'a pas été évalué sur des échantillons pédiatriques et néonatals.

PRINCIPE

La bandelette de test de HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) est pré-enduite d'antigènes du VIH-1 et du sous-type O sur la ligne de test T1 et de l'antigène du VIH-2 sur la ligne de test T2. Tout d'abord, l'échantillon puis le tampon sont ajoutés au puits d'échantillonnage, ce qui initie la migration de l'échantillon/du tampon. L'échantillon/le tampon passe par le tampon de conjugué qui contient un mélange d'antigènes de l'enveloppe du VIH-1, de la capside et de l'enveloppe du VIH-2. Ces antigènes de détection sont conjugués à des particules de latex. S'ils sont présents, les anticorps dirigés contre le VIH-1 ou le VIH-2 réagissent et se lient à l'antigène-conjugué de détection. Le mélange anticorps/antigène-conjugué migre ensuite plus loin et se lie aux antigènes présents sur les lignes de test. Si l'échantillon contient des anticorps dirigés contre le VIH-1, l'échantillon se lie à la ligne de test T1 et produira une ligne. Si l'échantillon contient des anticorps dirigés contre le VIH-2, l'échantillon se lie à la ligne de test T2. À mesure que le liquide migre vers le bas de la bandelette de test, la ligne de contrôle apparaît. Si la ligne de contrôle est présente, en plus d'une ou des deux lignes de test, alors le test est réactif pour les anticorps au VIH-1/2. Si l'échantillon ne contient pas d'anticorps au VIH-1 ou au VIH-2, aucune ligne colorée ne s'affiche sur l'une ou l'autre zone de ligne de test, indiquant ainsi un résultat non réactif. Veuillez noter que l'apparition de lignes colorées sur les lignes de test T1 et T2 est peu probablement le signe d'une co-infection par le VIH-1 et le VIH-2, mais plutôt le résultat d'une réactivité croisée entre les antigènes. Une ligne colorée apparaît dans la zone de la ligne de contrôle si la migration du liquide est réussie. Elle doit être présente pour que le test soit valide. Si la ligne de contrôle n'apparaît pas, le résultat du test n'est pas valide.

CONSERVATION ET STABILITÉ

Conservez le produit conditionné dans la pochette scellée entre 2 et 30 °C (la conservation dans un réfrigérateur est autorisée). **Ne conservez pas le produit dans le congélateur**. Conservez le kit de test à l'abri de l'humidité. Le dispositif de test est stable jusqu'à la date d'expiration imprimée sur le kit de test et/ou sur la pochette scellée du dispositif de test. N'utilisez pas le dispositif de test au-delà de la date de péremption. Le dispositif de test doit rester dans sa pochette scellée jusqu'à son utilisation.

MISES EN GARDE ET PRÉCAUTIONS

- Pour une utilisation de diagnostic *in vitro* uniquement.
- Lisez attentivement les instructions avant de réaliser le test.
- Appliquez les précautions standard en matière de biosécurité lors de la manipulation et de l'élimination des matériels potentiellement infectieux.
- Manipulez tous les échantillons comme des échantillons potentiellement infectieux.
- Lors des tests, portez des vêtements de protection tels que des gants, des blouses de laboratoire et des lunettes de protection.
- Le dispositif de test et ses accessoires doivent être mis au rebut dans une poubelle pour déchets présentant un risque biologique après le test.
- Ne mangez pas, ne buvez pas ou ne fumez pas dans la pièce où les échantillons et les kits sont manipulés.
- Évitez les éclaboussures et nettoyez-les immédiatement avec un désinfectant adapté.
- Le tampon contient 0,02 % d'azoture de sodium comme agent conservateur qui peut être toxique si ingéré. Lorsque vous le mettez au rebut dans l'évier, rincez avec de grandes quantités d'eau.
- N'utilisez pas le kit de test au-delà de la date d'expiration.
- Ne l'utilisez pas si l'emballage est endommagé.
- N'utilisez pas le tube capillaire (pour sang total par prélèvement au doigt), la lancette à usage unique et le tampon imbibé d'alcool s'ils sont déjà endommagés.
- Jetez le tube capillaire (pour sang total par prélèvement au doigt) et la lancette à usage unique dans la poubelle pour objets tranchants s'ils sont déjà endommagés avant utilisation.
- Ne posez pas la lancette avant de le mettre au rebut.
- Ne réutilisez pas la lancette.
- En cas de prophylaxie post-exposition au VIH, les opérateurs doivent se familiariser avec la politique de la PPE avant de réaliser les tests.
- L'humidité et la température peuvent affecter négativement les résultats.
- Le nombre optimal d'échantillons à tester en une seule fois est de 10.
- N'utilisez pas d'autres échantillons que ceux spécifiés. Pour le sang total par ponction veineuse/le plasma, l'EDTA-K_2/l'héparine de sodium/le citrate de sodium/l'héparine de lithium peuvent être utilisés comme anticoagulants. D'autres anticoagulants n'ont pas été testés et peuvent donner des résultats incorrects.
- Ne formez pas de bulles d'air pendant l'ajout de l'échantillon. La formation de bulles peut entraîner l'ajout d'un volume d'échantillon insuffisant et par conséquent un faux résultat non réactif.

PRÉLÈVEMENT D'ÉCHANTILLONS ET PRÉPARATION

- HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) peut être utilisé avec du sang total (par ponction veineuse ou prélèvement au doigt), du sérum ou du plasma.
- Pour prélever des échantillons de **sang total par prélèvement au doigt :**
  - Portez des gants.
  - Nettoyez le bout du doigt (de préférence le 3e ou 4e doigt de la main non dominante) avec un tampon imbibé d'alcool. Laissez sécher (30 secondes).
  - Effectuez une ponction sur le côté du doigt avec une nouvelle lancette à chaque fois. Mettez la lancette au rebut dans une poubelle pour objets tranchants immédiatement après son utilisation. N'utilisez pas la lancette si le capuchon a déjà été retiré. Essuyez la première goutte de sang avec un tampon de gaze ou un morceau de coton stérile.
  - Maintenez le tube capillaire fourni (pour sang total par prélèvement au doigt) à l'horizontale sous la poire. NE TOUCHEZ PAS OU N'APPUYEZ PAS SUR LA POIRE.
  - Immergez l'extrémité ouverte du tube capillaire dans la goutte de sang et laissez le sang monter grâce au phénomène de capillarité jusqu'à la **jointure** (position du volume). Évitez les bulles d'air.
  - Appuyez sur la poire et ajoutez **l'intégralité du sang total** (environ 50 µl) dans le puits d'échantillonnage (S) du dispositif de test. ASSUREZ-VOUS QUE LE COMPTE-GOUTTES EST EN CONTACT AVEC LE FOND DU PUITS D'ÉCHANTILLONNAGE. Ensuite, ajoutez 2 gouttes de tampon (environ 80 µl) dans le puits d'échantillonnage (S).
- Pour prélever des échantillons de **sérum, de plasma ou de sang total par ponction veineuse :**
  - Prélevez en respectant les procédures de phlébotomie sécurisées, en utilisant la technique du vide dans des tubes pour les préparations de sérum, de plasma ou de sang total par ponction veineuse.
  - Préparez le sérum ou le plasma à partir du sang total dès que possible pour éviter l'hémolyse. N'utilisez pas d'échantillons troubles ou hémolysés.

CONSERVATION DES ÉCHANTILLONS

- Les tests doivent être effectués immédiatement après le prélèvement d'échantillon. Ne laissez pas les échantillons à température ambiante (entre 15 et 30 °C) pendant des périodes prolongées. Les échantillons de sérum et de plasma peuvent être conservés entre 2 et 8 °C jusqu'à 3 jours. Pour la conservation à long terme, les échantillons doivent être conservés à -20 °C. Le sang total prélevé par ponction veineuse doit être conservé entre 2 et 8 °C si le test doit être réalisé dans les 2 jours suivant le prélèvement. Ne congelez pas les échantillons de sang total. Le sang total prélevé par prélèvement au doigt doit être testé immédiatement.
- Laissez les échantillons s'équilibrer à température ambiante avant de réaliser les tests. Les échantillons congelés doivent être complètement décongelés et mélangés avant de commencer le test.
- Aucune différence de performance qualitative n'a été observée entre les contrôles expérimentaux et 20 échantillons non réactifs ou 20 échantillons réactifs soumis à 6 cycles de congélation/décongélation ; cependant, plusieurs cycles de congélation/décongélation doivent être évités.

MATÉRIEL

Matériel fourni

Composants	IHI-T402WE
1. Dispositif de test	x40
2. Compte-gouttes à échantillon (Pour sérum/plasma/sang total par ponction veineuse)	x40
3. Tampon de 3 ml	x2
4. Tampon imbibé d'alcool	x40
5. Lancette à usage unique	x40
6. Tube capillaire (Pour sang total par prélèvement au doigt)	x40
7. Mode d'emploi	x1

Matériel requis mais non fourni

- Équipement de prélèvement d'échantillons et conteneurs
- Coton ou tampon de gaze (pour sang total par prélèvement au doigt uniquement)
- Centrifugeuse
- Chronomètre
- Poubelles pour déchets présentant un risque biologique pour objets tranchants et non tranchants

PROCÉDURE DE TEST

Laissez le dispositif de test, le tampon et l'échantillon s'équilibrer à température ambiante (entre 15 et 30 °C) avant le test.

1. Retirez le dispositif de test de la pochette en aluminium et utilisez-le dès que possible (dans l'heure).
2. Placez le dispositif de test sur une surface propre et plane. Indiquez l'ID de l'échantillon. Ajoutez l'échantillon et le tampon. Évitez la formation de bulles lors de l'ajout de l'échantillon et du tampon.
   Pour les échantillons de **sérum ou de plasma** : tenez le compte-gouttes à échantillon (pour sérum/plasma/sang total par ponction veineuse) à la verticale et **transférez 1 goutte de sérum ou de plasma** (environ 25 µl) dans le puits d'échantillonnage (S) du dispositif de test, puis **ajoutez 1 goutte de tampon** (environ 40 µl) et lancez le chronomètre.
   Pour les échantillons de **sang total par prélèvement au doigt** : prélevez un échantillon de sang total avec le tube capillaire de 50 µl (pour sang total par prélèvement au doigt) jusqu'à la **jointure** (position du volume). **Ajoutez l'échantillon** (environ 50 µl) dans le puits d'échantillonnage (S) du dispositif de test, puis **ajoutez 2 gouttes de tampon** (environ 80 µl) et lancez le chronomètre.
   Pour les échantillons de **sang total par prélèvement au doigt** : prélevez un échantillon de sang total avec un compte-gouttes à échantillon de 50 µl (pour sang total prélevé au doigt) jusqu'à la ligne de remplissage marquée. **Ajoutez l'échantillon** (environ 50 µl) sur le puits d'échantillonnage (S) du dispositif de test, puis **ajoutez 2 gouttes de tampon** (environ 80 µl) et lancez le chronomètre.
3. Attendez qu'une ou plusieurs lignes colorées apparaissent. **Lisez les résultats au bout de 10 minutes. Ne lisez pas les résultats après 20 minutes.**

INTERPRÉTATION DES RÉSULTATS

RÉACTIF : deux ou trois lignes colorées différentes apparaissent*. Une ligne doit toujours apparaître dans la zone de ligne de contrôle (C) et une ou deux lignes colorées doivent apparaître dans les zones de lignes de test (T1 et/ou T2).
RÉACTIF AU VIH-1 : si la ligne de contrôle (C) et la ligne de test T1 apparaissent, cela indique un résultat réactif à l'infection par le VIH-1.
RÉACTIF AU VIH-2 : si la ligne de contrôle (C) et la ligne de test T2 apparaissent, cela indique un résultat réactif à l'infection par le VIH-2.
Si la ligne de contrôle (C) et les lignes de test T1 et T2 apparaissent, cela est plus susceptible d'être causé par une réactivité croisée, due à une certaine similarité des séquences d'acides aminés du VIH-1 et du VIH-2. Il peut s'agir d'une seule infection par le VIH-1/VIH-2 ou d'une double infection par le VIH-1 et le VIH-2. Dans ce cas, il est impossible d'établir un résultat discriminant et un test supplémentaire de différenciation des anticorps est nécessaire. Veuillez vous reporter à la section Limitation pour connaître le taux estimé de réactivité croisée entre le VIH-1 et le VIH-2 pour ce produit et les cas de double infection signalés.
*** Remarque :** l'intensité de la couleur dans la zone de ligne de test (T1 et/ou T2) peut varier, mais n'importe quelle nuance de couleur dans la zone de ligne de test (T1 et/ou T2) doit être considérée comme réactive.
NON RÉACTIF : une ligne colorée apparaît dans la zone de contrôle (C). Aucune ligne colorée n'apparaît dans les zones de lignes de test (T1 et/ou T2).
NON VALIDE : aucune ligne n'apparaît dans la zone de ligne de contrôle (C). Si tel est le cas, lisez la procédure de test et répétez le test avec un nouveau dispositif de test. Si le résultat n'est toujours pas valide, arrêtez immédiatement d'utiliser le kit de test et contactez votre distributeur local.

CONTRÔLE QUALITÉ

Une ligne de contrôle est incluse dans le test en tant que contrôle interne. Le test doit absorber le liquide et lui permettre de migrer le long de la membrane pour que la ligne de contrôle apparaisse. Le contrôle de procédure interne repose sur l'apparition d'une ligne colorée dans la zone de contrôle (C).
Les échantillons de contrôle qualité ne sont pas fournis avec ce kit. Cependant, il est recommandé que les échantillons de contrôle qualité soient testés en tant que bonnes pratiques de laboratoire.

LIMITATION

1. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) est conçu pour une utilisation de diagnostic *in vitro* uniquement. Ce test doit être utilisé pour la détection des anticorps dirigés contre le VIH-1/2 dans le sang total, le sérum ou le plasma humain. La concentration d'anticorps au VIH-1/2 ne peut pas être déterminée par ce test qualitatif.
2. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) indique uniquement la présence d'anticorps au VIH-1/2 dans l'échantillon et ne doit pas être utilisé comme seul critère dans le diagnostic d'une infection par le VIH-1, le VIH-2 et/ou le VIH-1 sous-type O.
3. Pour confirmer les résultats réactifs des tests, les échantillons doivent subir d'autres tests à l'aide de différents dosages, tels que les tests de diagnostic rapide, l'EIA et/ou le Western blot (technique des immuno-empreintes) conformément à un algorithme de dépistage du VIH validé.
4. Comme pour tous les tests de diagnostic, tous les résultats doivent être interprétés conjointement avec les autres informations cliniques à la disposition du médecin.
5. Les résultats ne doivent pas être utilisés pour déterminer le génotype des infections par le VIH.
6. En raison d'une possible réactivité croisée des anticorps, l'apparition de lignes dans les lignes T1 et T2 n'indique pas nécessairement une co-infection par le VIH-1 et le VIH-2.
7. De faux résultats réactifs peuvent survenir en raison de facteurs rhumatoïdes, d'anticorps antinucléaires, d'autres infections virales (par exemple, l'hépatite B ou l'hépatite C), d'infections parasitaires (par exemple, la schistosomiase et la trypanosomiase), de composants de test endommagés par la chaleur ou l'humidité, ou de la substitution d'autres composants du kit de test (par exemple, les compte-gouttes ou le tampon) entre plusieurs kits de test.
8. De faux résultats non réactifs peuvent survenir lorsque les titres des anticorps au VIH-1/2 sont très faibles, lorsque les titres des anticorps au VIH-1/2 sont très élevés (effet « High-hook »), lorsqu'un volume insuffisant d'échantillon est ajouté, lorsqu'un volume excessif de tampon est ajouté ou lorsque des composants de test sont endommagés par la chaleur ou l'humidité.
9. Des faux négatifs peuvent être observés chez les individus recevant un traitement antirétroviral efficace. [1,2,3]
10. Le taux estimé de réactivité croisée entre les échantillons positifs au VIH-1 et au VIH-2 était de 32,6 % en utilisant HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)[4]. Bien que la double infection par le VIH-1 et le VIH-2 soit peu courante, il a été signalé que 9 % des personnes présentant une infection par le VIH-2 sont co-infectées par le VIH-1 en Espagne[5,6].

CARACTÉRISTIQUES DE PERFORMANCE

Sensibilité clinique, spécificité et précision

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) a été évalué avec 1 640 échantillons provenant de différents pays dans une étude de terrain multicentrique non publiée, avec 1 000 échantillons dans un centre de don du sang et avec 3 430 échantillons dans une étude clinique en interne. Sur les 6 070 échantillons au total (qui comprennent du sang total, du sérum et du plasma), 1 602 se sont révélés séropositifs au VIH et 4 468 échantillons se sont révélés séronégatifs au VIH par un algorithme de test de caractérisation comprenant une EIA et/ou un Western blot (technique des immunoempreintes). HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) a montré une sensibilité relative de 99,9 % et une spécificité relative de 99,8 % par rapport à l'EIA et/ou au Western blot (technique des immuno-empreintes).

Dispositif de test rapide tri-ligne VIH 1/2/O contre EIA et/ou Western blot (technique des immuno-empreintes)

		EIA et/ou Western blot (technique des immuno-empreintes)		Résultats totaux
Dispositif de test rapide tri-ligne VIH 1/2/O	Résultats	Positif	Negative	
	Réactif	1 601	10	1 611
	Non réactif	1	4 458	4 459
Résultats totaux		1 602	4 468	6 070

Sensibilité relative : 99,9 % (99,7-100,0 %)*
Spécificité relative : 99,8 % (99,6-99,9 %)*
Précision relative : 99,8 % (99,7-100,0 %)*
* Intervalle de confiance de 95 %

Homogénéité des types d'échantillons

50 échantillons appariés de plasma et de sang total séropositifs au VIH, 26 échantillons appariés de plasma, de sérum et de sang total séropositifs au VIH et 50 échantillons appariés de plasma, de sérum et de sang total négatifs ont été testés avec HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

EIA et/ou Western blot (technique des immuno-empreintes)	Type d'échantillon	Nombre testé	Dispositif de test rapide tri-ligne VIH 1/2/O	
			Non réactif	Réactif
Négatif	Plasma	50	50	0
	Sérum	50	50	0
	Sang total	50	50	0
Positif	Sérum	26	0	26
	Plasma	76	0	76
	Sang total	76	0	76

Les échantillons appariés de sang total, de plasma et de sérum montrent des résultats cohérents avec HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

Précision

Intradosage (même lot)

La précision pendant un cycle a été déterminée à l'aide de 10 reproductions de cinq échantillons : un négatif, un positif au VIH-1 au titre faible, un positif au VIH-1 **(sous-type O)** au titre faible, un positif au VIH-1 au titre moyen et un positif au VIH-2. Toutes les valeurs ci-dessus ont été identifiées correctement >99 % du temps.

