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

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 the WHO prequalification assessment for the 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	7-9 June 2023	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 the WHO has been notified and has undertaken a review. Amendments to the report are summarised in the following table, and details of each amendment are provided below.

Version	Summary of the amendments	Date of report amendment
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
9.0	Labelling change for alcohol pad.	29 October 2025
10.0	1. Change in the manufacturer's address of lancets for IHI-T402WE, IHI-T402WI, and IHI-T402WF(PQC-IVD-0045). 2. Addition of a customised box artwork and IFU in Ukrainian for Ukraine: - Box: Add info on accessories and the Ukraine authorised representative. - Box label: (1) Create a standard box label for Ukraine based on the English version, but update the UDI info; (2) add an additional customised box label in Ukrainian to include LM information and Ukraine's authorised representative information. -IFU: Translated to Ukrainian based on the English version and added the Ukraine authorised representative information (PQC-IVD-2025-0114).	22 April 2026

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."*

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 IHI-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 between 2 and 30 °C.

Shelf-life upon manufacture[1]:
24 months

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

[1] The assigned device shelf-life is based on stability data generated from the date of manufacture. The finished goods shelf-life, calculated from the date of packaging completion, may be shorter depending on the time elapsed between manufacture and final packaging of the device.

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.

Based on the product dossier screening and assessment findings, the product dossier for the ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device meets WHO prequalification requirements.

Manufacturing site inspection

The inspection of the manufacturing site(s) was conducted to assess whether the manufacturer's quality management system (QMS) and manufacturing practices are in alignment with:
(i) applicable international standards, such as ISO 13485 (Medical devices – Quality management systems – Requirements for regulatory purposes);
(ii) the manufacturer's own documented procedures and quality requirements; and
(iii) other relevant international standards and guidelines applicable to in vitro diagnostic (IVD) medical devices. The WHO's Public Inspection Reports are accessible at:

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

Based on the site inspection and corrective action plan review, the quality management system for the ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device meets WHO prequalification requirements.

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 review

The labelling submitted for the ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test was reviewed by WHO staff and external technical experts appointed by WHO. The review evaluated the labelling for clarity and consistency with the information submitted in the product dossier, alignment with international guidance and standards, and suitability for the intended users and settings in WHO Member States, including low- and middle-income countries.

The table below provides traceability of the labelling documents reviewed during the assessment, including document titles, version numbers, approval dates, and control identifiers.

Controlled Labelling References

IHI-T402WA Standard

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer box artwork	(WHO)ABT ABON HIV 40T box	01	2023/6/7	1135929501
Box label	(WHO)ABT ABON IHI-T402WA (40T) English box label ink printing (GS1 2D barcode)	02	2023/7/21	NB00019-02
Pouch artwork	(WHO)ABT ABON ID device pouch	01	2023/6/2	1125907001
Pouch label	(WHO)ABT ABON IHI-T402WP pouch ink jetting(YYMMDD)	01	2023/6/7	NP00007-01

Buffer label	(WHO)ABT ABON HIV English bottle label ink printing (YYMMDD)	01	2023/6/7	NB00020-01
Sterile safety lancets, single-use	N/A	N/A	N/A	N/A
Capillary tubes (For Fingerstick Whole Blood)	N/A	N/A	N/A	N/A
Alcohol swab	N/A	N/A	N/A	N/A
Specimen dropper (For Serum/Plasma/Venipuncture Whole Blood)	Packaging Specification of Pouched Dropper	N/A	N/A	TC-0930

Customised label and IFU

Document Type	**Document Title**	**Version / Revision**	**Date Approved**	**Controlled Document No.**
Box label (add FR)	(WHO) ABT ABON IHI-T402WA (40T) EN FR box label ink printing	01	2024/4/11	NB02182-01
IFU (FR)	ABT WHO ABON IHI-T402WA English PI	07	2023/6/7	1156213401
Box label (add customer info)	(WHO)ABT ABON IHI-T402WA (40T) English box label ink printing (GS1 2D barcode) for Biogene	01	2024/5/28	KB00792-01

IHI-T402WG Standard

Document Type	**Document Title**	**Version / Revision**	**Date Approved**	**Controlled Document No.**
Outer box artwork	(WHO)ABT ABON HIV 40T box(big)	01	2023/6/7	1135929601
Box label	(WHO)ABT ABON IHI-T402WG(40T)EN box label ink printing (GS1 2D barcode)rose Ⅱ	02	2023/7/21	NB00604-02
Pouch artwork	(WHO)ABT ABON ID device pouch	01	2023/6/2	1125907001
Pouch label	(WHO)ABT ABON IHI-T402WP pouch ink jetting(YYMMDD)	01	2023/6/7	NP00007-01

Buffer label	(WHO)ABT ABON HIV English bottle label ink printing (YYMMDD)	01	2023/6/7	NB00020-01
Sterile safety lancets, single-use	Specification of Single-use Lancet	N/A	N/A	TC-0884
Capillary tubes (For Fingerstick Whole Blood)	Packaging Specification of Pouched Dropper	N/A	N/A	TC-0930
Alcohol swab	Specification of Alcohol Pad	N/A	N/A	TC-2204
Specimen dropper (For Serum/Plasma/Venipuncture Whole Blood)	Packaging Specification of Pouched Dropper	N/A	N/A	TC-0930
Instructions for Use (IFU)	WHO ABT ABON IHI-T402WG EN PI	06	2023/6/7	1156230401

Customised label and IFU

Document Type	**Document Title**	**Version / Revision**	**Date Approved**	**Controlled Document No.**
Box label (FR)	(WHO)ABT ABON IHI-T402WG(40T)FR box label ink printing (GS1 2D barcode)rose Ⅱ	02	2023/7/21	NB00606-02
IFU (FR)	WHO ABT ABON IHI-T402WG FR PI	06	2023/6/7	1156230501
Buffer label (FR)	(WHO)ABT ABON HIV French bottle label ink printing(YYMMDD)	01	2023/6/7	NB00055-01
Box label (add customer info)	Abbott PTY ZA WHO ABT ABON NON CE IHI-T402WG EN BOX LABEL ink printing (GS1 2D barcode, LC dropper, with importer)	01	2023/6/7	KB00320-01
box label (add customer info)	(WHO)ABT ABON IHI-T402WG (40T) English box label ink printing (GS1 2D barcode) for Biogene	01	2024/5/28	KB00794-01
Box artwork (add info for Ukraine)	WHO ABT ABON IHI-T402WG box 40T	01	2026/3/19	40008347
IFU (in Ukrainian)	WHO ABT ABON IHI-T402WG UK PI	01	2026/3/19	40006923
Box label (add for Ukraine)	(WHO)ABT ABON Non-CE IHI-T402WG(40T) Ukraine box label ink printing	01	2026/3/19	KB00972-01
Box label (add for Ukraine)	(WHO)ABT ABON Non-CE IHI-T402WG(40T) box label ink printing(GS1 code) for Ukraine	01	2026/3/19	KB00979-01