Intradosage

La précision pendant un cycle a été déterminée par 10 dosages indépendants sur les cinq mêmes échantillons : un négatif, un positif au VIH-1 au titre faible, un positif au VIH-1 (sous-type O) au titre faible, un positif au VIH-1 au titre moyen et un positif au VIH-2. Trois lots différents de HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) ont été testés à l'aide des échantillons ci-dessus. Les échantillons ont été identifiés correctement >99 % du temps.

BIBLIOGRAPHIE

1. K.P. Delaney, B.M. Branson, A. Uniyal, et al. *Evaluation of the Performance Characteristics of 6 Rapid HIV Antibody Tests.* Clinical Infectious Diseases. 2011 ; 52 (2) : 257-263.
2. R.J. O'Connell, T.M. Merritt, J.A. Malia, *et al. Performance of the OraQuick Rapid Antibody Test for Diagnosis of Human Immunodeficiency Virus Type 1 Infection in Patients with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2003 ; 41 (5) : 2153-2155
3. R.J. O'Connell, B.K. Agan, S.A. Anderson, *et al. Sensitivity of the Multispot HIV-1/HIV-2 Rapid Test Using Samples from Human Immunodeficiency Virus Type 1-Positive Individuals with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2006 ; 44 (5) : 1831-1833
4. WHO HIV ASSAY REPORT 18: *Laboratory performance and other operational characteristics rapid diagnostic test.*
5. Requena S, Caballero E, Lozano AB, Ríos-Villegas MJ, Benito R, Rojo S, Cabezas T, Macià MD, Nieto MDC, Soriano V, de Mendoza C; *Spanish HIV-2 Study Group. Treatment outcome in dually HIV-1 and HIV-2 coinfected patients living in Spain.* AIDS. 2019 Nov 15;33(14):2167-2172.
6. Zbinden A, Dürig R, Shah C, Böni J, Schüpbach J. *Importance of an Early HIV Antibody Differentiation Immunoassay for Detection of Dual Infection with HIV-1 and HIV-2.* PLoS One. 2016 Jun 16;11(6):e0157690.

Index des symboles

	Consulter les instructions d'utilisation		Contenu suffisant pour <n> tests	REF	Référence catalogue
LOT	Code de lot		Date d'expiration		Ne pas réutiliser
2°C 4°C	Conservation entre 2 et 30 °C		Fabricant	IVD	Dispositif médical de diagnostic *in vitro*

Support Technique

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

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

© 2022 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.

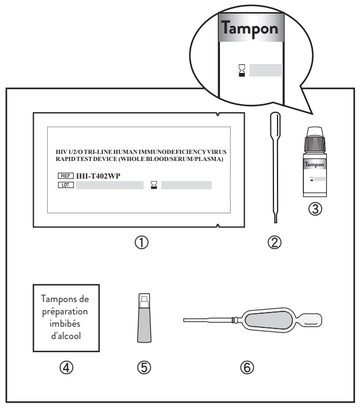
Abbott

ABON™

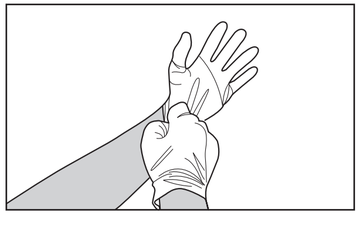
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PRÉPARATION

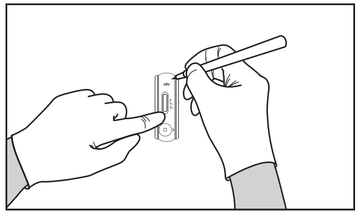
1 Ouvrez l'emballage et vérifiez le contenu et la date d'expiration.



2 Portez des gants.

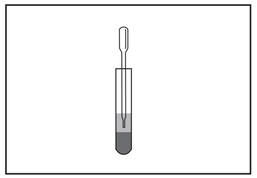


3 Ouvrez le sachet, étiquetez avec l'ID de l'échantillon. Utilisez-le dès que possible (dans l'heure).

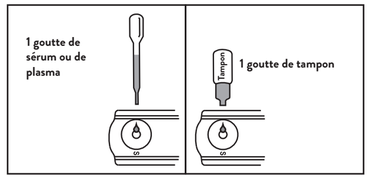


ÉCHANTILLONS DE SÉRUM OU DE PLASMA

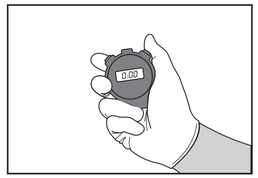
4 Prélevez l'échantillon du tube d'échantillon avec un compte-gouttes (pour sérum/plasma/sang total par ponction veineuse).



5 Transférez 1 goutte de sérum ou de plasma (environ 25 µl), puis ajoutez 1 goutte de tampon (environ 40 µl).

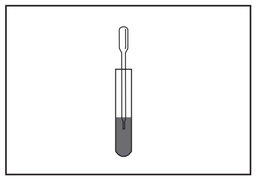


6 Lancez le chronomètre.

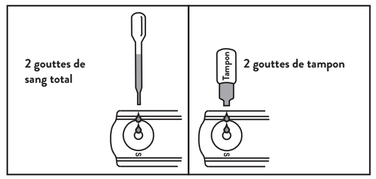


ÉCHANTILLONS DE SANG TOTAL PAR PONCTION VEINEUSE

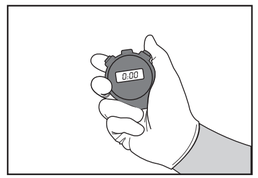
4 Prélevez l'échantillon du tube d'échantillon avec un compte-gouttes (pour sérum/plasma/sang total par ponction veineuse).



5 Transférez 2 gouttes de sang total (environ 50 µl), puis ajoutez 2 gouttes de tampon (environ 80 µl).



6 Lancez le chronomètre.



ÉCHANTILLONS DE SANG TOTAL PAR PRÉLÈVEMENT AU DOIGT

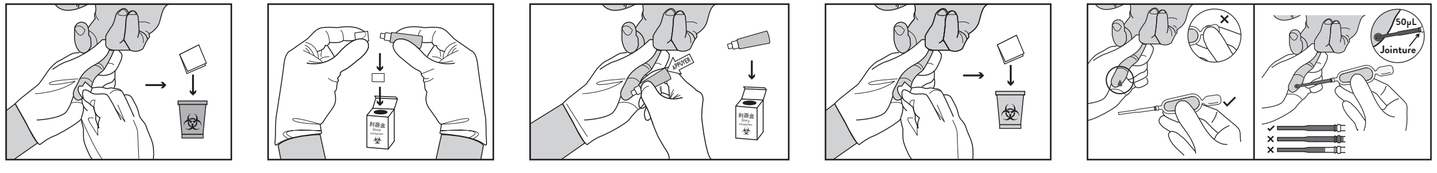
4 Nettoyez le bout du doigt (de préférence le 3e ou 4e doigt de la main non dominante) avec un tampon imbibé d'alcool. Jetez le tampon imbibé d'alcool.

5 Retirez le capuchon de la lancette et jetez le capuchon dans une poubelle pour objets tranchants.

6 Effectuez une ponction sur le côté du doigt. Mettez la lancette au rebut dans la poubelle pour objets tranchants immédiatement après son utilisation.

7 Essuyez la première goutte de sang avec un tampon de gaze ou un morceau de coton stérile.

8 Maintenez le tube capillaire fourni (pour sang total par prélèvement au doigt) à l'horizontale sous la poire. NE TOUCHEZ PAS OU N'APPUYEZ PAS SUR LA POIRE. Immergez l'extrémité ouverte du tube capillaire dans la goutte de sang et laissez le sang monter grâce au phénomène de capillarité jusqu'à la **jointure** (position du volume). Évitez les bulles d'air.

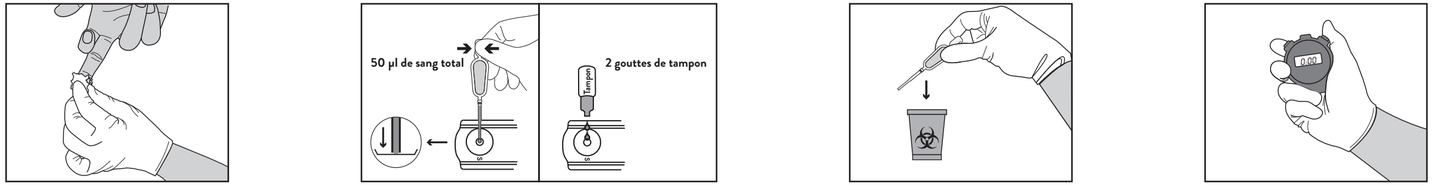


9 Après le prélèvement de l'échantillon, placez un tampon de gaze ou de coton sur le doigt jusqu'à l'arrêt du saignement.

10 Appuyez sur la poire et ajoutez **l'intégralité du sang total** (environ 50 µl) dans le puits d'échantillonnage (S) du dispositif de test. ASSUREZ-VOUS QUE LE COMPTE-GOUTTES EST EN CONTACT AVEC LE FOND DU PUITS D'ÉCHANTILLONNAGE. Ensuite, ajoutez 2 gouttes de tampon (environ 80 µl) dans le puits d'échantillonnage (S).

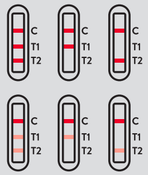
11 Jetez le compte-gouttes à échantillon (pour sang total par prélèvement au doigt) après le test.

12 Lancez le chronomètre.



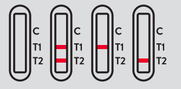
LECTURE DES RÉSULTATS

Attendez qu'une ou plusieurs lignes colorées apparaissent.
Lisez les résultats au bout de **10 à 20 minutes.**



RÉACTIF : deux ou trois lignes colorées différentes apparaissent*. Une ligne doit toujours apparaître dans la zone de ligne de contrôle (C) et une ou deux lignes colorées doivent apparaître dans les zones de lignes de test (T1 et/ou T2).
RÉACTIF AU VIH-2 : si la ligne de contrôle (C) et la ligne de test T2 apparaissent, cela indique un résultat réactif à l'infection par le VIH-2.
Si la ligne de contrôle (C) et les lignes de test T1 et T2 apparaissent, cela est plus susceptible d'être causé par une réactivité croisée, due à une certaine similarité des séquences d'acides aminés du VIH-1 et du VIH-2. Il peut s'agir d'une seule infection par le VIH-1/VIH-2 ou d'une double infection par le VIH-1 et le VIH-2. Dans ce cas, il est impossible d'établir un résultat discriminant et un test supplémentaire de différenciation des anticorps est nécessaire. Veuillez vous reporter à la section Limitation pour connaître le taux estimé de réactivité croisée entre le VIH-1 et le VIH-2 pour ce produit et les cas de double infection signalés.
*** Remarque :** l'intensité de la couleur dans la zone de ligne de test (T1 et/ou T2) peut varier, mais n'importe quelle nuance de couleur dans la zone de ligne de test (T1 et/ou T2) doit être considérée comme réactive.

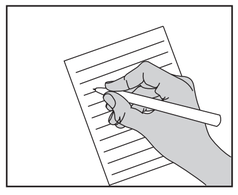
NON RÉACTIF : une ligne colorée apparaît dans la zone de contrôle (C). Aucune ligne colorée n'apparaît dans les zones de lignes de test (T1 et/ou T2).



NON VALIDE : aucune ligne n'apparaît dans la zone de ligne de contrôle (C). Si tel est le cas, lisez la procédure de test et répétez le test avec un nouveau dispositif de test. Si le résultat n'est toujours pas valide, arrêtez immédiatement d'utiliser le kit de test et contactez votre distributeur local.

MISE AU REBUT/ ENREGISTREMENT

Mettez les dispositifs et les gants au rebut dans une poubelle pour les déchets présentant un risque biologique.



Enregistrez les résultats des tests.

Abbott

1156231101

Revision date: 2022-02-22
IFU version 01

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

REF IHI-T402WF IVD

Instructions for Use

English

A rapid diagnostic test for the qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) type 1, including subtype O, and type 2 in whole blood, serum or plasma.
For professional use only.

INTENDED USE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is an *in vitro* diagnostic rapid immunochromatographic assay for the qualitative detection of antibodies to HIV-1, including subtype O, and HIV-2 in venous and capillary whole blood, serum and plasma specimens. The product may be used as an aid in the diagnosis of HIV infection. A reactive result should be confirmed by supplemental testing as part of a validated HIV testing algorithm. This product has not been evaluated on paediatric and neonatal specimens.

PRINCIPLE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) test strip is pre-coated with HIV-1 and subtype O antigens on T1 test line and HIV-2 antigen on T2 test line. Firstly, specimen and then buffer is added to the specimen well, thus starting the migration of the specimen/buffer. The specimen/buffer passes the conjugate pad which contains a mixture of HIV-1 envelope and capsid antigen and HIV-2 envelope antigen. These detection antigens are conjugated to latex particles. If present, the HIV-1 or HIV-2 antibodies react and bind to the detection antigen-conjugate. The antibody/antigen-conjugate mixture then migrates further and binds to antigens present on the test lines. If the specimen contains antibodies to HIV-1, the specimen will bind to the T1 test line and produce a line, if specimen contains antibodies to HIV-2, the specimen will bind to the T2 test line. As liquid continues to migrate down the test strip, the control line will appear. If the control line is present, in addition to either or both test lines, then the test is reactive for HIV1/2 antibodies. If the specimen does not contain HIV-1 or HIV-2 antibodies, no colored lines will appear for either of the test lines region indicating a non-reactive result. Please note that the appearance of colored lines at T1 and T2 is highly unlikely to be indicative of co-infection with HIV-1 and HIV-2 but rather is a result of cross-reactivity between antigens. A colored line will appear in the control line region if the migration of liquid has been successful, and must be present for the test to be valid. If the control line does not appear, the test result is not valid.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (storage in refrigerator is permitted). **Do not store in the freezer**. Protect the test kit from humidity. The test device is stable until the expiration date printed on the test kit and/or sealed test device pouch. Do not use beyond the expiration date. The test device must remain in the sealed pouch until use.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Read the instruction carefully before performing the test.
- Apply standard biosafety precautions when handling and disposing of potentially infectious material.
- Handle all specimens as potentially infectious.
- Wear protective clothing such as gloves, laboratory coats, and eye protection when specimens are being tested.
- The test device and accessory should be disposed in a proper biohazard waste container after testing.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Avoid splashes and clean up spills immediately with appropriate disinfectant.
- The buffer contains 0.02% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities of water.
- Do not use the test kit beyond the expiration date.
- Do not use if the packaging is damaged.
- Do not use the capillary tube (for fingerstick whole blood), single-use lancet or alcohol pad if it is already damaged.
- Dispose the capillary tube (for fingerstick whole blood) and single-use lancet in the sharps container if it is already damaged before use.
- Do not set the lancet down before discarding it.
- Do not reuse the lancet.
- In case of Post-exposure prophylaxis for HIV, operators should familiarize themselves with PPE policy prior to conducting the testing.
- Humidity and temperature can adversely affect results.
- The optimal number of specimens to be tested at one time is 10.
- Do not use any other specimen than those specified. For plasma/venipuncture whole blood, EDTA-K_2/sodium heparin/sodium citrate/lithium heparin can be used as anticoagulant. Other anticoagulants have not been tested and may give incorrect results.
- Do not form air bubbles during addition of specimen. Bubble formation may lead to insufficient specimen volume added and a false non-reactive result may occur accordingly.

SPECIMEN COLLECTION AND PREPARATION

- HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **fingerstick whole blood** specimens:
  - Wear gloves.
  - Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Allow to dry (30 seconds).
  - Puncture the side of the finger with a new lancet each time. Dispose the lancet in sharps container immediately after using it. Do not use the lancet if the cap is already pulled off. Wipe away the first blood drop with a sterile gauze pad or cotton wool.
  - Hold the provided capillary tube (for fingerstick whole blood) horizontally below the bulb. DO NOT TOUCH OR SQUEEZE BULB.
  - Immerse the open end of the capillary tube into the blood drop and let the blood rise by capillarity to the **joint** (volume position). Avoid air bubbles.
  - Squeeze the bulb and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).
- To collect **serum or plasma or venipuncture whole blood** specimens:
  - Collect according to safe phlebotomy procedures, using vacuum technique into 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.

SPECIMEN STORAGE

- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature (15-30°C) for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be stored at -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 experimental controls and 20 nonreactive or 20 reactive specimens subjected to 6 freeze/thaw cycles; however, multiple freeze/thaw cycles should be avoided.

MATERIALS

Materials Provided

Components	IHI-T402WF
1. Test Device	x10
2. Specimen Dropper (For Serum/Plasma/Venipuncture Whole Blood)	x10
3. 3mL Buffer	x1
4. Alcohol Swab	x10
5. Single-use Lancet	x10
6. Capillary Tube (For Fingerstick Whole Blood)	x10
7. Instructions for Use	x1

Materials Required But Not Provided

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

TEST PROCEDURE

Allow the test device, buffer and specimen to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible (within one hour).
2. Place the test device on a clean and level surface. Label with specimen ID. Add specimen and buffer. Avoid bubbles formation during addition of specimen and buffer.
   For **serum or plasma** specimens: Hold the specimen dropper (for serum/plasma/venipuncture whole blood) vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µL) and start the timer.
   For **venipuncture whole blood** specimens: Hold the specimen dropper (for serum/plasma/venipuncture whole blood) vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
   For **fingerstick whole blood** specimens: Take whole blood specimen with the 50 µL capillary tube (for fingerstick whole blood) until **joint** (volume position). And **add specimen** (approximately 50 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes. Do not read results after 20 minutes.**

INTERPRETATION OF RESULTS

REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
***Note:** The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).
INVALID: No line appears in the control line region (C). If this occurs, read the test procedure again and repeat the test with a new test device. If the result is still invalid, stop using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A control line is included in the test as an internal control. The test must absorb liquid and allow it to migrate along the membrane for the control line to appear. A colored line appearing in the control region (C) is the internal procedural control.
Quality control specimens are not supplied with this kit; however, it is recommended that quality control specimens be tested as a good laboratory practice.

LIMITATION

1. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HIV-1/2 in human whole blood, serum or plasma. The concentration of antibodies to HIV-1/2 can not be determined by this qualitative test.
2. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HIV-1/2 in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1, HIV-2, and/or HIV-1 subtype O infection.
3. For confirmation of reactive test results, specimens should undergo further testing using different assays, such as rapid diagnostic tests, EIA and/or Western blotting in accordance with a validated HIV testing algorithm.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Results should not be used to determine the genotype of HIV infections.
6. Due to possible antibody cross reactivity, the appearance of lines in both T1 and T2 does not necessarily indicate co-infection from HIV-1 and HIV-2.
7. False reactive results may arise due to rheumatoid factors, antinuclear antibodies, other viral infections (i.e. hepatitis B or hepatitis C), parasitic infections (i.e. schistosomiasis and trypanosomiasis), damage to test components by heat or humidity, or other test kit components (e.g. buffer or droppers) substituted between test kits.
8. False non-reactive results may arise when titers of antibodies to HIV1/2 are very low, titers of antibodies to HIV1/2 are very high (high-hook effect), insufficient specimen volume added, excess of buffer was added, or damage to test components by heat or humidity.
9. False-negative results may be observed in individuals who are receiving effective antiretroviral therapy. [1,2,3]
10. The estimated rate of Cross-reactivity between HIV-1 and HIV-2 positive samples was 32.6% using HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)[4]. Although dual infection of HIV-1 and HIV-2 is uncommon, it is reported that 9% of individuals with HIV-2 infection are coinfected with HIV-1 in Spain[5,6].

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) was evaluated with 1,640 specimens from different countries in an unpublished multi-center field study, 1,000 specimens from a blood donation center and 3,430 specimens from an in-house clinical study. Of the 6,070 total specimens (which included whole blood, serum and plasma specimens), 1,602 were found HIV seropositive and 4,468 specimens were found HIV seronegative by a characterization testing algorithm comprising of EIA and/or Western blot. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/ Serum/Plasma) showed 99.9% relative sensitivity, and 99.8% relative specificity compared to EIA and/or Western blot.

HIV 1/2/O Tri-line Rapid Test Device vs. EIA and/or Western blot

		EIA and/or Western blot		Total Results
	Results	Positive	Negative	
HIV 1/2/O Tri-line Rapid Test Device	Reactive	1,601	10	1,611
	Non-reactive	1	4,458	4,459
Total Results		1,602	4,468	6,070

Relative Sensitivity: 99.9% (99.7-100.0%)*
Relative Specificity: 99.8% (99.6-99.9%)*
Relative Accuracy: 99.8% (99.7-100.0%)*
* 95% Confidence Interval

Specimen Types Consistency

50 HIV seropositive whole blood and paired plasma specimens, 26 HIV seropositive whole blood, paired plasma and serum specimens, 50 negative whole blood, paired plasma and serum specimens were tested with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

EIA and/or Western blot	Specimen type	No. tested	HIV 1/2/O Tri-line Rapid Test Device	
			Non-reactive	Reactive
Negative	Plasma	50	50	0
	Serum	50	50	0
	Whole blood	50	50	0
Positive	Serum	26	0	26
	Plasma	76	0	76
	Whole blood	76	0	76

Paired whole blood, plasma, serum specimens show the consistent results with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

Precision

Intra-Assay (same lot)

Within-run precision has been determined by using 10 replicates of five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 **(subtype O)** positive, a medium titer HIV-1 positive and a HIV-2 positive. All above values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 (subtype O) positive, a medium titer HIV-1 positive and a HIV-2 positive. Three different lots of the HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/ Plasma) have been tested using above specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. Delaney KP, Branson BM, Uniyal A, et al. *Evaluation of the Performance Characteristics of 6 Rapid HIV Antibody Tests.* Clinical Infectious Diseases. 2011; 52(2): 257-263.
2. O'Connell RJ, Merritt TM, Malia JA, et al. *Performance of the OraQuick Rapid Antibody Test for Diagnosis of Human Immunodeficiency Virus Type 1 Infection in Patients with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2003; 41(5):2153-2155
3. O'Connell RJ, Agan BK, Anderson SA, et al. *Sensitivity of the Multispot HIV-1/HIV-2 Rapid Test Using Samples from Human Immunodeficiency Virus Type 1-Positive Individuals with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2006; 44(5): 1831-1833
4. WHO HIV ASSAY REPORT 18: *Laboratory performance and other operational characteristics rapid diagnostic test*.
5. Requena S, Caballero E, Lozano AB, Ríos-Villegas MJ, Benito R, Rojo S, Cabezas T, Macià MD, Nieto MDC, Soriano V, de Mendoza C; *Spanish HIV-2 Study Group. Treatment outcome in dually HIV-1 and HIV-2 coinfected patients living in Spain*. AIDS. 2019 Nov 15;33(14):2167-2172.
6. Zbinden A, Dürig R, Shah C, Böni J, Schüpbach J. *Importance of an Early HIV Antibody Differentiation Immunoassay for Detection of Dual Infection with HIV-1 and HIV-2*. PLoS One. 2016 Jun 16;11(6):e0157690.

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

Technical Support

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

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

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

Asia-Pacific
+61 7 3363 7100
AP.TechSupport@abbott.com

Latin America
57 1 4824033
LA.TechSupport@abbott.com

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

© 2022 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.

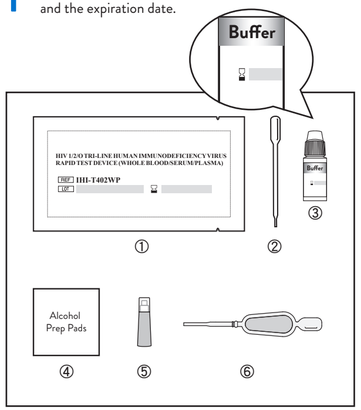
Abbott

ABON™

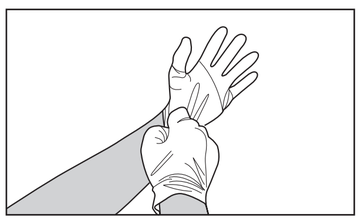
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

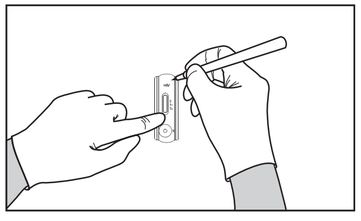
1 Open the package and check the content and the expiration date.



2 Wear gloves

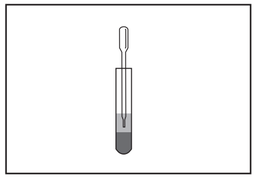


3 Open the pouch, Label with specimen ID. Use it as soon as possible (within one hour).

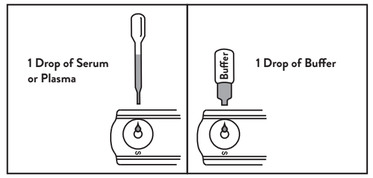


SERUM OR PLASMA SPECIMENS

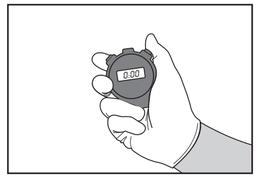
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



5 Transfer 1 drop of serum or plasma (approximately 25 µL), then add 1 drop of buffer (approximately 40 µL).

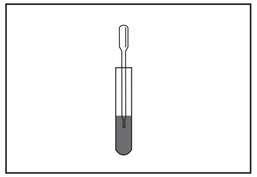


6 Start the timer.

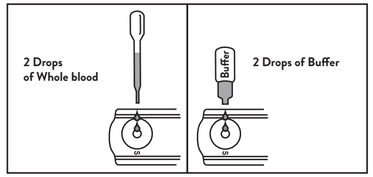


VENIPUNCTURE WHOLE BLOOD SPECIMENS

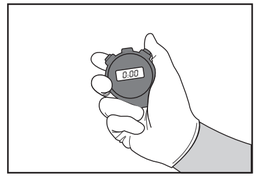
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



5 Transfer 2 drops of whole blood (approximately 50 µL), then add 2 drops of buffer (approximately 80 µL).

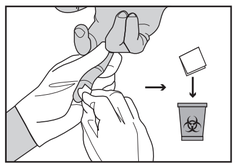


6 Start the timer.

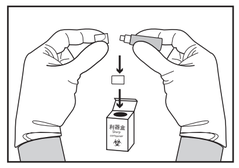


FINGERSTICK WHOLE BLOOD SPECIMENS

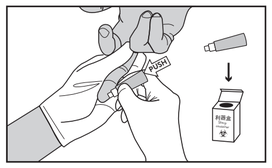
4 Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



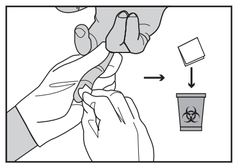
5 Take off the cap of the lancet and dispose the cap in sharps container.



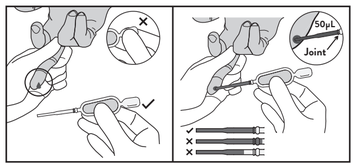
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



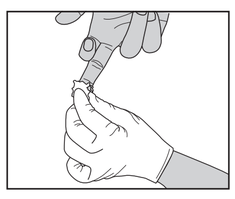
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



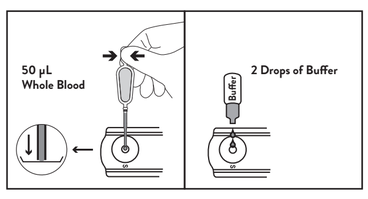
8 Hold the provided capillary tube (for fingerstick whole blood) horizontally below the bulb. DO NOT TOUCH OR SQUEEZE BULB. Immerse the open end of the capillary tube into the blood drop and let the blood rise by capillarity to the **joint** (volume position). Avoid air bubbles.



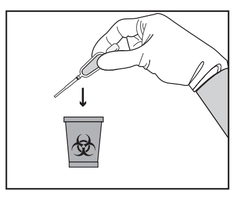
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



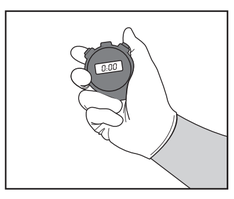
10 Squeeze the bulb and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).



11 Dispose the specimen dropper (for fingerstick whole blood) after testing.

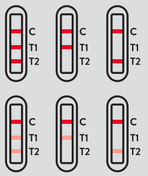


12 Start the timer.



READ RESULTS

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



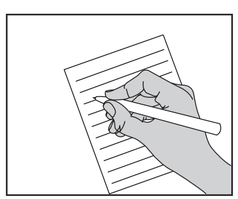
REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
***Note:** The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.

NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).

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

CLEAN UP/RECORD

Dispose devices and gloves in a proper biohazard waste container.



Record the test results.

Abbott

1156231001

Revision date: 2022-02-22
IFU version 01

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

REF IHI-T402WI IVD

Instructions for Use

English

A rapid diagnostic test for the qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) type 1, including subtype O, and type 2 in whole blood, serum or plasma.
For professional use only.

INTENDED USE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is an *in vitro* diagnostic rapid immunochromatographic assay for the qualitative detection of antibodies to HIV-1, including subtype O, and HIV-2 in venous and capillary whole blood, serum and plasma specimens. The product may be used as an aid in the diagnosis of HIV infection. A reactive result should be confirmed by supplemental testing as part of a validated HIV testing algorithm. This product has not been evaluated on paediatric and neonatal specimens.

PRINCIPLE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) test strip is pre-coated with HIV-1 and subtype O antigens on T1 test line and HIV-2 antigen on T2 test line. Firstly, specimen and then buffer is added to the specimen well, thus starting the migration of the specimen/buffer. The specimen/buffer passes the conjugate pad which contains a mixture of HIV-1 envelope and capsid antigen and HIV-2 envelope antigen. These detection antigens are conjugated to latex particles. If present, the HIV-1 or HIV-2 antibodies react and bind to the detection antigen-conjugate. The antibody/antigen-conjugate mixture then migrates further and binds to antigens present on the test lines. If the specimen contains antibodies to HIV-1, the specimen will bind to the T1 test line and produce a line, if specimen contains antibodies to HIV-2, the specimen will bind to the T2 test line. As liquid continues to migrate down the test strip, the control line will appear. If the control line is present, in addition to either or both test lines, then the test is reactive for HIV1/2 antibodies. If the specimen does not contain HIV-1 or HIV-2 antibodies, no colored lines will appear for either of the test lines region indicating a non-reactive result. Please note that the appearance of colored lines at T1 and T2 is highly unlikely to be indicative of co-infection with HIV-1 and HIV-2 but rather is a result of cross-reactivity between antigens. A colored line will appear in the control line region if the migration of liquid has been successful, and must be present for the test to be valid. If the control line does not appear, the test result is not valid.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (storage in refrigerator is permitted). **Do not store in the freezer**. Protect the test kit from humidity. The test device is stable until the expiration date printed on the test kit and/or sealed test device pouch. Do not use beyond the expiration date. The test device must remain in the sealed pouch until use.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Read the instruction carefully before performing the test.
- Apply standard biosafety precautions when handling and disposing of potentially infectious material.
- Handle all specimens as potentially infectious.
- Wear protective clothing such as gloves, laboratory coats, and eye protection when specimens are being tested.
- The test device and accessory should be disposed in a proper biohazard waste container after testing.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Avoid splashes and clean up spills immediately with appropriate disinfectant.
- The buffer contains 0.02% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities of water.
- Do not use the test kit beyond the expiration date.
- Do not use if the packaging is damaged.
- Do not use the capillary tube (for fingerstick whole blood) and single-use lancet if it is already damaged.
- Dispose the capillary tube (for fingerstick whole blood) and single-use lancet in the sharps container if it is already damaged before use.
- Do not set the lancet down before discarding it.
- Do not reuse the lancet.
- In case of Post-exposure prophylaxis for HIV, operators should familiarize themselves with PPE policy prior to conducting the testing.
- Humidity and temperature can adversely affect results.
- The optimal number of specimens to be tested at one time is 10.
- Do not use any other specimen than those specified. For plasma/venipuncture whole blood, EDTA-K_2/sodium heparin/sodium citrate/lithium heparin can be used as anticoagulant. Other anticoagulants have not been tested and may give incorrect results.
- Do not form air bubbles during addition of specimen. Bubble formation may lead to insufficient specimen volume added and a false non-reactive result may occur accordingly.

SPECIMEN COLLECTION AND PREPARATION

- HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **fingerstick whole blood** specimens:
  - Wear gloves.
  - Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Allow to dry (30 seconds).
  - Puncture the side of the finger with a new lancet each time. Dispose the lancet in sharps container immediately after using it. Do not use the lancet if the cap is already pulled off. Wipe away the first blood drop with a sterile gauze pad or cotton wool.
  - Hold the provided capillary tube (for fingerstick whole blood) horizontally below the bulb. DO NOT TOUCH OR SQUEEZE BULB.
  - Immerse the open end of the capillary tube into the blood drop and let the blood rise by capillarity to the **joint** (volume position). Avoid air bubbles.
  - Squeeze the bulb and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).
- To collect **serum or plasma or venipuncture whole blood** specimens:
  - Collect according to safe phlebotomy procedures, using vacuum technique into 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.

SPECIMEN STORAGE

- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature (15-30°C) for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be stored at -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 experimental controls and 20 nonreactive or 20 reactive specimens subjected to 6 freeze/thaw cycles; however, multiple freeze/thaw cycles should be avoided.

MATERIALS

Materials Provided

Components	IHI-T402WI
1. Test Device	x40
2. Specimen Dropper (For Serum/Plasma/Venipuncture Whole Blood)	x40
3. 3mL Buffer	x2
4. Single-use Lancet	x40
5. Capillary Tube (For Fingerstick Whole Blood)	x40
6. Instructions for Use	x1

Materials Required But Not Provided

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

TEST PROCEDURE

Allow the test device, buffer and specimen to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible (within one hour).
2. Place the test device on a clean and level surface. Label with specimen ID. Add specimen and buffer. Avoid bubbles formation during addition of specimen and buffer.
   For **serum or plasma** specimens: Hold the specimen dropper (for serum/plasma/venipuncture whole blood) vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µL) and start the timer.
   For **venipuncture whole blood** specimens: Hold the specimen dropper (for serum/plasma/venipuncture whole blood) vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
   For **fingerstick whole blood** specimens: Take whole blood specimen with the 50 µL capillary tube (for fingerstick whole blood) until **joint** (volume position). And **add specimen** (approximately 50 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes. Do not read results after 20 minutes.**

INTERPRETATION OF RESULTS

REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
***Note:** The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).
INVALID: No line appears in the control line region (C). If this occurs, read the test procedure again and repeat the test with a new test device. If the result is still invalid, stop using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A control line is included in the test as an internal control. The test must absorb liquid and allow it to migrate along the membrane for the control line to appear. A colored line appearing in the control region (C) is the internal procedural control.
Quality control specimens are not supplied with this kit; however, it is recommended that quality control specimens be tested as a good laboratory practice.

LIMITATION

1. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HIV-1/2 in human whole blood, serum or plasma. The concentration of antibodies to HIV-1/2 can not be determined by this qualitative test.
2. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HIV-1/2 in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1, HIV-2, and/or HIV-1 subtype O infection.
3. For confirmation of reactive test results, specimens should undergo further testing using different assays, such as rapid diagnostic tests, EIA and/or Western blotting in accordance with a validated HIV testing algorithm.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Results should not be used to determine the genotype of HIV infections.
6. Due to possible antibody cross reactivity, the appearance of lines in both T1 and T2 does not necessarily indicate co-infection from HIV-1 and HIV-2.
7. False reactive results may arise due to rheumatoid factors, antinuclear antibodies, other viral infections (i.e. hepatitis B or hepatitis C), parasitic infections (i.e. schistosomiasis and trypanosomiasis), damage to test components by heat or humidity, or other test kit components (e.g. buffer or droppers) substituted between test kits.
8. False non-reactive results may arise when titers of antibodies to HIV1/2 are very low, titers of antibodies to HIV1/2 are very high (high-hook effect), insufficient specimen volume added, excess of buffer was added, or damage to test components by heat or humidity.
9. False-negative results may be observed in individuals who are receiving effective antiretroviral therapy. [1,2,3]
10. The estimated rate of Cross-reactivity between HIV-1 and HIV-2 positive samples was 32.6% using HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)[4]. Although dual infection of HIV-1 and HIV-2 is uncommon, it is reported that 9% of individuals with HIV-2 infection are coinfected with HIV-1 in Spain[5,6].