IHI-T402WB Standard

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer box artwork	(WHO)ABT ABON HIV 40T box(big)	01	2023/6/7	1135929601
Box label	(WHO)ABT ABON IHI-T402WB(40T)EN box label ink printing (GS1 2D barcode)rose Ⅱ	02	2023/7/21	NB00610-02
Pouch artwork	(WHO)ABT ABON ID device pouch	01	2023/6/2	1125907001
Pouch label	(WHO)ABT ABON IHI-T402WP pouch ink jetting(YYMMDD)	01	2023/6/7	NP00007-01
Buffer label	(WHO)ABT ABON HIV English bottle label ink printing (YYMMDD)	01	2023/6/7	NB00020-01
Sterile safety lancets, single-use	Specification of Single-use Lancet	N/A	N/A	TC-0884
Capillary tubes (For Fingerstick Whole Blood)	Packaging Specification of Pouched Dropper	N/A	N/A	TC-0930
Specimen dropper (For Serum/Plasma/Venipuncture Whole Blood)	Packaging Specification of Pouched Dropper	N/A	N/A	TC-0930
IFU	WHO ABT ABON IHI-T402WB EN PI	04	2023/6/7	1156230601

Customised label and IFU

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Box artwork (add info for Ukraine)	WHO ABT ABON IHI-T402WB box 40T	01	2026/3/19	40008348
IFU (in Ukrainian)	WHO ABT ABON IHI-T402WB UK PI	01	2026/3/19	40008232
Box label (add for Ukraine)	(WHO)ABT ABON Non-CE IHI-T402WB(40T) box label ink printing(GS1 code) for Ukraine	01	2026/3/19	KB01032-01
Box label (add for Ukraine)	(WHO)ABT ABON Non-CE IHI-T402WB(40T) Ukraine box label ink printing	01	2026/3/19	KB01030-01

IHI-T402WD Standard

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer box artwork	WHO)ABT ABON HIV 10T box(big)	01	2023/6/7	1135929401
Box label	(WHO)ABT ABON IHI-T402WD(10T)EN box label ink printing (GS1 2D barcode)rose Ⅱ	02	2023/7/21	NB00608-02
Pouch artwork	(WHO)ABT ABON ID device pouch	01	2023/6/2	1125907001
Pouch label	(WHO)ABT ABON IHI-T402WP pouch ink jetting(YYMMDD)	01	2023/6/7	NP00007-01
Buffer label	(WHO)ABT ABON HIV English bottle label ink printing (YYMMDD)	01	2023/6/7	NB00020-01
Sterile safety lancets, single-use	Specification of Single-use Lancet	N/A	N/A	TC-0884
Capillary tubes (For Fingerstick Whole Blood)	Packaging Specification of Pouched Dropper	N/A	N/A	TC-0930
Alcohol swab	Specification of Alcohol Pad	N/A	N/A	TC-2204
Specimen dropper (For Serum/Plasma/Venipuncture Whole Blood)	Packaging Specification of Pouched Dropper	N/A	N/A	TC-0930
IFU	WHO ABT ABON IHI-T402WD EN PI	03	2023/6/7	1156230701

IHI-T402WE

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer box artwork	(WHO)ABT ABON HIV 40T box(big)	01	2023/6/7	1135929601
Box label	(WHO)ABT ABON IHI-T402WE(40T)EN box label ink printing (GS1 2D barcode)rose	02	2023/7/21	NB00612-02
Pouch artwork	(WHO)ABT ABON ID device pouch	01	2023/6/2	1125907001

Pouch label	(WHO)ABT ABON IHI-T402WP pouch ink jetting(YYMMDD)	01	2023/6/7	NP00007-01
Buffer label	(WHO)ABT ABON HIV English bottle label ink printing (YYMMDD)	01	2023/6/7	NB00020-01
Sterile safety lancets, single-use	Specification of Single-use Lancet	N/A	N/A	TC-0884
Capillary tubes (For Fingerstick Whole Blood)	Specification of Plastic Capillary Tube	N/A	N/A	TC-0961
Alcohol swab	Specification of Alcohol Pad	N/A	N/A	TC-2204
Specimen dropper (For Serum/Plasma/Venipuncture Whole Blood)	Packaging Specification of Pouched Dropper	N/A	N/A	TC-0930
IFU	WHO ABT ABON IHI-T402WE EN PI	01	2023/6/7	1156230801

IHI-T402WF

Document Type	**Document Title**	**Version / Revision**	**Date Approved**	**Controlled Document No.**
Outer box artwork	(WHO)ABT ABON HIV 10T box(big)	01	2023/6/7	1135929401
Box label	(WHO)ABT ABON IHI-T402WF(10T)EN box label ink printing (GS1 2D barcode)rose	02	2023/7/21	NB00616-02
Pouch artwork	(WHO)ABT ABON ID device pouch	01	2023/6/2	1125907001
Pouch label	(WHO)ABT ABON IHI-T402WP pouch ink jetting(YYMMDD)	01	2023/6/7	NP00007-01
Buffer label	(WHO)ABT ABON HIV English bottle label ink printing (YYMMDD)	01	2023/6/7	NB00020-01
Sterile safety lancets, single-use	Specification of Single-use Lancet	N/A	N/A	TC-0884
Capillary tubes (For Fingerstick Whole Blood)	Specification of Plastic Capillary Tube	N/A	N/A	TC-0961
Alcohol swab	Specification of Alcohol Pad	N/A	N/A	TC-2204
Specimen dropper (For Serum/Plasma/	Packaging Specification of Pouched Dropper	N/A	N/A	TC-0930