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) was evaluated with 1,640 specimens from different countries in an unpublished multi-center field study, 1,000 specimens from a blood donation center and 3,430 specimens from an in-house clinical study. Of the 6,070 total specimens (which included whole blood, serum and plasma specimens), 1,602 were found HIV seropositive and 4,468 specimens were found HIV seronegative by a characterization testing algorithm comprising of EIA and/or Western blot. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/ Serum/Plasma) showed 99.9% relative sensitivity, and 99.8% relative specificity compared to EIA and/or Western blot.

HIV 1/2/O Tri-line Rapid Test Device vs. EIA and/or Western blot

		EIA and/or Western blot		Total Results
	Results	Positive	Negative	
HIV 1/2/O Tri-line Rapid Test Device	Reactive	1,601	10	1,611
	Non-reactive	1	4,458	4,459
Total Results		1,602	4,468	6,070

Relative Sensitivity: 99.9% (99.7-100.0%)*
Relative Specificity: 99.8% (99.6-99.9%)*
Relative Accuracy: 99.8% (99.7-100.0%)*
* 95% Confidence Interval

Specimen Types Consistency

50 HIV seropositive whole blood and paired plasma specimens, 26 HIV seropositive whole blood, paired plasma and serum specimens, 50 negative whole blood, paired plasma and serum specimens were tested with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

EIA and/or Western blot	Specimen type	No. tested	HIV 1/2/O Tri-line Rapid Test Device	
			Non-reactive	Reactive
Negative	Plasma	50	50	0
	Serum	50	50	0
	Whole blood	50	50	0
Positive	Serum	26	0	26
	Plasma	76	0	76
	Whole blood	76	0	76

Paired whole blood, plasma, serum specimens show the consistent results with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

Precision

Intra-Assay (same lot)

Within-run precision has been determined by using 10 replicates of five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 **(subtype O)** positive, a medium titer HIV-1 positive and a HIV-2 positive. All above values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 (subtype O) positive, a medium titer HIV-1 positive and a HIV-2 positive. Three different lots of the HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/ Plasma) have been tested using above specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. Delaney KP, Branson BM, Uniyal A, et al. *Evaluation of the Performance Characteristics of 6 Rapid HIV Antibody Tests.* Clinical Infectious Diseases. 2011; 52(2): 257-263.
2. O'Connell RJ, Merritt TM, Malia JA, et al. *Performance of the OraQuick Rapid Antibody Test for Diagnosis of Human Immunodeficiency Virus Type 1 Infection in Patients with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2003; 41(5):2153-2155
3. O'Connell RJ, Agan BK, Anderson SA, et al. *Sensitivity of the Multispot HIV-1/HIV-2 Rapid Test Using Samples from Human Immunodeficiency Virus Type 1-Positive Individuals with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2006; 44(5): 1831-1833
4. WHO HIV ASSAY REPORT 18: *Laboratory performance and other operational characteristics rapid diagnostic test*.
5. Requena S, Caballero E, Lozano AB, Ríos-Villegas MJ, Benito R, Rojo S, Cabezas T, Macià MD, Nieto MDC, Soriano V, de Mendoza C; *Spanish HIV-2 Study Group. Treatment outcome in dually HIV-1 and HIV-2 coinfected patients living in Spain*. AIDS. 2019 Nov 15;33(14):2167-2172.
6. Zbinden A, Dürig R, Shah C, Böni J, Schüpbach J. *Importance of an Early HIV Antibody Differentiation Immunoassay for Detection of Dual Infection with HIV-1 and HIV-2*. PLoS One. 2016 Jun 16;11(6):e0157690.

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

Technical Support

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

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

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

Asia-Pacific
+61 7 3363 7100
AP.TechSupport@abbott.com

Latin America
57 1 4824033
LA.TechSupport@abbott.com

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

© 2022 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.

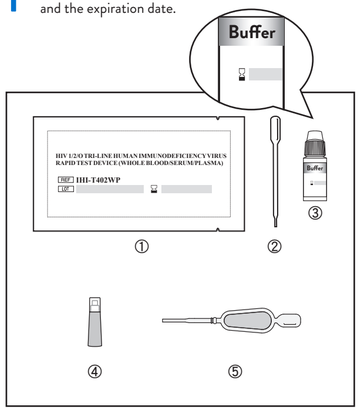
Abbott

ABON™

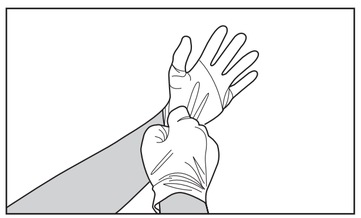
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

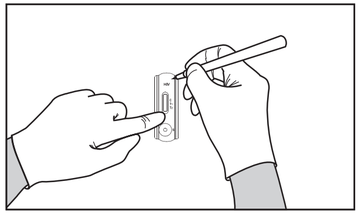
1 Open the package and check the content and the expiration date.



2 Wear gloves

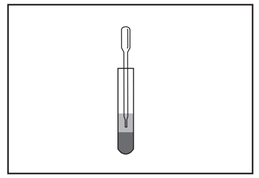


3 Open the pouch, Label with specimen ID. Use it as soon as possible (within one hour).

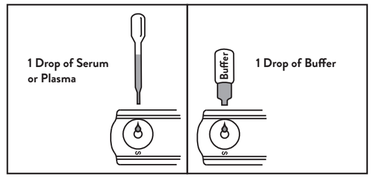


SERUM OR PLASMA SPECIMENS

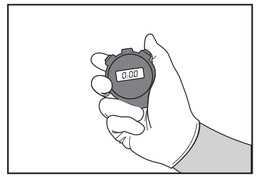
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



5 Transfer 1 drop of serum or plasma (approximately 25 µL), then add 1 drop of buffer (approximately 40 µL).

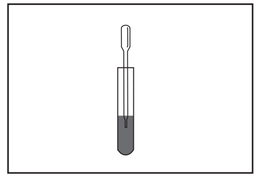


6 Start the timer.

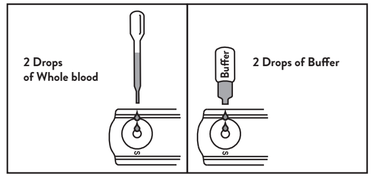


VENIPUNCTURE WHOLE BLOOD SPECIMENS

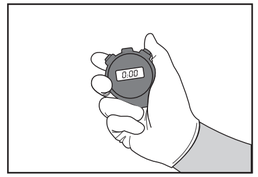
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



5 Transfer 2 drops of whole blood (approximately 50 µL), then add 2 drops of buffer (approximately 80 µL).

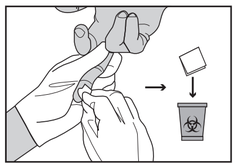


6 Start the timer.

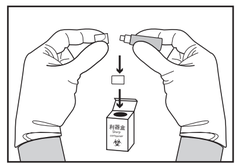


FINGERSTICK WHOLE BLOOD SPECIMENS

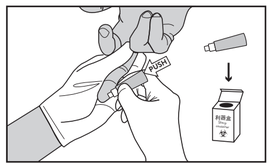
4 Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



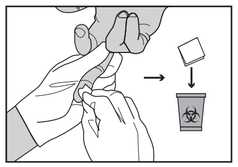
5 Take off the cap of the lancet and dispose the cap in sharps container.



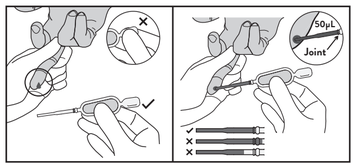
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



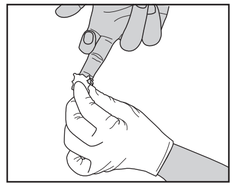
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



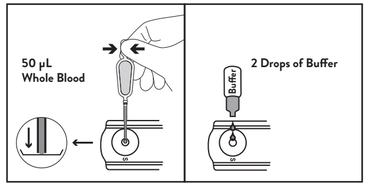
8 Hold the provided capillary tube (for fingerstick whole blood) horizontally below the bulb. DO NOT TOUCH OR SQUEEZE BULB. Immerse the open end of the capillary tube into the blood drop and let the blood rise by capillarity to the **joint** (volume position). Avoid air bubbles.



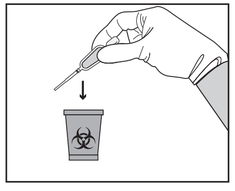
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



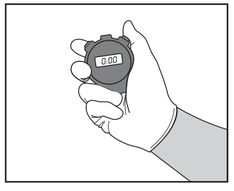
10 Squeeze the bulb and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).



11 Dispose the specimen dropper (for fingerstick whole blood) after testing.

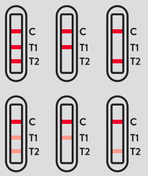


12 Start the timer.



READ RESULTS

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



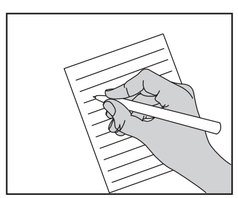
REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
***Note:** The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.

NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).

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

CLEAN UP/RECORD

Dispose devices and gloves in a proper biohazard waste container.



Record the test results.

Abbott

1156230601

Revision date: 2022-02-22
IFU version 04

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

REF IHI-T402WB IVD

Instructions for Use English

A rapid diagnostic test for the qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) type 1, including subtype O, and type 2 in whole blood, serum or plasma.
For professional use only.

INTENDED USE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is an *in vitro* diagnostic rapid immunochromatographic assay for the qualitative detection of antibodies to HIV-1, including subtype O, and HIV-2 in venous and capillary whole blood, serum and plasma specimens. The product may be used as an aid in the diagnosis of HIV infection. A reactive result should be confirmed by supplemental testing as part of a validated HIV testing algorithm. This product has not been evaluated on paediatric and neonatal specimens.

PRINCIPLE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) test strip is pre-coated with HIV-1 and subtype O antigens on T1 test line and HIV-2 antigen on T2 test line. Firstly, specimen and then buffer is added to the specimen well, thus starting the migration of the specimen/buffer. The specimen/buffer passes the conjugate pad which contains a mixture of HIV-1 envelope and capsid antigen and HIV-2 envelope antigen. These detection antigens are conjugated to latex particles. If present, the HIV-1 or HIV-2 antibodies react and bind to the detection antigen-conjugate. The antibody/antigen-conjugate mixture then migrates further and binds to antigens present on the test lines. If the specimen contains antibodies to HIV-1, the specimen will bind to the T1 test line and produce a line, if specimen contains antibodies to HIV-2, the specimen will bind to the T2 test line. As liquid continues to migrate down the test strip, the control line will appear. If the control line is present, in addition to either or both test lines, then the test is reactive for HIV1/2 antibodies. If the specimen does not contain HIV-1 or HIV-2 antibodies, no colored lines will appear for either of the test lines region indicating a non-reactive result. Please note that the appearance of colored lines at T1 and T2 is highly unlikely to be indicative of co-infection with HIV-1 and HIV-2 but rather is a result of cross-reactivity between antigens. A colored line will appear in the control line region if the migration of liquid has been successful, and must be present for the test to be valid. If the control line does not appear, the test result is not valid.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (storage in refrigerator is permitted). **Do not store in the freezer**. Protect the test kit from humidity. The test device is stable until the expiration date printed on the test kit and/or sealed test device pouch. Do not use beyond the expiration date. The test device must remain in the sealed pouch until use.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Read the instruction carefully before performing the test.
- Apply standard biosafety precautions when handling and disposing of potentially infectious material.
- Handle all specimens as potentially infectious.
- Wear protective clothing such as gloves, laboratory coats, and eye protection when specimens are being tested.
- The test device and accessory should be disposed in a proper biohazard waste container after testing.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Avoid splashes and clean up spills immediately with appropriate disinfectant.
- The buffer contains 0.02% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities of water.
- Do not use the test kit beyond the expiration date.
- Do not use if the packaging is damaged.
- Do not use the specimen dropper (for fingerstick whole blood) and single-use lancet if it is already damaged.
- Dispose the specimen dropper (for fingerstick whole blood) and single-use lancet in the sharps container if it is already damaged before use.
- Do not set the lancet down before discarding it.
- Do not reuse the lancet.
- In case of Post-exposure prophylaxis for HIV, operators should familiarize themselves with PPE policy prior to conducting the testing.
- Humidity and temperature can adversely affect results.
- The optimal number of specimens to be tested at one time is 10.
- Do not use any other specimen than those specified. For plasma/venipuncture whole blood, EDTA-K_2/sodium heparin/sodium citrate/lithium heparin can be used as anticoagulant. Other anticoagulants have not been tested and may give incorrect results.
- Do not form air bubbles during addition of specimen. Bubble formation may lead to insufficient specimen volume added and a false non-reactive result may occur accordingly.

SPECIMEN COLLECTION AND PREPARATION

- HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **fingerstick whole blood** specimens:
  - Wear gloves.
  - Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Allow to dry (30 seconds).
  - Puncture the side of the finger with a new lancet each time. Dispose the lancet in sharps container immediately after using it. Do not use the lancet if the cap is already pulled off. Wipe away the first blood drop with a sterile gauze pad or cotton wool.
  - Take the provided specimen dropper (for fingerstick whole blood) vertically, squeeze the middle of the dropper, immerse the open end into the blood drop, and then slowly release the pressure to draw blood until mark line. Avoid air bubbles.
  - Squeeze the specimen dropper and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).
- To collect **serum or plasma or venipuncture whole blood** specimens:
  - Collect according to safe phlebotomy procedures, using vacuum technique into 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.

SPECIMEN STORAGE

- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature (15-30°C) for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be stored at -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 experimental controls and 20 nonreactive or 20 reactive specimens subjected to 6 freeze/thaw cycles; however, multiple freeze/thaw cycles should be avoided.

MATERIALS

Materials Provided

Components	IHI-T402WB
1. Test Device	x40
2. Specimen Dropper (For Serum/Plasma/Venipuncture Whole Blood)	x40
3. 3mL Buffer	x2
4. Single-use Lancet	x40
5. Specimen Dropper (For Fingerstick Whole Blood)	x40
6. Instructions for Use	x1

Materials Required But Not Provided

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

TEST PROCEDURE

Allow the test device, buffer and specimen to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible (within one hour).
2. Place the test device on a clean and level surface. Label with specimen ID. Add specimen and buffer. Avoid bubbles formation during addition of specimen and buffer.
   For **serum or plasma** specimens: Hold the specimen dropper (for serum/plasma/venipuncture whole blood) vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µL) and start the timer.
   For **venipuncture whole blood** specimens: Hold the specimen dropper (for serum/plasma/venipuncture whole blood) vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
   For **fingerstick whole blood** specimens: Take whole blood specimen with the 50 µL specimen dropper (for fingerstick whole blood) until mark line. And **add specimen** (approximately 50 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes. Do not read results after 20 minutes.**

INTERPRETATION OF RESULTS

REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
***Note:** The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).
INVALID: No line appears in the control line region (C). If this occurs, read the test procedure again and repeat the test with a new test device. If the result is still invalid, stop using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A control line is included in the test as an internal control. The test must absorb liquid and allow it to migrate along the membrane for the control line to appear. A colored line appearing in the control region (C) is the internal procedural control.
Quality control specimens are not supplied with this kit; however, it is recommended that quality control specimens be tested as a good laboratory practice.

LIMITATION

1. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HIV-1/2 in human whole blood, serum or plasma. The concentration of antibodies to HIV-1/2 can not be determined by this qualitative test.
2. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HIV-1/2 in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1, HIV-2, and/or HIV-1 subtype O infection.
3. For confirmation of reactive test results, specimens should undergo further testing using different assays, such as rapid diagnostic tests, EIA and/or Western blotting in accordance with a validated HIV testing algorithm.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Results should not be used to determine the genotype of HIV infections.
6. Due to possible antibody cross reactivity, the appearance of lines in both T1 and T2 does not necessarily indicate co-infection from HIV-1 and HIV-2.
7. False reactive results may arise due to rheumatoid factors, antinuclear antibodies, other viral infections (i.e. hepatitis B or hepatitis C), parasitic infections (i.e. schistosomiasis and trypanosomiasis), damage to test components by heat or humidity, or other test kit components (e.g. buffer or droppers) substituted between test kits.
8. False non-reactive results may arise when titers of antibodies to HIV1/2 are very low, titers of antibodies to HIV1/2 are very high (high-hook effect), insufficient specimen volume added, excess of buffer was added, or damage to test components by heat or humidity.
9. False-negative results may be observed in individuals who are receiving effective antiretroviral therapy. [1,2,3]
10. The estimated rate of Cross-reactivity between HIV-1 and HIV-2 positive samples was 32.6% using HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)[4]. Although dual infection of HIV-1 and HIV-2 is uncommon, it is reported that 9% of individuals with HIV-2 infection are coinfected with HIV-1 in Spain[5,6].

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) was evaluated with 1,640 specimens from different countries in an unpublished multi-center field study, 1,000 specimens from a blood donation center and 3,430 specimens from an in-house clinical study. Of the 6,070 total specimens (which included whole blood, serum and plasma specimens), 1,602 were found HIV seropositive and 4,468 specimens were found HIV seronegative by a characterization testing algorithm comprising of EIA and/or Western blot. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/ Serum/Plasma) showed 99.9% relative sensitivity, and 99.8% relative specificity compared to EIA and/or Western blot.

HIV 1/2/O Tri-line Rapid Test Device vs. EIA and/or Western blot

HIV 1/2/O Tri-line Rapid Test Device	Results	EIA and/or Western blot		Total Results
		Positive	Negative	
	Reactive	1,601	10	1,611
	Non-reactive	1	4,458	4,459
Total Results		1,602	4,468	6,070

Relative Sensitivity: 99.9% (99.7-100.0%)*
Relative Specificity: 99.8% (99.6-99.9%)*
Relative Accuracy: 99.8% (99.7-100.0%)*
* 95% Confidence Interval

Specimen Types Consistency

50 HIV seropositive whole blood and paired plasma specimens, 26 HIV seropositive whole blood, paired plasma and serum specimens, 50 negative whole blood, paired plasma and serum specimens were tested with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/ Serum/Plasma).

EIA and/or Western blot	Specimen type	No. tested	HIV 1/2/O Tri-line Rapid Test Device	
			Non-reactive	Reactive
Negative	Plasma	50	50	0
	Serum	50	50	0
	Whole blood	50	50	0
Positive	Serum	26	0	26
	Plasma	76	0	76
	Whole blood	76	0	76

Paired whole blood, plasma, serum specimens show the consistent results with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

Precision

Intra-Assay (same lot)

Within-run precision has been determined by using 10 replicates of five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 **(subtype O)** positive, a medium titer HIV-1 positive and a HIV-2 positive. All above values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 (subtype O) positive, a medium titer HIV-1 positive and a HIV-2 positive. Three different lots of the HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/ Plasma) have been tested using above specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. Delaney KP, Branson BM, Uniyal A, et al. *Evaluation of the Performance Characteristics of 6 Rapid HIV Antibody Tests.* Clinical Infectious Diseases. 2011; 52(2): 257-263.
2. O'Connell RJ, Merritt TM, Malia JA, et al. *Performance of the OraQuick Rapid Antibody Test for Diagnosis of Human Immunodeficiency Virus Type 1 Infection in Patients with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2003; 41(5):2153-2155
3. O'Connell RJ, Agan BK, Anderson SA, et al. *Sensitivity of the Multispot HIV-1/HIV-2 Rapid Test Using Samples from Human Immunodeficiency Virus Type 1-Positive Individuals with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2006; 44(5): 1831-1833
4. WHO HIV ASSAY REPORT 18: *Laboratory performance and other operational characteristics rapid diagnostic test*.
5. Requena S, Caballero E, Lozano AB, Ríos-Villegas MJ, Benito R, Rojo S, Cabezas T, Macià MD, Nieto MDC, Soriano V, de Mendoza C; *Spanish HIV-2 Study Group. Treatment outcome in dually HIV-1 and HIV-2 coinfected patients living in Spain*. AIDS. 2019 Nov 15;33(14):2167-2172.
6. Zbinden A, Dürig R, Shah C, Böni J, Schüpbach J. *Importance of an Early HIV Antibody Differentiation Immunoassay for Detection of Dual Infection with HIV-1 and HIV-2*. PLoS One. 2016 Jun 16;11(6):e0157690.

Index of Symbols

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

Technical Support

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

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

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

Asia-Pacific
+61 7 3363 7100
AP.TechSupport@abbott.com

Latin America
57 1 4824033
LA.TechSupport@abbott.com

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

© 2022 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.

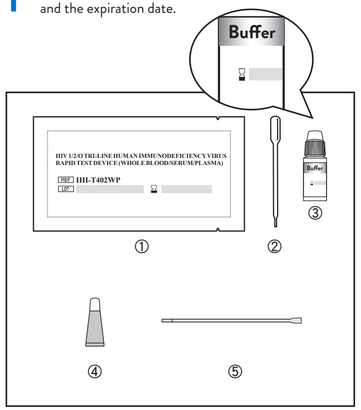
Abbott

ABON™

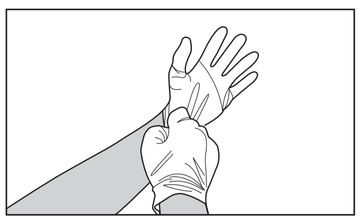
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

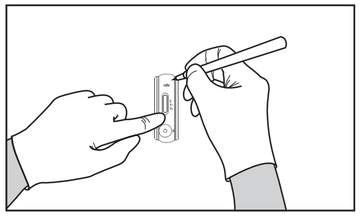
1 Open the package and check the content and the expiration date.



2 Wear gloves

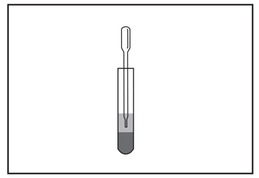


3 Open the pouch, Label with specimen ID. Use it as soon as possible (within one hour).

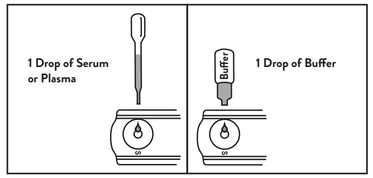


SERUM OR PLASMA SPECIMENS

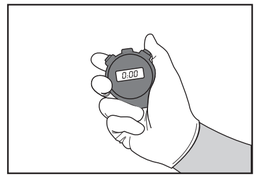
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



5 Transfer 1 drop of serum or plasma (approximately 25 µL), then add 1 drop of buffer (approximately 40 µL).

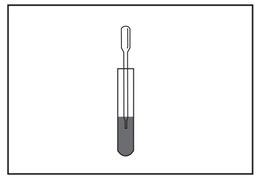


6 Start the timer.

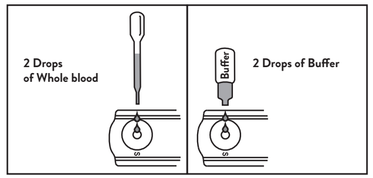


VENIPUNCTURE WHOLE BLOOD SPECIMENS

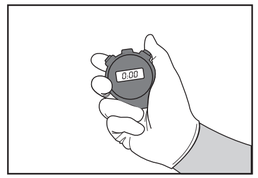
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



5 Transfer 2 drops of whole blood (approximately 50 µL), then add 2 drops of buffer (approximately 80 µL).

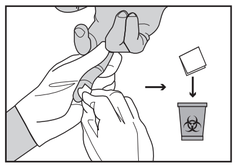


6 Start the timer.

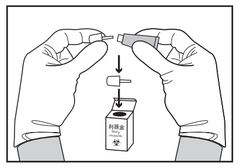


FINGERSTICK WHOLE BLOOD SPECIMENS

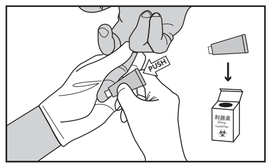
4 Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



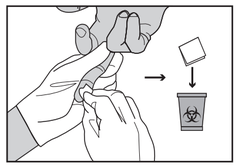
5 Take off the cap of the lancet and dispose the cap in sharps container.



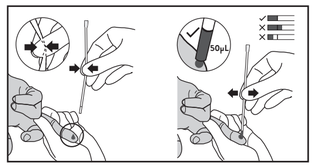
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



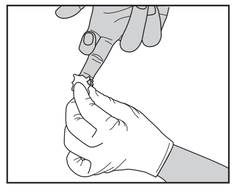
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



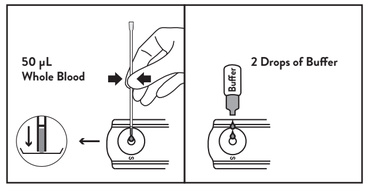
8 Take the provided specimen dropper (for fingerstick whole blood) vertically, squeeze the middle of the dropper, immerse the open end into the blood drop, and then slowly release the pressure to draw blood until mark line. Avoid air bubbles.



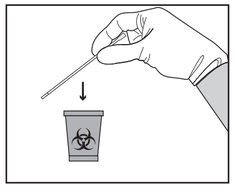
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



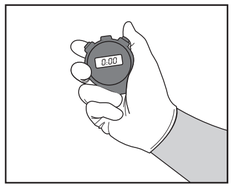
10 Squeeze the specimen dropper and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).



11 Dispose the specimen dropper (for fingerstick whole blood) after testing.



12 Start the timer.

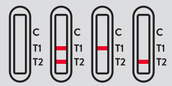


READ RESULTS

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

REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
***Note:** The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.

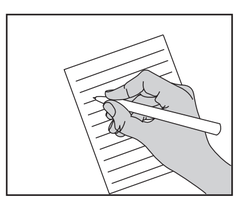
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).



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

CLEAN UP/RECORD

Dispose devices and gloves in a proper biohazard waste container.



Record the test results.

Abbott

1156230701

Revision date: 2022-02-22
IFU version 03

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

REF IHI-T402WD IVD

Instructions for Use English

A rapid diagnostic test for the qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) type 1, including subtype O, and type 2 in whole blood, serum or plasma.
For professional use only.

INTENDED USE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is an *in vitro* diagnostic rapid immunochromatographic assay for the qualitative detection of antibodies to HIV-1, including subtype O, and HIV-2 in venous and capillary whole blood, serum and plasma specimens. The product may be used as an aid in the diagnosis of HIV infection. A reactive result should be confirmed by supplemental testing as part of a validated HIV testing algorithm. This product has not been evaluated on paediatric and neonatal specimens.

PRINCIPLE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) test strip is pre-coated with HIV-1 and subtype O antigens on T1 test line and HIV-2 antigen on T2 test line. Firstly, specimen and then buffer is added to the specimen well, thus starting the migration of the specimen/buffer. The specimen/buffer passes the conjugate pad which contains a mixture of HIV-1 envelope and capsid antigen and HIV-2 envelope antigen. These detection antigens are conjugated to latex particles. If present, the HIV-1 or HIV-2 antibodies react and bind to the detection antigen-conjugate. The antibody/antigen-conjugate mixture then migrates further and binds to antigens present on the test lines. If the specimen contains antibodies to HIV-1, the specimen will bind to the T1 test line and produce a line, if specimen contains antibodies to HIV-2, the specimen will bind to the T2 test line. As liquid continues to migrate down the test strip, the control line will appear. If the control line is present, in addition to either or both test lines, then the test is reactive for HIV1/2 antibodies. If the specimen does not contain HIV-1 or HIV-2 antibodies, no colored lines will appear for either of the test lines region indicating a non-reactive result. Please note that the appearance of colored lines at T1 and T2 is highly unlikely to be indicative of co-infection with HIV-1 and HIV-2 but rather is a result of cross-reactivity between antigens. A colored line will appear in the control line region if the migration of liquid has been successful, and must be present for the test to be valid. If the control line does not appear, the test result is not valid.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (storage in refrigerator is permitted). **Do not store in the freezer**. Protect the test kit from humidity. The test device is stable until the expiration date printed on the test kit and/or sealed test device pouch. Do not use beyond the expiration date. The test device must remain in the sealed pouch until use.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Read the instruction carefully before performing the test.
- Apply standard biosafety precautions when handling and disposing of potentially infectious material.
- Handle all specimens as potentially infectious.
- Wear protective clothing such as gloves, laboratory coats, and eye protection when specimens are being tested.
- The test device and accessory should be disposed in a proper biohazard waste container after testing.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Avoid splashes and clean up spills immediately with appropriate disinfectant.
- The buffer contains 0.02% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities of water.
- Do not use the test kit beyond the expiration date.
- Do not use if the packaging is damaged.
- Do not use the specimen dropper (for fingerstick whole blood), single-use lancet or alcohol pad if it is already damaged.
- Dispose the specimen dropper (for fingerstick whole blood) and single-use lancet in the sharps container if it is already damaged before use.
- Do not set the lancet down before discarding it.
- Do not reuse the lancet.
- In case of Post-exposure prophylaxis for HIV, operators should familiarize themselves with PPE policy prior to conducting the testing.
- Humidity and temperature can adversely affect results.
- The optimal number of specimens to be tested at one time is 10.
- Do not use any other specimen than those specified. For plasma/venipuncture whole blood, EDTA-K_2/sodium heparin/sodium citrate/lithium heparin can be used as anticoagulant. Other anticoagulants have not been tested and may give incorrect results.
- Do not form air bubbles during addition of specimen. Bubble formation may lead to insufficient specimen volume added and a false non-reactive result may occur accordingly.

SPECIMEN COLLECTION AND PREPARATION

- HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **fingerstick whole blood** specimens:
  - Wear gloves.
  - Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Allow to dry (30 seconds).
  - Puncture the side of the finger with a new lancet each time. Dispose the lancet in sharps container immediately after using it. Do not use the lancet if the cap is already pulled off. Wipe away the first blood drop with a sterile gauze pad or cotton wool.
  - Take the provided specimen dropper (for fingerstick whole blood) vertically, squeeze the middle of the dropper, immerse the open end into the blood drop, and then slowly release the pressure to draw blood until mark line. Avoid air bubbles.
  - Squeeze the specimen dropper and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).
- To collect **serum or plasma or venipuncture whole blood** specimens:
  - Collect according to safe phlebotomy procedures, using vacuum technique into 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.

SPECIMEN STORAGE

- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature (15-30°C) for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be stored at -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 experimental controls and 20 nonreactive or 20 reactive specimens subjected to 6 freeze/thaw cycles; however, multiple freeze/thaw cycles should be avoided.

MATERIALS

Materials Provided

Components	IHI-T402WD
1. Test Device	x10
2. Specimen Dropper (For Serum/Plasma/Venipuncture Whole Blood)	x10
3. 3mL Buffer	x1
4. Alcohol Swab	x10
5. Single-use Lancet	x10
6. Specimen Dropper (For Fingerstick Whole Blood)	x10
7. Instructions for Use	x1

Materials Required But Not Provided

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

TEST PROCEDURE

Allow the test device, buffer and specimen to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible (within one hour).
2. Place the test device on a clean and level surface. Label with specimen ID. Add specimen and buffer. Avoid bubbles formation during addition of specimen and buffer.
   For **serum or plasma** specimens: Hold the specimen dropper (for serum/plasma/venipuncture whole blood) vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µL) and start the timer.
   For **venipuncture whole blood** specimens: Hold the specimen dropper (for serum/plasma/venipuncture whole blood) vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
   For **fingerstick whole blood** specimens: Take whole blood specimen with the 50 µL specimen dropper (for fingerstick whole blood) until mark line. And **add specimen** (approximately 50 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes. Do not read results after 20 minutes.**

INTERPRETATION OF RESULTS

REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
***Note:** The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).
INVALID: No line appears in the control line region (C). If this occurs, read the test procedure again and repeat the test with a new test device. If the result is still invalid, stop using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A control line is included in the test as an internal control. The test must absorb liquid and allow it to migrate along the membrane for the control line to appear. A colored line appearing in the control region (C) is the internal procedural control.
Quality control specimens are not supplied with this kit; however, it is recommended that quality control specimens be tested as a good laboratory practice.

LIMITATION

1. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HIV-1/2 in human whole blood, serum or plasma. The concentration of antibodies to HIV-1/2 can not be determined by this qualitative test.
2. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HIV-1/2 in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1, HIV-2, and/or HIV-1 subtype O infection.
3. For confirmation of reactive test results, specimens should undergo further testing using different assays, such as rapid diagnostic tests, EIA and/or Western blotting in accordance with a validated HIV testing algorithm.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Results should not be used to determine the genotype of HIV infections.
6. Due to possible antibody cross reactivity, the appearance of lines in both T1 and T2 does not necessarily indicate co-infection from HIV-1 and HIV-2.
7. False reactive results may arise due to rheumatoid factors, antinuclear antibodies, other viral infections (i.e. hepatitis B or hepatitis C), parasitic infections (i.e. schistosomiasis and trypanosomiasis), damage to test components by heat or humidity, or other test kit components (e.g. buffer or droppers) substituted between test kits.
8. False non-reactive results may arise when titers of antibodies to HIV1/2 are very low, titers of antibodies to HIV1/2 are very high (high-hook effect), insufficient specimen volume added, excess of buffer was added, or damage to test components by heat or humidity.
9. False-negative results may be observed in individuals who are receiving effective antiretroviral therapy. [1,2,3]
10. The estimated rate of Cross-reactivity between HIV-1 and HIV-2 positive samples was 32.6% using HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)[4]. Although dual infection of HIV-1 and HIV-2 is uncommon, it is reported that 9% of individuals with HIV-2 infection are coinfected with HIV-1 in Spain[5,6].

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) was evaluated with 1,640 specimens from different countries in an unpublished multi-center field study, 1,000 specimens from a blood donation center and 3,430 specimens from an in-house clinical study. Of the 6,070 total specimens (which included whole blood, serum and plasma specimens), 1,602 were found HIV seropositive and 4,468 specimens were found HIV seronegative by a characterization testing algorithm comprising of EIA and/or Western blot. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/ Serum/Plasma) showed 99.9% relative sensitivity, and 99.8% relative specificity compared to EIA and/or Western blot.

HIV 1/2/O Tri-line Rapid Test Device vs. EIA and/or Western blot

HIV 1/2/O Tri-line Rapid Test Device	Results	EIA and/or Western blot: Positive	EIA and/or Western blot: Negative	Total Results
	Reactive	1,601	10	1,611
	Non-reactive	1	4,458	4,459
Total Results		1,602	4,468	6,070

Relative Sensitivity: 99.9% (99.7-100.0%)*
Relative Specificity: 99.8% (99.6-99.9%)*
Relative Accuracy: 99.8% (99.7-100.0%)*
* 95% Confidence Interval

Specimen Types Consistency

50 HIV seropositive whole blood and paired plasma specimens, 26 HIV seropositive whole blood, paired plasma and serum specimens, 50 negative whole blood, paired plasma and serum specimens were tested with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/ Serum/Plasma).

EIA and/or Western blot	Specimen type	No. tested	HIV 1/2/O Tri-line Rapid Test Device: Non-reactive	HIV 1/2/O Tri-line Rapid Test Device: Reactive
Negative	Plasma	50	50	0
	Serum	50	50	0
	Whole blood	50	50	0
Positive	Serum	26	0	26
	Plasma	76	0	76
	Whole blood	76	0	76

Paired whole blood, plasma, serum specimens show the consistent results with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

Precision

Intra-Assay (same lot)

Within-run precision has been determined by using 10 replicates of five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 **(subtype O)** positive, a medium titer HIV-1 positive and a HIV-2 positive. All above values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 (subtype O) positive, a medium titer HIV-1 positive and a HIV-2 positive. Three different lots of the HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/ Plasma) have been tested using above specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. Delaney KP, Branson BM, Uniyal A, et al. *Evaluation of the Performance Characteristics of 6 Rapid HIV Antibody Tests.* Clinical Infectious Diseases. 2011; 52(2): 257-263.
2. O'Connell RJ, Merritt TM, Malia JA, et al. *Performance of the OraQuick Rapid Antibody Test for Diagnosis of Human Immunodeficiency Virus Type 1 Infection in Patients with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2003; 41(5):2153-2155
3. O'Connell RJ, Agan BK, Anderson SA, et al. *Sensitivity of the Multispot HIV-1/HIV-2 Rapid Test Using Samples from Human Immunodeficiency Virus Type 1-Positive Individuals with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2006; 44(5): 1831-1833
4. WHO HIV ASSAY REPORT 18: *Laboratory performance and other operational characteristics rapid diagnostic test.*
5. Requena S, Caballero E, Lozano AB, Ríos-Villegas MJ, Benito R, Rojo S, Cabezas T, Macià MD, Nieto MDC, Soriano V, de Mendoza C; *Spanish HIV-2 Study Group. Treatment outcome in dually HIV-1 and HIV-2 coinfected patients living in Spain.* AIDS. 2019 Nov 15;33(14):2167-2172.
6. Zbinden A, Dürig R, Shah C, Böni J, Schüpbach J. *Importance of an Early HIV Antibody Differentiation Immunoassay for Detection of Dual Infection with HIV-1 and HIV-2.* PLoS One. 2016 Jun 16;11(6):e0157690.