Venipuncture Whole Blood)				
IFU	WHO ABT ABON IHI-T402WF EN PI	01	2023/6/7	1156231101

IHI-T402WI

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer box artwork	(WHO)ABT ABON HIV 40T box(big)	01	2023/6/7	1135929601
Box label	(WHO)ABT ABON IHI-T402WI(40T)EN box label ink printing (GS1 2D barcode)rose	02	2023/7/21	NB00618-02
Pouch artwork	(WHO)ABT ABON ID device pouch	01	2023/6/2	1125907001
Pouch label	(WHO)ABT ABON IHI-T402WP pouch ink jetting(YYMMDD)	01	2023/6/7	NP00007-01
Buffer label	(WHO)ABT ABON HIV English bottle label ink printing (YYMMDD)	01	2023/6/7	NB00020-01
Sterile safety lancets, single-use	Specification of Single-use Lancet	N/A	N/A	TC-0884
Capillary tubes (For Fingerstick Whole Blood)	Specification of Plastic Capillary Tube	N/A	N/A	TC-0961
Alcohol swab	N/A	N/A	N/A	N/A
Specimen dropper (For Serum/Plasma/Venipuncture Whole Blood)	Packaging Specification of Pouched Dropper	N/A	N/A	TC-0930
IFU	WHO ABT ABON IHI-T402WI EN PI-	01	2023/6/7	1156231001

Labels

1. Box label

For IHI-T402WD and IHI-T402WF

Pantone 2925 C

Pantone 303 C

Pantone 285 C

2/10x
1/10x
4/10x
1/10x
4/10x
1/10x
4/10x
1/10x
2/10x

1135929401

X

2/10x
1/10x
3/10x
1/10x
3/10x
2/10x

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

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2°C 30°C IVD

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2°C 30°C IVD

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(WHOLE BLOOD/SERUM/PLASMA)

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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

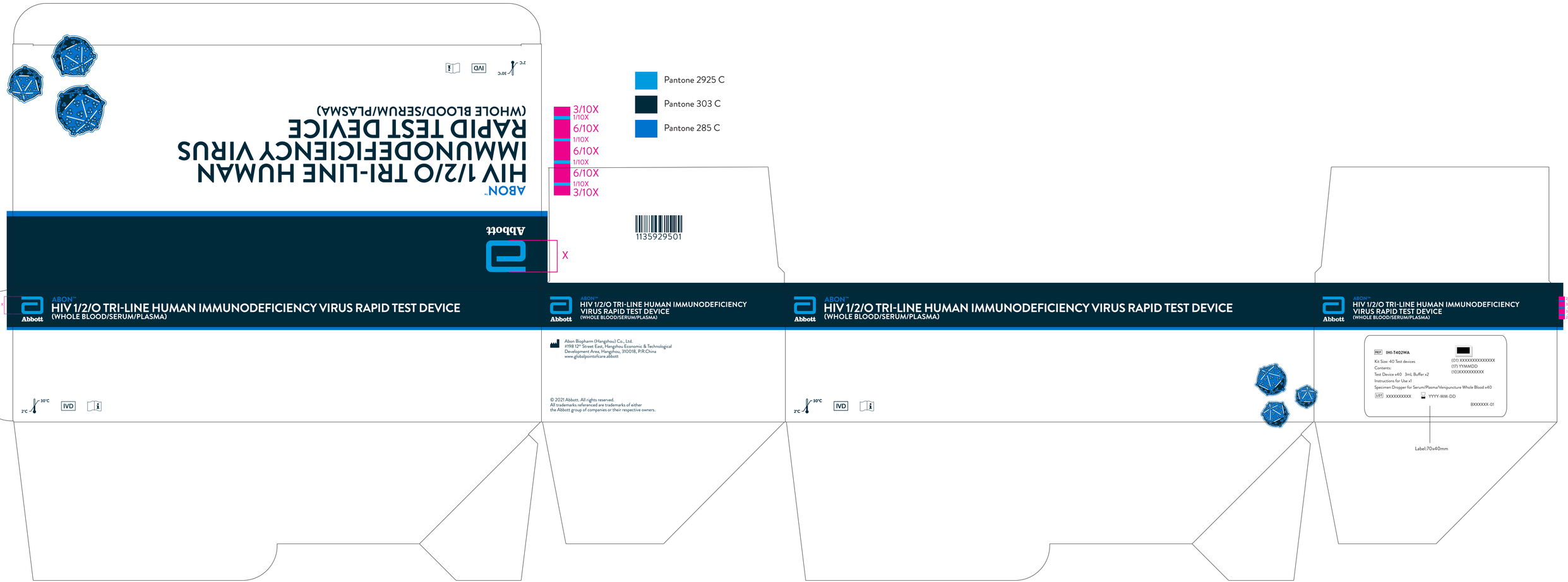
(01) xxxxxxxxxxxxx
(17) YYMMDD
(10)XXXXXXXXXX

LOT XXXXXXXXXX YYYY-MM-DD

Bxxxxxx-01

Label:70x40mm

For IHI-T402WA


Pantone 2925 C
Pantone 303 C
Pantone 285 C
3/10X
1/10X
6/10X
1/10X
6/10X
1/10X
6/10X
1/10X
3/10X
X
11135929501
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2°C 30°C
IVD
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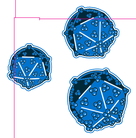
REF IHI-T402WA
Kit Size: 40 Test devices
Contents:
Test Device x40 3mL Buffer x2
Instructions for Use x1
Specimen Dropper for Serum/Plasma/Venipuncture Whole Blood x40
LOT XXXXXXXXX
YYYY-MM-DD
(01) XXXXXXXXXXXXX
(17) YYMMDD
(10)XXXXXXXXXX
BXXXXXX-01
Label:70x40mm

For IHI-T402WG, IHI-T402WB, IHI-T402WE, IHI-T402WI



2°C 30°C IVD

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

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3/10X
1/10X
6/10X
1/10X
6/10X
1/10X
6/10X
1/10X
3/10X

1135929601

Pantone 2925 C
Pantone 303 C
Pantone 285 C

3/10X
1/10X
6/10X
1/10X

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

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2°C 30°C IVD

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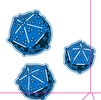
ABON™
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