Index of Symbols

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

Technical Support

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

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

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

Asia-Pacific
+61 7 3363 7100
AP.TechSupport@abbott.com

Latin America
57 1 4824033
LA.TechSupport@abbott.com

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

© 2022 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.

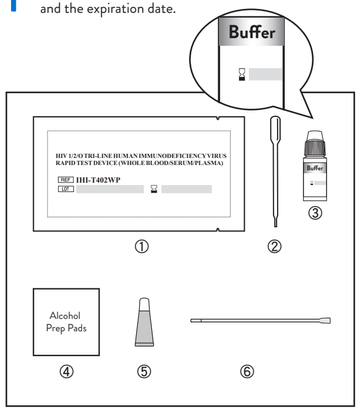
Abbott

ABON™

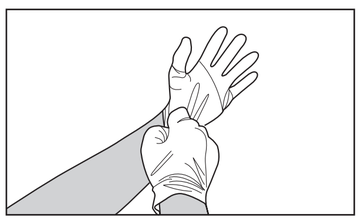
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

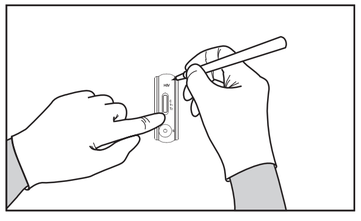
1 Open the package and check the content and the expiration date.



2 Wear gloves

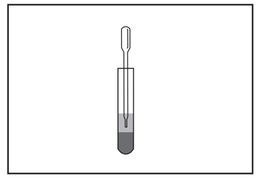


3 Open the pouch, Label with specimen ID. Use it as soon as possible (within one hour).

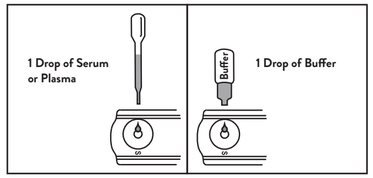


SERUM OR PLASMA SPECIMENS

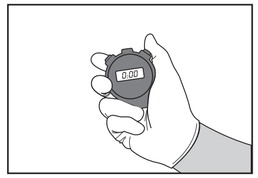
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



5 Transfer 1 drop of serum or plasma (approximately 25 µL), then add 1 drop of buffer (approximately 40 µL).

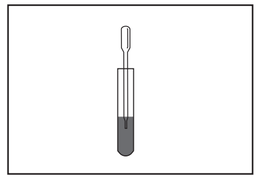


6 Start the timer.

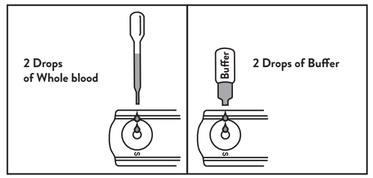


VENIPUNCTURE WHOLE BLOOD SPECIMENS

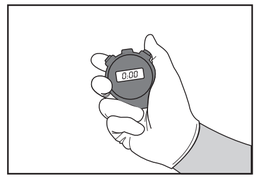
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



5 Transfer 2 drops of whole blood (approximately 50 µL), then add 2 drops of buffer (approximately 80 µL).

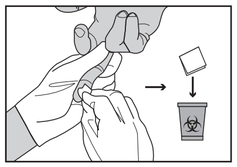


6 Start the timer.

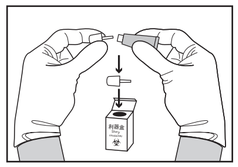


FINGERSTICK WHOLE BLOOD SPECIMENS

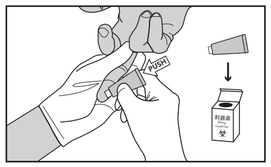
4 Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



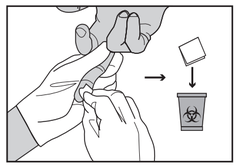
5 Take off the cap of the lancet and dispose the cap in sharps container.



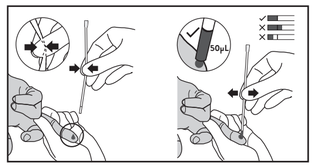
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



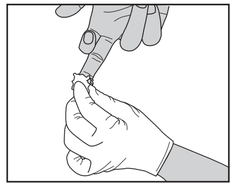
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



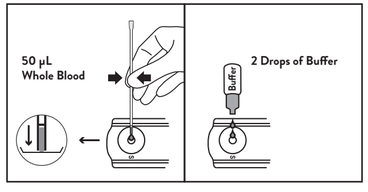
8 Take the provided specimen dropper (for fingerstick whole blood) vertically, squeeze the middle of the dropper, immerse the open end into the blood drop, and then slowly release the pressure to draw blood until mark line. Avoid air bubbles.



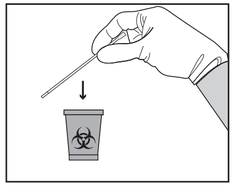
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



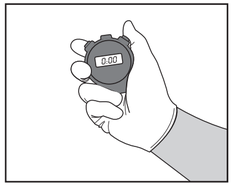
10 Squeeze the specimen dropper and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).



11 Dispose the specimen dropper (for fingerstick whole blood) after testing.

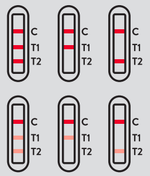


12 Start the timer.



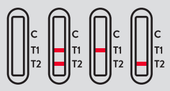
READ RESULTS

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



REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
***Note:** The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.

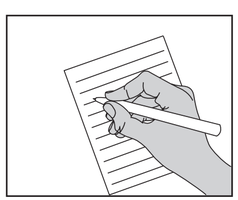
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).



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

CLEAN UP/RECORD

Dispose devices and gloves in a proper biohazard waste container.



Record the test results.

Abbott

1156230401

Revision date: 2022-02-22
IFU version 06

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

REF IHI-T402WG IVD

Instructions for Use English

A rapid diagnostic test for the qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) type 1, including subtype O, and type 2 in whole blood, serum or plasma.
For professional use only.

INTENDED USE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is an *in vitro* diagnostic rapid immunochromatographic assay for the qualitative detection of antibodies to HIV-1, including subtype O, and HIV-2 in venous and capillary whole blood, serum and plasma specimens. The product may be used as an aid in the diagnosis of HIV infection. A reactive result should be confirmed by supplemental testing as part of a validated HIV testing algorithm. This product has not been evaluated on paediatric and neonatal specimens.

PRINCIPLE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) test strip is pre-coated with HIV-1 and subtype O antigens on T1 test line and HIV-2 antigen on T2 test line. Firstly, specimen and then buffer is added to the specimen well, thus starting the migration of the specimen/buffer. The specimen/buffer passes the conjugate pad which contains a mixture of HIV-1 envelope and capsid antigen and HIV-2 envelope antigen. These detection antigens are conjugated to latex particles. If present, the HIV-1 or HIV-2 antibodies react and bind to the detection antigen-conjugate. The antibody/antigen-conjugate mixture then migrates further and binds to antigens present on the test lines. If the specimen contains antibodies to HIV-1, the specimen will bind to the T1 test line and produce a line, if specimen contains antibodies to HIV-2, the specimen will bind to the T2 test line. As liquid continues to migrate down the test strip, the control line will appear. If the control line is present, in addition to either or both test lines, then the test is reactive for HIV1/2 antibodies. If the specimen does not contain HIV-1 or HIV-2 antibodies, no colored lines will appear for either of the test lines region indicating a non-reactive result. Please note that the appearance of colored lines at T1 and T2 is highly unlikely to be indicative of co-infection with HIV-1 and HIV-2 but rather is a result of cross-reactivity between antigens. A colored line will appear in the control line region if the migration of liquid has been successful, and must be present for the test to be valid. If the control line does not appear, the test result is not valid.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (storage in refrigerator is permitted). **Do not store in the freezer**. Protect the test kit from humidity. The test device is stable until the expiration date printed on the test kit and/or sealed test device pouch. Do not use beyond the expiration date. The test device must remain in the sealed pouch until use.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Read the instruction carefully before performing the test.
- Apply standard biosafety precautions when handling and disposing of potentially infectious material.
- Handle all specimens as potentially infectious.
- Wear protective clothing such as gloves, laboratory coats, and eye protection when specimens are being tested.
- The test device and accessory should be disposed in a proper biohazard waste container after testing.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Avoid splashes and clean up spills immediately with appropriate disinfectant.
- The buffer contains 0.02% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities of water.
- Do not use the test kit beyond the expiration date.
- Do not use if the packaging is damaged.
- Do not use the specimen dropper (for fingerstick whole blood), single-use lancet or alcohol pad if it is already damaged.
- Dispose the specimen dropper (for fingerstick whole blood) and single-use lancet in the sharps container if it is already damaged before use.
- Do not set the lancet down before discarding it.
- Do not reuse the lancet.
- In case of Post-exposure prophylaxis for HIV, operators should familiarize themselves with PPE policy prior to conducting the testing.
- Humidity and temperature can adversely affect results.
- The optimal number of specimens to be tested at one time is 10.
- Do not use any other specimen than those specified. For plasma/venipuncture whole blood, EDTA-K_2/sodium heparin/sodium citrate/lithium heparin can be used as anticoagulant. Other anticoagulants have not been tested and may give incorrect results.
- Do not form air bubbles during addition of specimen. Bubble formation may lead to insufficient specimen volume added and a false non-reactive result may occur accordingly.

SPECIMEN COLLECTION AND PREPARATION

- HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **fingerstick whole blood** specimens:
  - Wear gloves.
  - Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Allow to dry (30 seconds).
  - Puncture the side of the finger with a new lancet each time. Dispose the lancet in sharps container immediately after using it. Do not use the lancet if the cap is already pulled off. Wipe away the first blood drop with a sterile gauze pad or cotton wool.
  - Take the provided specimen dropper (for fingerstick whole blood) vertically, squeeze the middle of the dropper, immerse the open end into the blood drop, and then slowly release the pressure to draw blood until mark line. Avoid air bubbles.
  - Squeeze the specimen dropper and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).
- To collect **serum or plasma or venipuncture whole blood** specimens:
  - Collect according to safe phlebotomy procedures, using vacuum technique into 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.

SPECIMEN STORAGE

- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature (15-30°C) for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be stored at -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 experimental controls and 20 nonreactive or 20 reactive specimens subjected to 6 freeze/thaw cycles; however, multiple freeze/thaw cycles should be avoided.

MATERIALS

Materials Provided

Components	IHI-T402WG
1. Test Device	x40
2. Specimen Dropper (For Serum/Plasma/Venipuncture Whole Blood)	x40
3. 3mL Buffer	x2
4. Alcohol Swab	x40
5. Single-use Lancet	x40
6. Specimen Dropper (For Fingerstick Whole Blood)	x40
7. Instructions for Use	x1

Materials Required But Not Provided

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

TEST PROCEDURE

Allow the test device, buffer and specimen to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible (within one hour).
2. Place the test device on a clean and level surface. Label with specimen ID. Add specimen and buffer. Avoid bubbles formation during addition of specimen and buffer.
   For **serum or plasma** specimens: Hold the specimen dropper (for serum/plasma/venipuncture whole blood) vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µL) and start the timer.
   For **venipuncture whole blood** specimens: Hold the specimen dropper (for serum/plasma/venipuncture whole blood) vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
   For **fingerstick whole blood** specimens: Take whole blood specimen with the 50 µL specimen dropper (for fingerstick whole blood) until mark line. And **add specimen** (approximately 50 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes. Do not read results after 20 minutes.**

INTERPRETATION OF RESULTS

REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
***Note:** The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).
INVALID: No line appears in the control line region (C). If this occurs, read the test procedure again and repeat the test with a new test device. If the result is still invalid, stop using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A control line is included in the test as an internal control. The test must absorb liquid and allow it to migrate along the membrane for the control line to appear. A colored line appearing in the control region (C) is the internal procedural control.
Quality control specimens are not supplied with this kit; however, it is recommended that quality control specimens be tested as a good laboratory practice.

LIMITATION

1. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HIV-1/2 in human whole blood, serum or plasma. The concentration of antibodies to HIV-1/2 can not be determined by this qualitative test.
2. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HIV-1/2 in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1, HIV-2, and/or HIV-1 subtype O infection.
3. For confirmation of reactive test results, specimens should undergo further testing using different assays, such as rapid diagnostic tests, EIA and/or Western blotting in accordance with a validated HIV testing algorithm.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Results should not be used to determine the genotype of HIV infections.
6. Due to possible antibody cross reactivity, the appearance of lines in both T1 and T2 does not necessarily indicate co-infection from HIV-1 and HIV-2.
7. False reactive results may arise due to rheumatoid factors, antinuclear antibodies, other viral infections (i.e. hepatitis B or hepatitis C), parasitic infections (i.e. schistosomiasis and trypanosomiasis), damage to test components by heat or humidity, or other test kit components (e.g. buffer or droppers) substituted between test kits.
8. False non-reactive results may arise when titers of antibodies to HIV1/2 are very low, titers of antibodies to HIV1/2 are very high (high-hook effect), insufficient specimen volume added, excess of buffer was added, or damage to test components by heat or humidity.
9. False-negative results may be observed in individuals who are receiving effective antiretroviral therapy. [1,2,3]
10. The estimated rate of Cross-reactivity between HIV-1 and HIV-2 positive samples was 32.6% using HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)[4]. Although dual infection of HIV-1 and HIV-2 is uncommon, it is reported that 9% of individuals with HIV-2 infection are coinfected with HIV-1 in Spain[5,6].

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) was evaluated with 1,640 specimens from different countries in an unpublished multi-center field study, 1,000 specimens from a blood donation center and 3,430 specimens from an in-house clinical study. Of the 6,070 total specimens (which included whole blood, serum and plasma specimens), 1,602 were found HIV seropositive and 4,468 specimens were found HIV seronegative by a characterization testing algorithm comprising of EIA and/or Western blot. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/ Serum/Plasma) showed 99.9% relative sensitivity, and 99.8% relative specificity compared to EIA and/or Western blot.

HIV 1/2/O Tri-line Rapid Test Device vs. EIA and/or Western blot

HIV 1/2/O Tri-line Rapid Test Device	Results	EIA and/or Western blot: Positive	EIA and/or Western blot: Negative	Total Results
	Reactive	1,601	10	1,611
	Non-reactive	1	4,458	4,459
Total Results		1,602	4,468	6,070

Relative Sensitivity: 99.9% (99.7-100.0%)*
Relative Specificity: 99.8% (99.6-99.9%)*
Relative Accuracy: 99.8% (99.7-100.0%)*
* 95% Confidence Interval

Specimen Types Consistency

50 HIV seropositive whole blood and paired plasma specimens, 26 HIV seropositive whole blood, paired plasma and serum specimens, 50 negative whole blood, paired plasma and serum specimens were tested with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/ Serum/Plasma).

EIA and/or Western blot	Specimen type	No. tested	HIV 1/2/O Tri-line Rapid Test Device: Non-reactive	HIV 1/2/O Tri-line Rapid Test Device: Reactive
Negative	Plasma	50	50	0
	Serum	50	50	0
	Whole blood	50	50	0
Positive	Serum	26	0	26
	Plasma	76	0	76
	Whole blood	76	0	76

Paired whole blood, plasma, serum specimens show the consistent results with HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

Precision

Intra-Assay (same lot)

Within-run precision has been determined by using 10 replicates of five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 **(subtype O)** positive, a medium titer HIV-1 positive and a HIV-2 positive. All above values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same five specimens: a negative, a low titer HIV-1 positive, a low titer HIV-1 (subtype O) positive, a medium titer HIV-1 positive and a HIV-2 positive. Three different lots of the HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/ Plasma) have been tested using above specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. Delaney KP, Branson BM, Uniyal A, et al. *Evaluation of the Performance Characteristics of 6 Rapid HIV Antibody Tests.* Clinical Infectious Diseases. 2011; 52(2): 257-263.
2. O'Connell RJ, Merritt TM, Malia JA, et al. *Performance of the OraQuick Rapid Antibody Test for Diagnosis of Human Immunodeficiency Virus Type 1 Infection in Patients with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2003; 41(5):2153-2155
3. O'Connell RJ, Agan BK, Anderson SA, et al. *Sensitivity of the Multispot HIV-1/HIV-2 Rapid Test Using Samples from Human Immunodeficiency Virus Type 1-Positive Individuals with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2006; 44(5): 1831-1833
4. WHO HIV ASSAY REPORT 18: *Laboratory performance and other operational characteristics rapid diagnostic test.*
5. Requena S, Caballero E, Lozano AB, Ríos-Villegas MJ, Benito R, Rojo S, Cabezas T, Macià MD, Nieto MDC, Soriano V, de Mendoza C; *Spanish HIV-2 Study Group. Treatment outcome in dually HIV-1 and HIV-2 coinfected patients living in Spain.* AIDS. 2019 Nov 15;33(14):2167-2172.
6. Zbinden A, Dürig R, Shah C, Böni J, Schüpbach J. *Importance of an Early HIV Antibody Differentiation Immunoassay for Detection of Dual Infection with HIV-1 and HIV-2.* PLoS One. 2016 Jun 16;11(6):e0157690.

Index of Symbols

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

Technical Support

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

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

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

Asia-Pacific
+61 7 3363 7100
AP.TechSupport@abbott.com

Latin America
57 1 4824033
LA.TechSupport@abbott.com

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

© 2022 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.

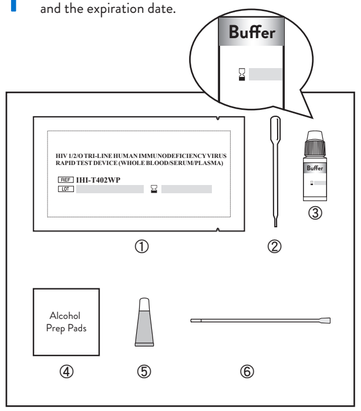
Abbott

ABON™

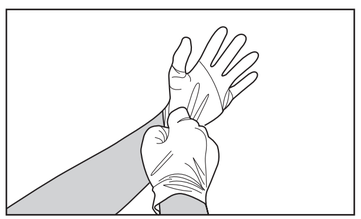
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

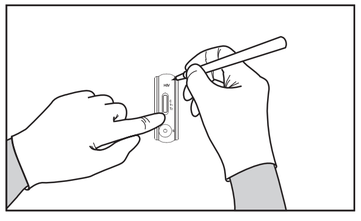
1 Open the package and check the content and the expiration date.