Abbott

2°C 30°C IVD



3/10X
1/10X
6/10X
1/10X

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

Abbott

REF IHI-T402WG

Kit Size: 40 Test devices
Contents:
Test Device x40 3ml, Buffer x2
Instructions for Use x1
Single-use Lancet x40 Alcohol Swab x40
Specimen Dropper for Fingerstick Whole Blood x40
Specimen Dropper for Serum/Plasma/Venipuncture Whole Blood x40

LOT XXXXXXXXXX YYYY-MM-DD

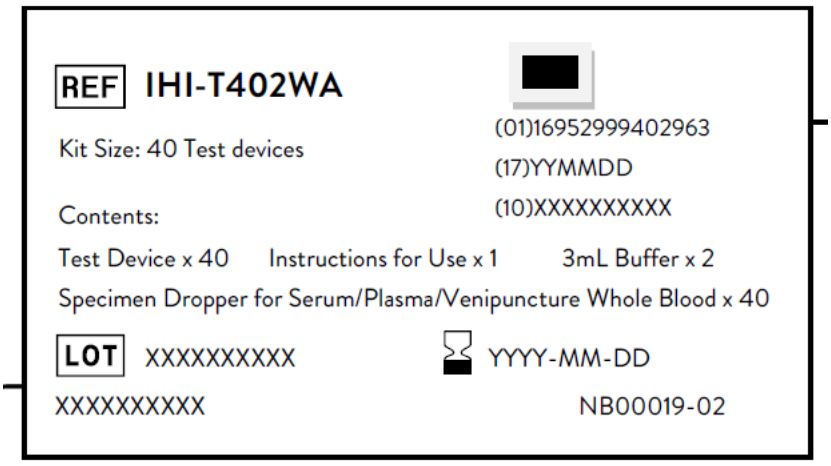
(01)xxxxxxxxxxxxxx
(17)YYMMDD
(10)XXXXXXXXXX

Bxxxxxx-01

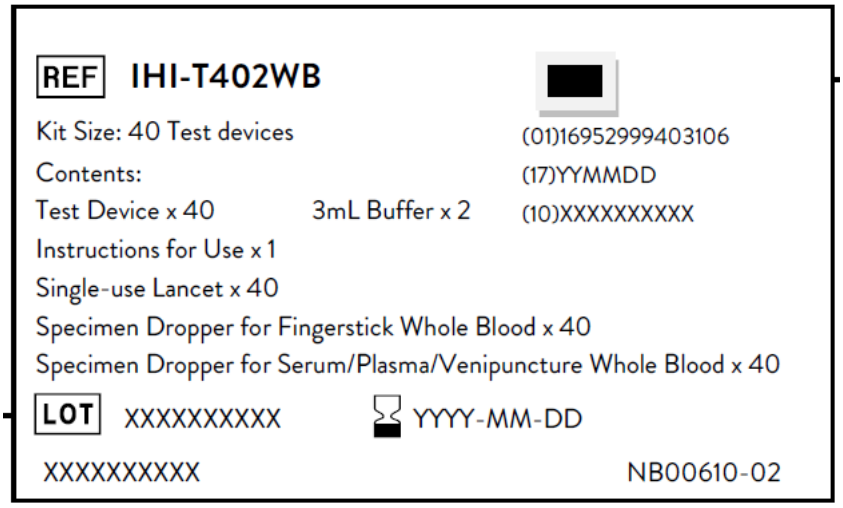
Label:75x45mm

2. Box label

IHI-T402WA



IHI-T402WB



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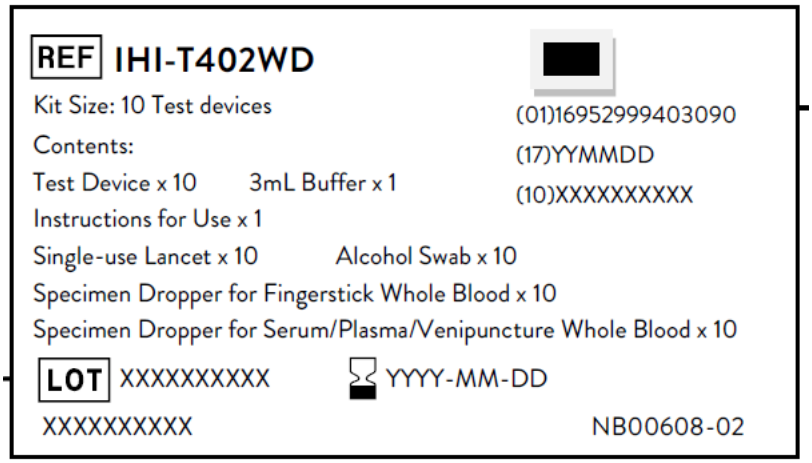

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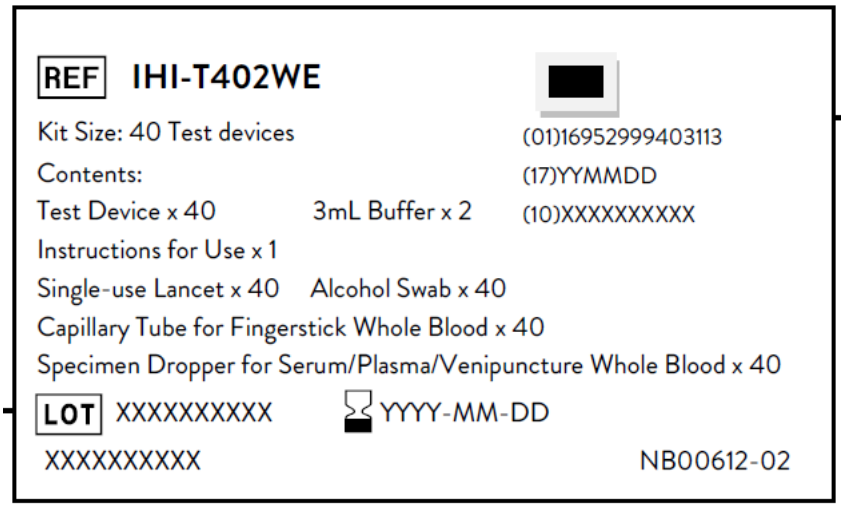