2 Wear gloves

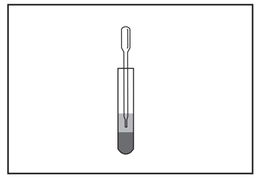


3 Open the pouch, Label with specimen ID. Use it as soon as possible (within one hour).

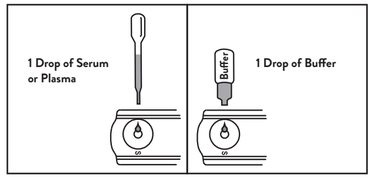


SERUM OR PLASMA SPECIMENS

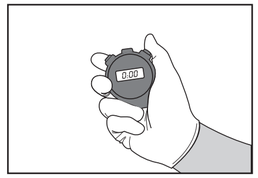
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



5 Transfer 1 drop of serum or plasma (approximately 25 µL), then add 1 drop of buffer (approximately 40 µL).

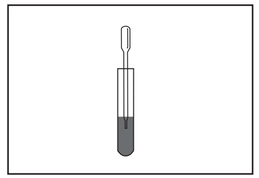


6 Start the timer.

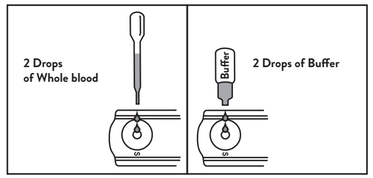


VENIPUNCTURE WHOLE BLOOD SPECIMENS

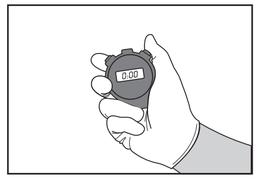
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



5 Transfer 2 drops of whole blood (approximately 50 µL), then add 2 drops of buffer (approximately 80 µL).

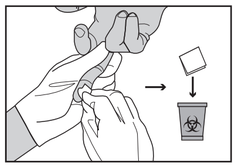


6 Start the timer.

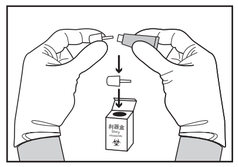


FINGERSTICK WHOLE BLOOD SPECIMENS

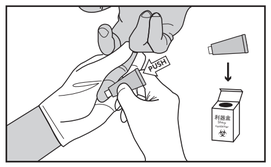
4 Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



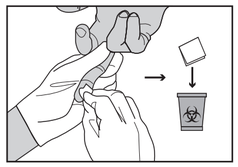
5 Take off the cap of the lancet and dispose the cap in sharps container.



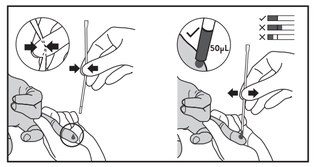
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



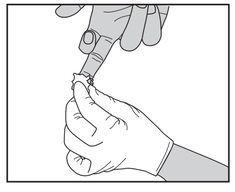
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



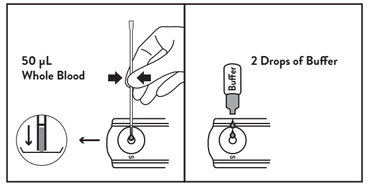
8 Take the provided specimen dropper (for fingerstick whole blood) vertically, squeeze the middle of the dropper, immerse the open end into the blood drop, and then slowly release the pressure to draw blood until mark line. Avoid air bubbles.



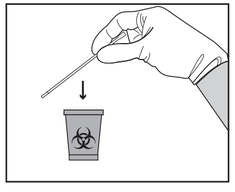
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



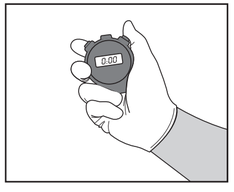
10 Squeeze the specimen dropper and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).



11 Dispose the specimen dropper (for fingerstick whole blood) after testing.

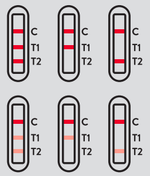


12 Start the timer.



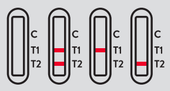
READ RESULTS

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



REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 infection.
HIV-2 REACTIVE: When C line and T2 line appear, this indicates a reactive result for HIV-2 infection.
When three lines C line, T1 line and T2 line appear, it is more likely to be caused by cross-reactivity due to certain homology in the amino acid sequences between HIV-1 and HIV-2. It can be either single HIV-1/HIV-2 infection or a dual infection of HIV-1 and HIV-2. In this case, a discrimination result cannot be defined and further antibody differentiation test is required. Please refer to the Limitation section for the estimated rate of cross-reactivity between HIV-1 and HIV-2 for this product and the reported dual infection cases.
***Note:** The intensity of the color in the test line region (T1 and/or T2) will vary but any shade of color in the test line region (T1 and/or T2) should be considered reactive.

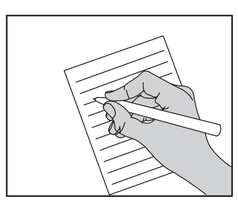
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).



INVALID: No line appears in the control line region (C). If this occurs, read the test procedure again and repeat the test with a new test device. 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.

1156230501

Date de révision: 2022-01-21
Mode d'emploi version 06

ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

REF IHI-T402WG IVD

Mode d'emploi — **Français**

Un test de diagnostic rapide pour la détection qualitative des anticorps dirigés contre le virus de l'immunodéficience humaine (VIH) de type 1, y compris le sous-type O et le type 2, dans le sang total, le sérum ou le plasma.
Réservé exclusivement à un usage professionnel.

UTILISATION PRÉVUE

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) est un dosage immunochromatographique rapide de diagnostic *in vitro* pour la détection qualitative des anticorps dirigés contre le VIH-1, y compris le sous-type O et le VIH-2, dans les échantillons de sang total veineux et capillaire, de sérum et de plasma. Le produit peut être utilisé pour faciliter le diagnostic d'une infection par le VIH. Un résultat réactif doit être confirmé par des tests complémentaires dans le cadre d'un algorithme de dépistage du VIH validé. Ce produit n'a pas été évalué sur des échantillons pédiatriques et néonatals.

PRINCIPE

La bandelette de test de HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) est pré-enduite d'antigènes du VIH-1 et du sous-type O sur la ligne de test T1 et de l'antigène du VIH-2 sur la ligne de test T2. Tout d'abord, l'échantillon puis le tampon sont ajoutés au puits d'échantillonnage, ce qui initie la migration de l'échantillon/du tampon. L'échantillon/le tampon passe par le tampon de conjugué qui contient un mélange d'antigènes de l'enveloppe du VIH-1, de la capside et de l'enveloppe du VIH-2. Ces antigènes de détection sont conjugués à des particules de latex. S'ils sont présents, les anticorps dirigés contre le VIH-1 ou le VIH-2 réagissent et se lient à l'antigène-conjugué de détection. Le mélange anticorps/antigène-conjugué migre ensuite plus loin et se lie aux antigènes présents sur les lignes de test. Si l'échantillon contient des anticorps dirigés contre le VIH-1, l'échantillon se lie à la ligne de test T1 et produira une ligne. Si l'échantillon contient des anticorps dirigés contre le VIH-2, l'échantillon se lie à la ligne de test T2. À mesure que le liquide migre vers le bas de la bandelette de test, la ligne de contrôle apparaît. Si la ligne de contrôle est présente, en plus d'une ou des deux lignes de test, alors le test est réactif pour les anticorps au VIH-1/2. Si l'échantillon ne contient pas d'anticorps au VIH-1 ou au VIH-2, aucune ligne colorée ne s'affiche sur l'une ou l'autre zone de ligne de test, indiquant ainsi un résultat non réactif. Veuillez noter que l'apparition de lignes colorées sur les lignes de test T1 et T2 est peu probablement le signe d'une co-infection par le VIH-1 et le VIH-2, mais plutôt le résultat d'une réactivité croisée entre les antigènes. Une ligne colorée apparaît dans la zone de la ligne de contrôle si la migration du liquide est réussie. Elle doit être présente pour que le test soit valide. Si la ligne de contrôle n'apparaît pas, le résultat du test n'est pas valide.

CONSERVATION ET STABILITÉ

Conservez le produit conditionné dans la pochette scellée entre 2 et 30 °C (la conservation dans un réfrigérateur est autorisée). **Ne conservez pas le produit dans le congélateur**. Conservez le kit de test à l'abri de l'humidité. Le dispositif de test est stable jusqu'à la date d'expiration imprimée sur le kit de test et/ou sur la pochette scellée du dispositif de test. N'utilisez pas le dispositif de test au-delà de la date de péremption. Le dispositif de test doit rester dans sa pochette scellée jusqu'à son utilisation.

MISES EN GARDE ET PRÉCAUTIONS

- Pour une utilisation de diagnostic *in vitro* uniquement.
- Lisez attentivement les instructions avant de réaliser le test.
- Appliquez les précautions standard en matière de biosécurité lors de la manipulation et de l'élimination des matériels potentiellement infectieux.
- Manipulez tous les échantillons comme des échantillons potentiellement infectieux.
- Lors des tests, portez des vêtements de protection tels que des gants, des blouses de laboratoire et des lunettes de protection.
- Le dispositif de test et ses accessoires doivent être mis au rebut dans une poubelle pour déchets présentant un risque biologique après le test.
- Ne mangez pas, ne buvez pas ou ne fumez pas dans la pièce où les échantillons et les kits sont manipulés.
- Évitez les éclaboussures et nettoyez-les immédiatement avec un désinfectant adapté.
- Le tampon contient 0,02 % d'azoture de sodium comme agent conservateur qui peut être toxique si ingéré. Lorsque vous le mettez au rebut dans l'évier, rincez avec de grandes quantités d'eau.
- N'utilisez pas le kit de test au-delà de la date d'expiration.
- Ne l'utilisez pas si l'emballage est endommagé.
- N'utilisez pas le compte-gouttes à échantillon (pour sang total par prélèvement au doigt), la lancette à usage unique et le tampon imbibé d'alcool s'ils sont déjà endommagés.
- Jetez le compte-gouttes à échantillon (pour sang total par prélèvement au doigt) et la lancette à usage unique dans la poubelle pour objets tranchants s'ils sont déjà endommagés avant utilisation.
- Ne posez pas la lancette avant de le mettre au rebut.
- Ne réutilisez pas la lancette.
- En cas de prophylaxie post-exposition au VIH, les opérateurs doivent se familiariser avec la politique de la PPE avant de réaliser les tests.
- L'humidité et la température peuvent affecter négativement les résultats.
- Le nombre optimal d'échantillons à tester en une seule fois est de 10.
- N'utilisez pas d'autres échantillons que ceux spécifiés. Pour le sang total par ponction veineuse/le plasma, l'EDTA-K$_2$/l'héparine de sodium/le citrate de sodium/l'héparine de lithium peuvent être utilisés comme anticoagulants. D'autres anticoagulants n'ont pas été testés et peuvent donner des résultats incorrects.
- Ne formez pas de bulles d'air pendant l'ajout de l'échantillon. La formation de bulles peut entraîner l'ajout d'un volume d'échantillon insuffisant et par conséquent un faux résultat non réactif.

PRÉLÈVEMENT D'ÉCHANTILLONS ET PRÉPARATION

- HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) peut être utilisé avec du sang total (par ponction veineuse ou prélèvement au doigt), du sérum ou du plasma.
- Pour prélever des échantillons de **sang total par prélèvement au doigt :**
  - Portez des gants.
  - Nettoyez le bout du doigt (de préférence le 3e ou 4e doigt de la main non dominante) avec un tampon imbibé d'alcool. Laissez sécher (30 secondes).
  - Effectuez une ponction sur le côté du doigt avec une nouvelle lancette à chaque fois. Mettez la lancette au rebut dans une poubelle pour objets tranchants immédiatement après son utilisation. N'utilisez pas la lancette si le capuchon a déjà été retiré. Essuyez la première goutte de sang avec un tampon de gaze ou un morceau de coton stérile.
  - Tenez le compte-gouttes à échantillon fourni (pour sang total par prélèvement au doigt) en position verticale, pressez la partie centrale du compte-gouttes, immergez l'extrémité ouverte dans la goutte de sang, puis relâchez lentement la pression pour aspirer le sang jusqu'à la ligne de remplissage marquée. Évitez les bulles d'air.
  - Appuyez sur le compte-gouttes à échantillon et ajoutez l'intégralité du sang total (environ 50 µl) dans le puits d'échantillonnage (S) du dispositif de test. ASSUREZ-VOUS QUE LE COMPTE-GOUTTES EST EN CONTACT AVEC LE FOND DU PUITS D'ÉCHANTILLONNAGE. Ensuite, ajoutez 2 gouttes de tampon (environ 80 µl) dans le puits d'échantillonnage (S).
- Pour prélever des échantillons de **sérum, de plasma ou de sang total par ponction veineuse :**
  - Prélevez en respectant les procédures de phlébotomie sécurisées, en utilisant la technique du vide dans des tubes pour les préparations de sérum, de plasma ou de sang total par ponction veineuse.
  - Préparez le sérum ou le plasma à partir du sang total dès que possible pour éviter l'hémolyse. N'utilisez pas d'échantillons troubles ou hémolysés.

CONSERVATION DES ÉCHANTILLONS

- Les tests doivent être effectués immédiatement après le prélèvement d'échantillon. Ne laissez pas les échantillons à température ambiante (entre 15 et 30 °C) pendant des périodes prolongées. Les échantillons de sérum et de plasma peuvent être conservés entre 2 et 8 °C jusqu'à 3 jours. Pour la conservation à long terme, les échantillons doivent être conservés à -20 °C. Le sang total prélevé par ponction veineuse doit être conservé entre 2 et 8 °C si le test doit être réalisé dans les 2 jours suivant le prélèvement. Ne congelez pas les échantillons de sang total. Le sang total prélevé par prélèvement au doigt doit être testé immédiatement.
- Laissez les échantillons s'équilibrer à température ambiante avant de réaliser les tests. Les échantillons congelés doivent être complètement décongelés et mélangés avant de commencer le test.
- Aucune différence de performance qualitative n'a été observée entre les contrôles expérimentaux et 20 échantillons non réactifs ou 20 échantillons réactifs soumis à 6 cycles de congélation/décongélation ; cependant, plusieurs cycles de congélation/décongélation doivent être évités.

MATÉRIEL

Matériel fourni

Composants	IHI-T402WG
1. Dispositif de test	**x40**
2. Compte-gouttes à échantillon (Pour sérum/plasma/sang total par ponction veineuse)	**x40**
3. Tampon de 3 ml	**x2**
4. Tampon imbibé d'alcool	**x40**
5. Lancette à usage unique	**x40**
6. Compte-gouttes à échantillon (Pour sang total par prélèvement au doigt)	**x40**
7. Mode d'emploi	**x1**

Matériel requis mais non fourni

- Équipement de prélèvement d'échantillons et conteneurs
- Coton ou tampon de gaze (pour sang total par prélèvement au doigt uniquement)
- Centrifugeuse
- Chronomètre
- Poubelles pour déchets présentant un risque biologique pour objets tranchants et non tranchants

PROCÉDURE DE TEST

Laissez le dispositif de test, le tampon et l'échantillon s'équilibrer à température ambiante (entre 15 et 30 °C) avant le test.

1. Retirez le dispositif de test de la pochette en aluminium et utilisez-le dès que possible (dans l'heure).
2. Placez le dispositif de test sur une surface propre et plane. Indiquez l'ID de l'échantillon. Ajoutez l'échantillon et le tampon. Évitez la formation de bulles lors de l'ajout de l'échantillon et du tampon.
   Pour les échantillons de **sérum ou de plasma** : Tenez le compte-gouttes à échantillon (pour sérum/plasma/sang total par ponction veineuse) à la verticale et **transférez 1 goutte de sérum ou de plasma** (environ 25 µl) dans le puits d'échantillonnage (S) du dispositif de test, puis **ajoutez 1 goutte de tampon** (environ 40 µl) et lancez le chronomètre.
   Pour les échantillons de **sang total par ponction veineuse** : Tenez le compte-gouttes à échantillon (pour sérum/plasma/sang total par ponction veineuse) à la verticale et **transférez 2 gouttes de sang total** (environ 50 µl) dans le puits d'échantillonnage (S) du dispositif de test, puis **ajoutez 2 gouttes de tampon** (environ 80 µl) et lancez le chronomètre.
   Pour les échantillons de **sang total par prélèvement au doigt** : Prélevez un échantillon de sang total avec le compte-gouttes à échantillon de 50 µl (pour sang total par prélèvement au doigt) jusqu'à la ligne de remplissage marquée. **Ajoutez l'échantillon** (environ 50 µl) dans le puits d'échantillonnage (S) du dispositif de test, puis **ajoutez 2 gouttes de tampon** (environ 80 µl) et lancez le chronomètre.
3. Attendez qu'une ou plusieurs lignes colorées apparaissent. **Lisez les résultats au bout de 10 minutes. Ne lisez pas les résultats après 20 minutes.**

INTERPRÉTATION DES RÉSULTATS

RÉACTIF : Deux ou trois lignes colorées différentes apparaissent*. Une ligne doit toujours apparaître dans la zone de ligne de contrôle (C) et une ou deux lignes colorées doivent apparaître dans les zones de lignes de test (T1 et/ou T2).
RÉACTIF AU VIH-1 : Si la ligne de contrôle (C) et la ligne de test T1 apparaissent, cela indique un résultat réactif à l'infection par le VIH-1.
RÉACTIF AU VIH-2 : Si la ligne de contrôle (C) et la ligne de test T2 apparaissent, cela indique un résultat réactif à l'infection par le VIH-2.
Si la ligne de contrôle (C) et les lignes de test T1 et T2 apparaissent, cela est plus susceptible d'être causé par une réactivité croisée, due à une certaine similarité des séquences d'acides aminés du VIH-1 et du VIH-2. Il peut s'agir d'une seule infection par le VIH-1/VIH-2 ou d'une double infection par le VIH-1 et le VIH-2. Dans ce cas, il est impossible d'établir un résultat discriminant et un test supplémentaire de différenciation des anticorps est nécessaire. Veuillez vous reporter à la section Limitation pour connaître le taux estimé de réactivité croisée entre le VIH-1 et le VIH-2 pour ce produit et les cas de double infection signalés.
*** Remarque :** L'intensité de la couleur dans la zone de ligne de test (T1 et/ou T2) peut varier, mais n'importe quelle nuance de couleur dans la zone de ligne de test (T1 et/ou T2) doit être considérée comme réactive.
NON RÉACTIF : Une ligne colorée apparaît dans la zone de contrôle (C). Aucune ligne colorée n'apparaît dans les zones de lignes de test (T1 et/ou T2).
NON VALIDE : Aucune ligne n'apparaît dans la zone de ligne de contrôle (C). Si tel est le cas, lisez la procédure de test et répétez le test avec un nouveau dispositif de test. Si le résultat n'est toujours pas valide, arrêtez immédiatement d'utiliser le kit de test et contactez votre distributeur local.