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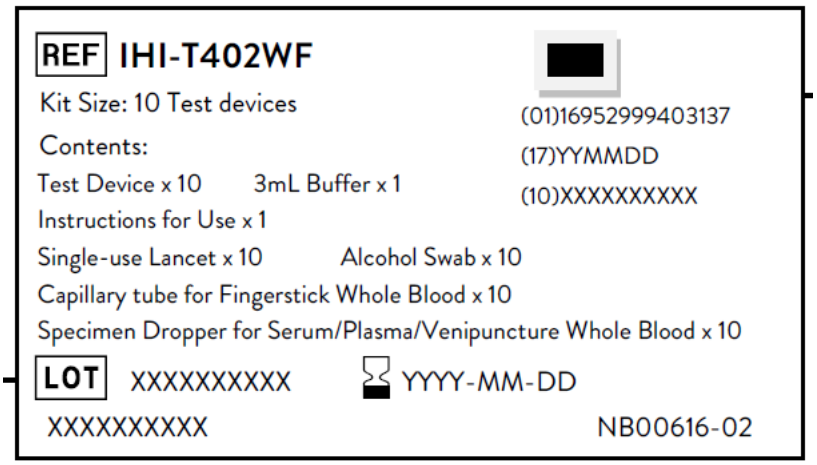

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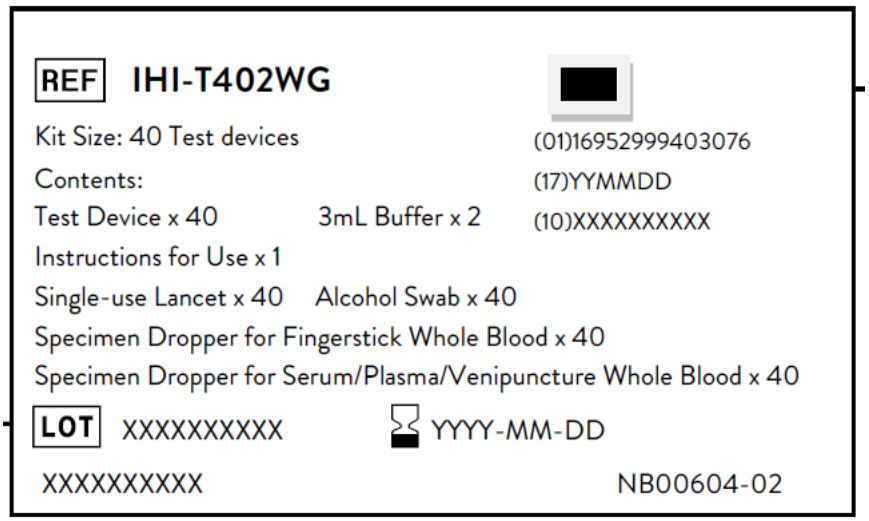


IHI-T402WI

REF IHI-T402WI

Kit Size: 40 Test devices

Contents:

Test Device x 40 3mL Buffer x 2

Instructions for Use x 1

Single-use Lancet x 40

Capillary Tube for Fingerstick Whole Blood x 40

Specimen Dropper for Serum/Plasma/Venipuncture Whole Blood x 40

(01)16952999403144

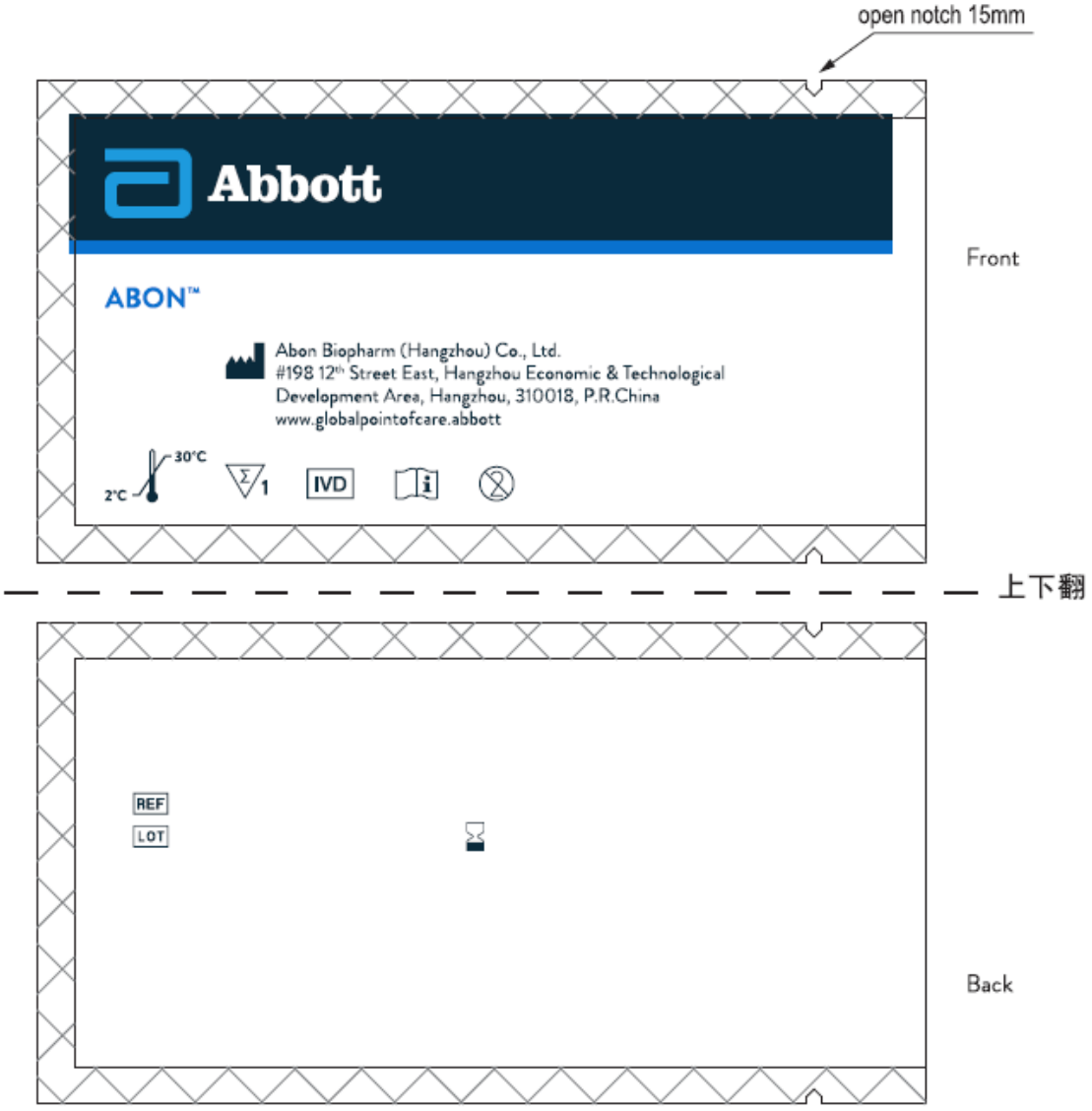
(17)YYMMDD

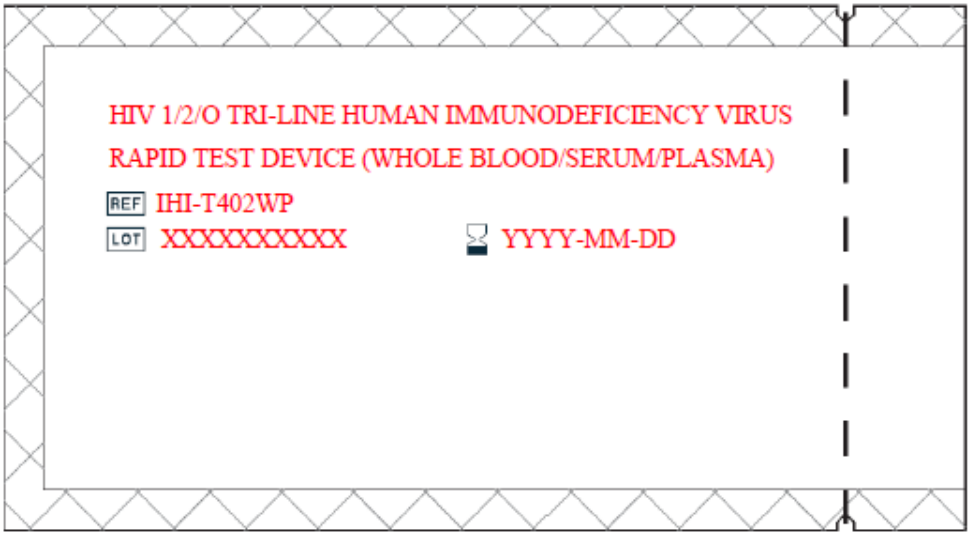
(10)XXXXXXXXXX

LOT XXXXXXXXXX YYYY-MM-DD

XXXXXXXXXX NB00618-02

3. Pouch (IHI-T402WA, IHI-T402WG, IHI-T402WB, IHI-T402WD, IHI-T402WE, IHI-T402WF and IHI-T402WI)





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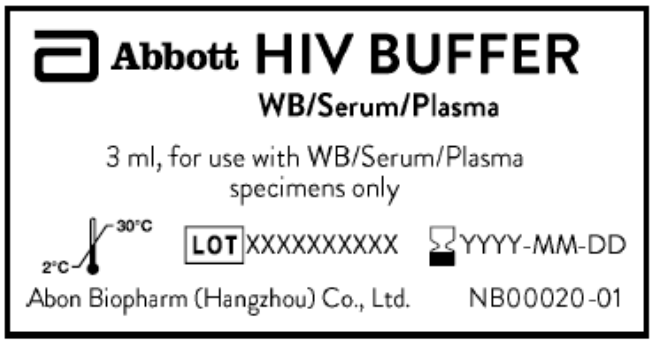
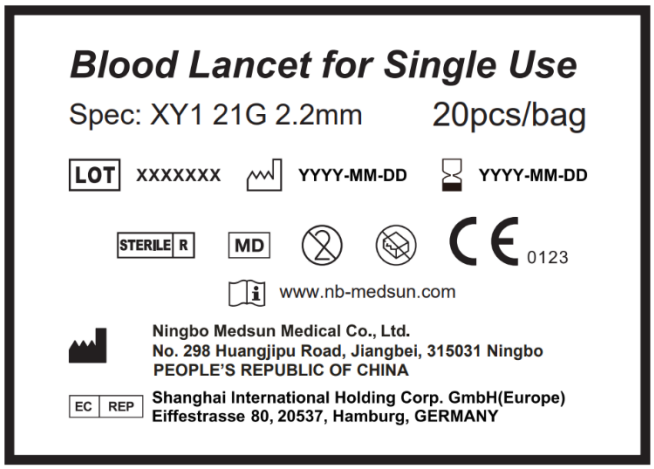


5. Lancet

IHI-T402WE, IHI-T402WI (internal material code: 1045803201)



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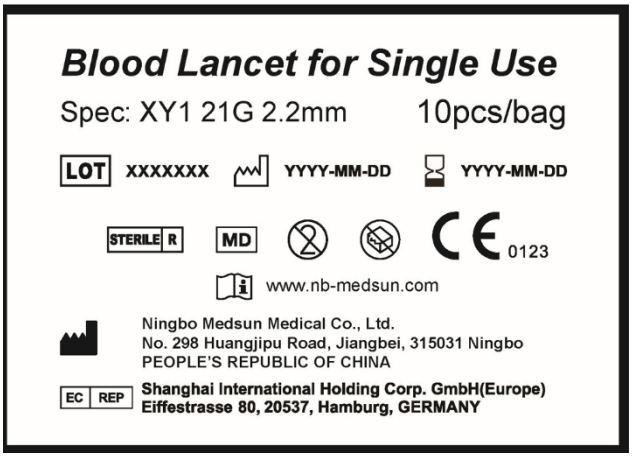
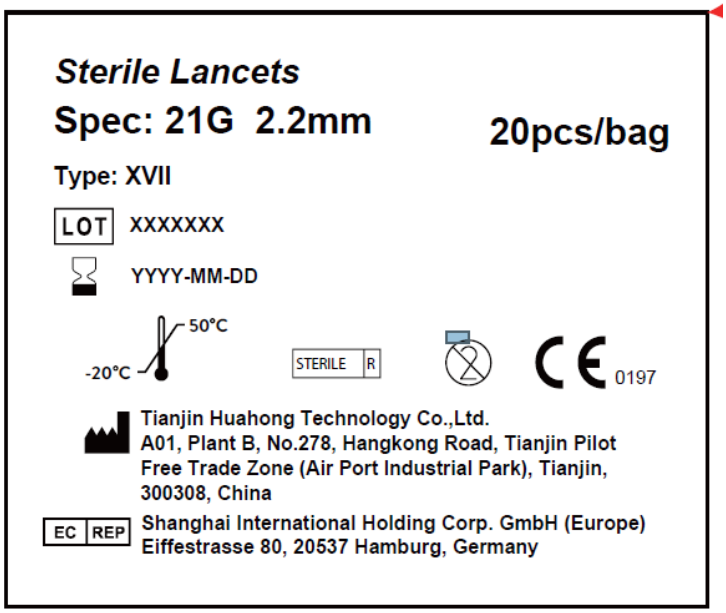