CONTRÔLE QUALITÉ

Une ligne de contrôle est incluse dans le test en tant que contrôle interne. Le test doit absorber le liquide et lui permettre de migrer le long de la membrane pour que la ligne de contrôle apparaisse. Le contrôle de procédure interne repose sur l'apparition d'une ligne colorée dans la zone de contrôle (C).
Les échantillons de contrôle qualité ne sont pas fournis avec ce kit. Cependant, il est recommandé que les échantillons de contrôle qualité soient testés en tant que bonnes pratiques de laboratoire.

LIMITATION

1. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) est conçu pour une utilisation de diagnostic *in vitro* uniquement. Ce test doit être utilisé pour la détection des anticorps dirigés contre le VIH-1/2 dans le sang total, le sérum ou le plasma humain. La concentration d'anticorps au VIH-1/2 ne peut pas être déterminée par ce test qualitatif.
2. HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) indique uniquement la présence d'anticorps au VIH-1/2 dans l'échantillon et ne doit pas être utilisé comme seul critère dans le diagnostic d'une infection par le VIH-1, le VIH-2 et/ou le VIH-1 sous-type O.
3. Pour confirmer les résultats réactifs des tests, les échantillons doivent subir d'autres tests à l'aide de différents dosages, tels que les tests de diagnostic rapide, l'EIA et/ou le Western blot (technique des immuno-empreintes) conformément à un algorithme de dépistage du VIH validé.
4. Comme pour tous les tests de diagnostic, tous les résultats doivent être interprétés conjointement avec les autres informations cliniques à la disposition du médecin.
5. Les résultats ne doivent pas être utilisés pour déterminer le génotype des infections par le VIH.
6. En raison d'une possible réactivité croisée des anticorps, l'apparition de lignes dans les lignes T1 et T2 n'indique pas nécessairement une co-infection par le VIH-1 et le VIH-2.
7. De faux résultats réactifs peuvent survenir en raison de facteurs rhumatoïdes, d'anticorps antinucléaires, d'autres infections virales (par exemple, l'hépatite B ou l'hépatite C), d'infections parasitaires (par exemple, la schistosomiase et la trypanosomiase), de composants de test endommagés par la chaleur ou l'humidité, ou de la substitution d'autres composants du kit de test (par exemple, les compte-gouttes ou le tampon) entre plusieurs kits de test.
8. De faux résultats non réactifs peuvent survenir lorsque les titres des anticorps au VIH-1/2 sont très faibles, lorsque les titres des anticorps au VIH-1/2 sont très élevés (effet « High-hook »), lorsqu'un volume insuffisant d'échantillon est ajouté, lorsqu'un volume excessif de tampon est ajouté ou lorsque des composants de test sont endommagés par la chaleur ou l'humidité.
9. Des faux négatifs peuvent être observés chez les individus recevant un traitement antirétroviral efficace. [1,2,3]
10. Le taux estimé de réactivité croisée entre les échantillons positifs au VIH-1 et au VIH-2 était de 32,6 % en utilisant HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)[4]. Bien que la double infection par le VIH-1 et le VIH-2 soit peu courante, il a été signalé que 9 % des personnes présentant une infection par le VIH-2 sont co-infectées par le VIH-1 en Espagne[5,6].

CARACTÉRISTIQUES DE PERFORMANCE

Sensibilité clinique, spécificité et précision

HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) a été évalué avec 1 640 échantillons provenant de différents pays dans une étude de terrain multicentrique non publiée, avec 1 000 échantillons dans un centre de don du sang et avec 3 430 échantillons dans une étude clinique en interne. Sur les 6 070 échantillons au total (qui comprennent du sang total, du sérum et du plasma), 1 602 se sont révélés séropositifs au VIH et 4 468 échantillons se sont révélés séronégatifs au VIH par un algorithme de test de caractérisation comprenant une EIA et/ou un Western blot (technique des immunoempreintes). HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) a montré une sensibilité relative de 99,9 % et une spécificité relative de 99,8 % par rapport à l'EIA et/ou au Western blot (technique des immuno-empreintes).

Dispositif de test rapide tri-ligne VIH 1/2/O contre EIA et/ou Western blot (technique des immuno-empreintes)

		EIA et/ou Western blot (technique des immuno-empreintes)		Résultats totaux
Dispositif de test rapide tri-ligne VIH 1/2/O	**Résultats**	Positif	Negative	
	Réactif	1 601	10	1 611
	Non réactif	1	4 458	4 459
Résultats totaux		1 602	4 468	6 070

Sensibilité relative : 99,9 % (99,7-100,0 %)*
Spécificité relative : 99,8 % (99,6-99,9 %)*
Précision relative : 99,8 % (99,7-100,0 %)*
* Intervalle de confiance de 95 %

Homogénéité des types d'échantillons

50 échantillons appariés de plasma et de sang total séropositifs au VIH, 26 échantillons appariés de plasma, de sérum et de sang total séropositifs au VIH et 50 échantillons appariés de plasma, de sérum et de sang total négatifs ont été testés avec HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

EIA et/ou Western blot (technique des immuno-empreintes)	Type d'échantillon	Nombre testé	Dispositif de test rapide tri-ligne VIH 1/2/O	
			Non réactif	Réactif
Négatif	Plasma	50	50	0
	Sérum	50	50	0
	Sang total	50	50	0
Positif	Sérum	26	0	26
	Plasma	76	0	76
	Sang total	76	0	76

Les échantillons appariés de sang total, de plasma et de sérum montrent des résultats cohérents avec HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma).

Précision

Intradosage (même lot)

La précision pendant un cycle a été déterminée à l'aide de 10 reproductions de cinq échantillons: un négatif, un positif au VIH-1 au titre faible, un positif au VIH-1 **(sous-type O)** au titre faible, un positif au VIH-1 au titre moyen et un positif au VIH-2. Toutes les valeurs ci-dessus ont été identifiées correctement >99 % du temps.

Intradosage

La précision pendant un cycle a été déterminée par 10 dosages indépendants sur les cinq mêmes échantillons : un négatif, un positif au VIH-1 au titre faible, un positif au VIH-1 (sous-type O) au titre faible, un positif au VIH-1 au titre moyen et un positif au VIH-2. Trois lots différents de HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) ont été testés à l'aide des échantillons ci-dessus. Les échantillons ont été identifiés correctement >99 % du temps.

BIBLIOGRAPHIE

1. K.P. Delaney, B.M. Branson, A. Uniyal, et al. *Evaluation of the Performance Characteristics of 6 Rapid HIV Antibody Tests.* Clinical Infectious Diseases. 2011 ; 52 (2) : 257-263.
2. R.J. O'Connell, T.M. Merritt, J.A. Malia, *et al. Performance of the OraQuick Rapid Antibody Test for Diagnosis of Human Immunodeficiency Virus Type 1 Infection in Patients with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2003 ; 41 (5) : 2153-2155
3. R.J. O'Connell, B.K. Agan, S.A. Anderson, *et al. Sensitivity of the Multispot HIV-1/HIV-2 Rapid Test Using Samples from Human Immunodeficiency Virus Type 1-Positive Individuals with Various Levels of Exposure to Highly Active Antiretroviral Therapy.* Journal of Clinical Microbiology. 2006 ; 44 (5) : 1831-1833
4. WHO HIV ASSAY REPORT 18: *Laboratory performance and other operational characteristics rapid diagnostic test.*
5. Requena S, Caballero E, Lozano AB, Ríos-Villegas MJ, Benito R, Rojo S, Cabezas T, Macià MD, Nieto MDC, Soriano V, de Mendoza C; *Spanish HIV-2 Study Group. Treatment outcome in dually HIV-1 and HIV-2 coinfected patients living in Spain.* AIDS. 2019 Nov 15;33(14):2167-2172.
6. Zbinden A, Dürig R, Shah C, Böni J, Schüpbach J. *Importance of an Early HIV Antibody Differentiation Immunoassay for Detection of Dual Infection with HIV-1 and HIV-2.* PLoS One. 2016 Jun 16;11(6):e0157690.

Index des symboles

	Consulter les instructions d'utilisation		Contenu suffisant pour <n> tests	REF	Référence catalogue
LOT	Code de lot		Date d'expiration		Ne pas réutiliser
2°C 30°C	Conservation entre 2 et 30 °C		Fabricant	IVD	Dispositif médical de diagnostic *in vitro*

Support Technique

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

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

© 2022 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.

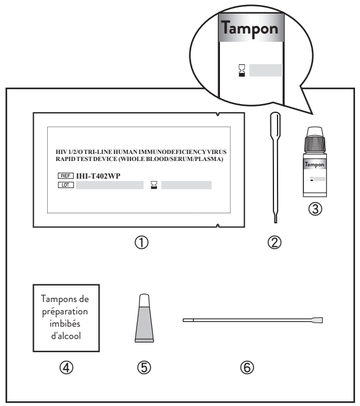
Abbott

ABON™

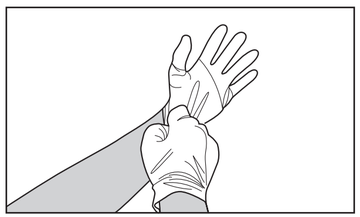
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PRÉPARATION

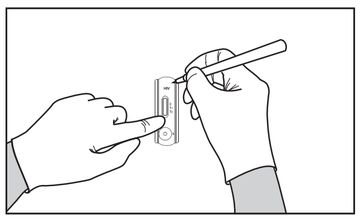
1 Ouvrez l'emballage et vérifiez le contenu et la date d'expiration.



2 Portez des gants.

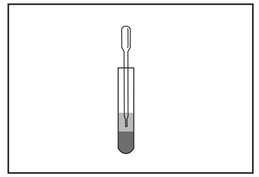


3 Ouvrez le sachet, étiquetez avec l'ID de l'échantillon. Utilisez-le dès que possible (dans l'heure).

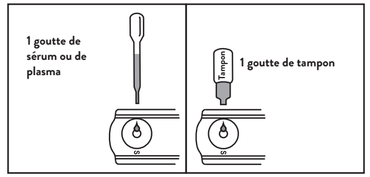


ÉCHANTILLONS DE SÉRUM OU DE PLASMA

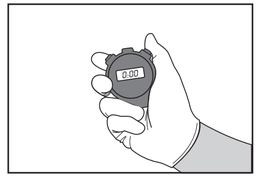
4 Prélevez l'échantillon du tube d'échantillon avec un compte-gouttes (pour sérum/plasma/sang total par ponction veineuse).



5 Transférez 1 goutte de sérum ou de plasma (environ 25 µl), puis ajoutez 1 goutte de tampon (environ 40 µl).

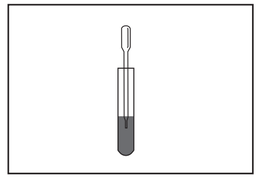


6 Lancez le chronomètre.

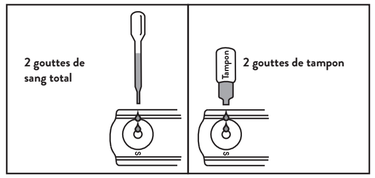


ÉCHANTILLONS DE SANG TOTAL PAR PONCTION VEINEUSE

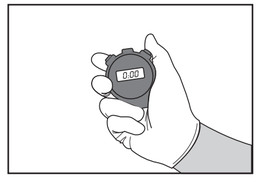
4 Prélevez l'échantillon du tube d'échantillon avec un compte-gouttes (pour sérum/plasma/sang total par ponction veineuse).



5 Transférez 2 gouttes de sang total (environ 50 µl), puis ajoutez 2 gouttes de tampon (environ 80 µl).

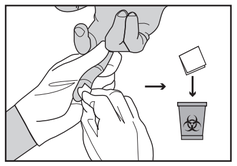


6 Lancez le chronomètre.

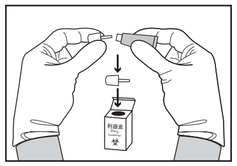


ÉCHANTILLONS DE SANG TOTAL PAR PRÉLÈVEMENT AU DOIGT

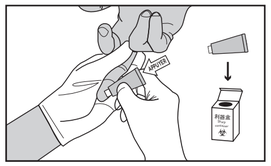
4 Nettoyez le bout du doigt (de préférence le 3e ou 4e doigt de la main non dominante) avec un tampon imbibé d'alcool. Jetez le tampon imbibé d'alcool.



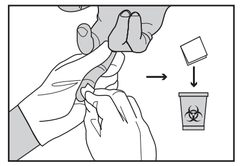
5 Retirez le capuchon de la lancette et jetez le capuchon dans une poubelle pour objets tranchants.



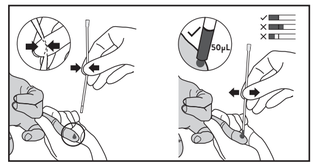
6 Effectuez une ponction sur le côté du doigt. Mettez la lancette au rebut dans la poubelle pour objets tranchants immédiatement après son utilisation.



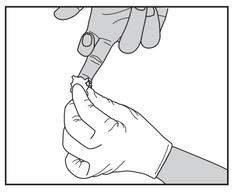
7 Essuyez la première goutte de sang avec un tampon de gaze ou un morceau de coton stérile.



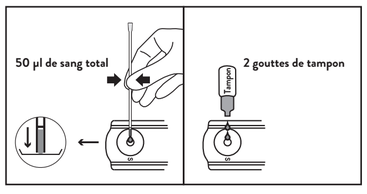
8 Tenez le compte-gouttes à échantillon fourni (pour sang total par prélèvement au doigt) en position verticale, pressez la partie centrale du compte-gouttes, immergez l'extrémité ouverte dans la goutte de sang, puis relâchez lentement la pression pour aspirer le sang jusqu'à la ligne de remplissage marquée. Évitez les bulles d'air.



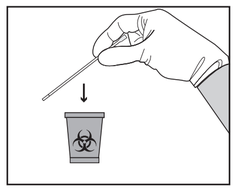
9 Après le prélèvement de l'échantillon, placez un tampon de gaze ou de coton sur le doigt jusqu'à l'arrêt du saignement.



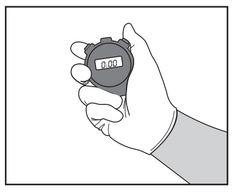
10 Appuyez sur le compte-gouttes à échantillon et ajoutez **l'intégralité du sang total** (environ 50 µl) dans le puits d'échantillonnage (S) du dispositif de test. ASSUREZ-VOUS QUE LE COMPTE-GOUTTES EST EN CONTACT AVEC LE FOND DU PUITS D'ÉCHANTILLONNAGE. Ensuite, ajoutez 2 gouttes de tampon (environ 80 µl) dans le puits d'échantillonnage (S).



11 Jetez le compte-gouttes à échantillon (pour sang total par prélèvement au doigt) après le test.

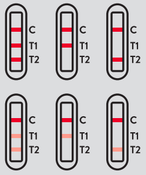


12 Lancez le chronomètre.



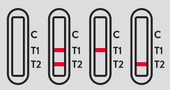
LECTURE DES RÉSULTATS

Attendez qu'une ou plusieurs lignes colorées apparaissent.
Lisez les résultats au bout de **10 à 20 minutes.**



RÉACTIF : Deux ou trois lignes colorées différentes apparaissent*. Une ligne doit toujours apparaître dans la zone de ligne de contrôle (C) et une ou deux lignes colorées doivent apparaître dans les zones de lignes de test (T1 et/ou T2).
RÉACTIF AU VIH-1 : Si la ligne de contrôle (C) et la ligne de test T1 apparaissent, cela indique un résultat réactif à l'infection par le VIH-1.
RÉACTIF AU VIH-2 : Si la ligne de contrôle (C) et la ligne de test T2 apparaissent, cela indique un résultat réactif à l'infection par le VIH-2.
Si la ligne de contrôle (C) et les lignes de test T1 et T2 apparaissent, cela est plus susceptible d'être causé par une réactivité croisée, due à une certaine similarité des séquences d'acides aminés du VIH-1 et du VIH-2. Il peut s'agir d'une seule infection par le VIH-1/VIH-2 ou d'une double infection par le VIH-1 et le VIH-2. Dans ce cas, il est impossible d'établir un résultat discriminant et un test supplémentaire de différenciation des anticorps est nécessaire. Veuillez vous reporter à la section Limitation pour connaître le taux estimé de réactivité croisée entre le VIH-1 et le VIH-2 pour ce produit et les cas de double infection signalés.
* **Remarque :** L'intensité de la couleur dans la zone de ligne de test (T1 et/ou T2) peut varier, mais n'importe quelle nuance de couleur dans la zone de ligne de test (T1 et/ou T2) doit être considérée comme réactive.

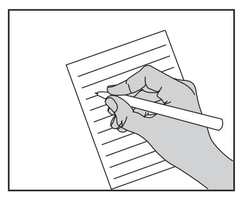
NON RÉACTIF : Une ligne colorée apparaît dans la zone de contrôle (C). Aucune ligne colorée n'apparaît dans les zones de lignes de test (T1 et/ou T2).



NON VALIDE : Aucune ligne n'apparaît dans la zone de ligne de contrôle (C). Si tel est le cas, lisez la procédure de test et répétez le test avec un nouveau dispositif de test. Si le résultat n'est toujours pas valide, arrêtez immédiatement d'utiliser le kit de test et contactez votre distributeur local.

MISE AU REBUT/ ENREGISTREMENT

Mettez les dispositifs et les gants au rebut dans une poubelle pour les déchets présentant un risque biologique.



Enregistrez les résultats des tests.