IHI-T402WG, IHI-T402WB (internal material code: 1045805201)



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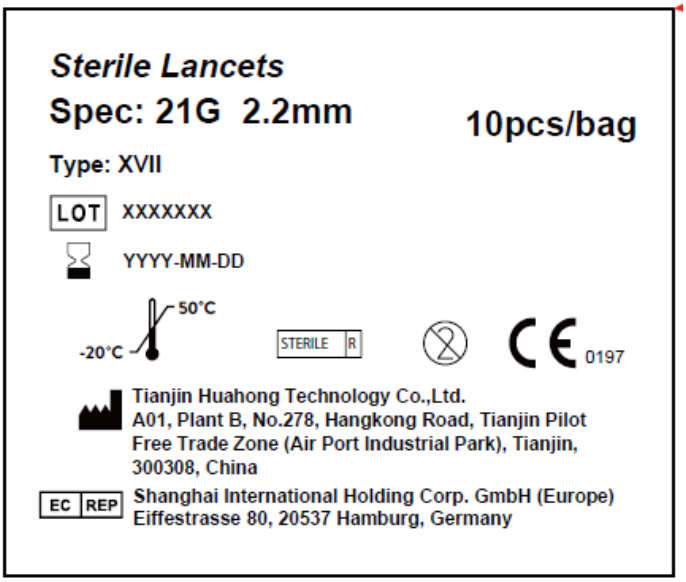
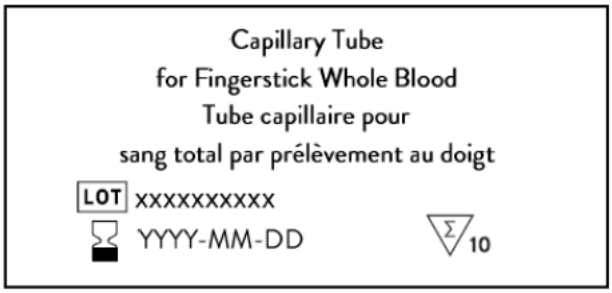


6. Capillary tubes (For Fingerstick Whole Blood)

IHI-T402WF (internal material code: 1045805301)



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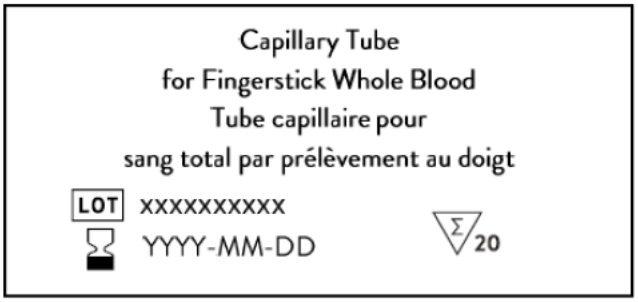

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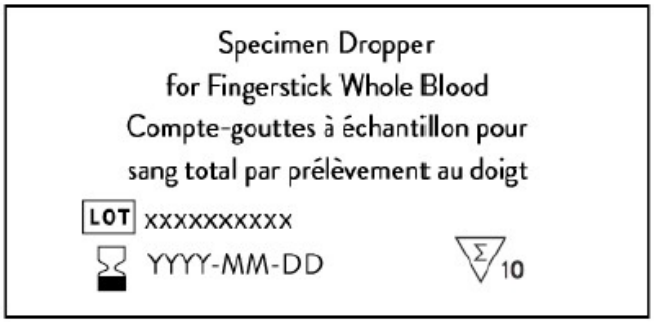
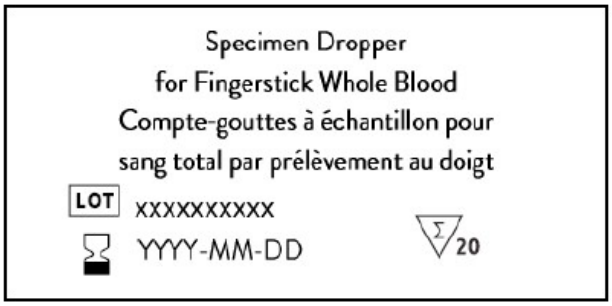


IHI-T402WG, IHI-T402WB (internal material code: 1115811501)



7. Specimen dropper (For Serum/Plasma/Venipuncture Whole Blood)

IHI-T402WD, IHI-T402WF (internal material code: 1115811201)

IHI-T402WA (internal material code: 40003977)

N/A

IHI-T402WG, IHI-T402WB, IHI-T402WE, IHI-T402WI (internal material code: 40003978)

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

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

		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

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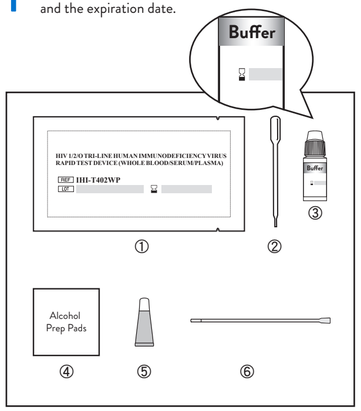
Abbott

ABON™

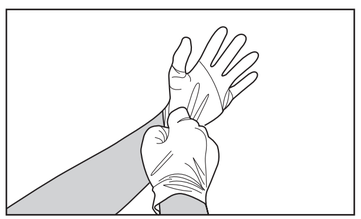
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

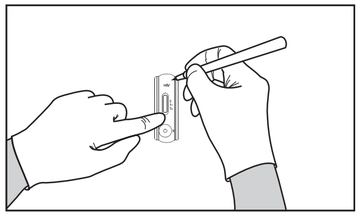
1 Open the package and check the content and the expiration date.



2 Wear gloves

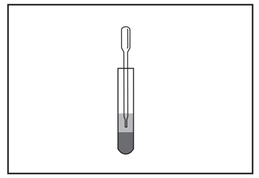


3 Open the pouch, Label with specimen ID. Use it as soon as possible (within one hour).

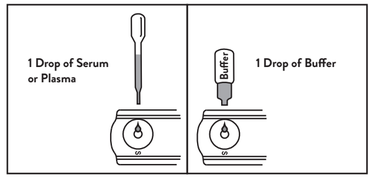


SERUM OR PLASMA SPECIMENS

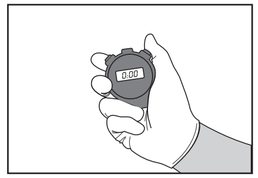
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



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

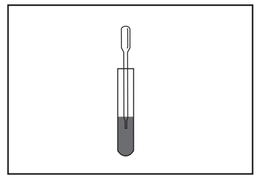


6 Start the timer.

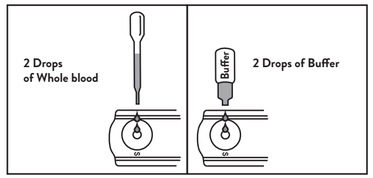


VENIPUNCTURE WHOLE BLOOD SPECIMENS

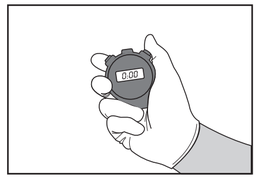
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



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

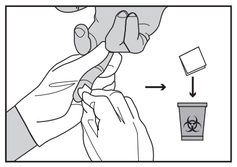


6 Start the timer.

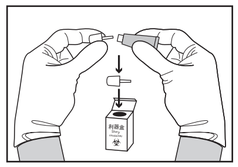


FINGERSTICK WHOLE BLOOD SPECIMENS

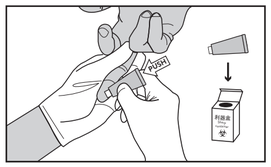
4 Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



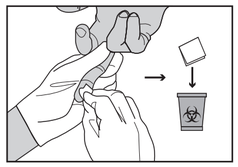
5 Take off the cap of the lancet and dispose the cap in sharps container.



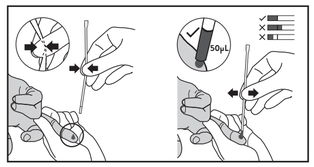
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



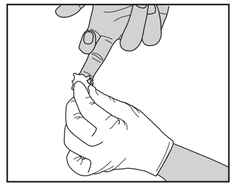
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



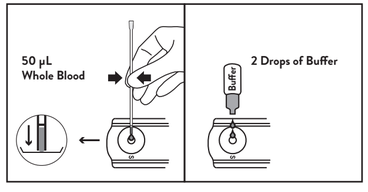
8 Take the provided specimen dropper (for fingerstick whole blood) vertically, squeeze the middle of the dropper, immerse the open end into the blood drop, and then slowly release the pressure to draw blood until mark line. Avoid air bubbles.



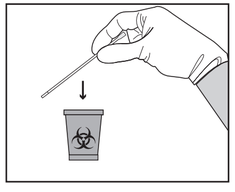
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



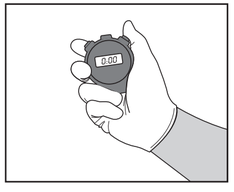
10 Squeeze the specimen dropper and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).



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

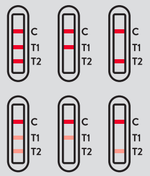


12 Start the timer.



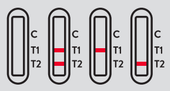
READ RESULTS

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.

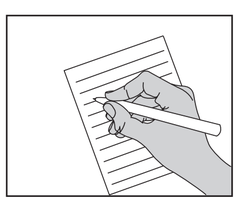
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).



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.

Pantone 2925C

Pantone 285C

Pantone 285C 40%

Pantone 185C

Pantone 185C 50%

Black

Black 0-100%

注意 **Attention**:

1. 所附的设计稿会直接应用于生产。客户批准所附的设计稿即代表客户已接受承担设计正确性的所有责任。如物料在随后的印刷和生产过程中发现有任何不适合销售的错误，客户将负责承担任何库存的费用。
   The enclosed design will be applied to manufacture directly. Once approving the enclosed design, customer will accept all responsibility for the accuracy of the design. If an error is detected following the printing or manufacturing of a material, customer will be responsible for the cost of any inventory which is deemed unsuitable for sale.
2. 法规所有人必须确保其销售区域适用法规的符合性。适用法规指的是所有联邦/州/地方性法律、法令、条例、规章以及强制的ISO标准，以用于产品在某区域的设计、开发、生产、控制和上市。
   Regulatory owner must ensure the compliance with all applicable regulations in the distribution territory. The applicable regulation means all federal, state and local laws, ordinances, rules, regulations, and mandatory ISO standards applicable to the design, development, manufacturer, control and marketing of the Product in the Territory.

■ 美国以外的国际区域OUS　　□ 美国US　　□ 内销China

描述 Description	WHO ABT ABON IHI-T402WD EN PI	物料号 Part Number	1156230701	尺寸 Size	360x580mm
打码号 Ink jetting/ Ink printing No.	/	设计者/日期/版本 Designer/Date/ Version	Zoe Feb.22, 2022/B	复核者/日期 Reviewer/Date	Amy
材质 Material	70g双胶	折法 Folding Method	折法22	尺寸/材质/折法审核/日期 Size/Material/ Folding Method checked by/Date	
模具号 Mold Number	/	模具号审核/日期 Mold Number checked by/Date	/		
生产确认/日期 Approved by Production/Date	/	技术确认/日期 Approved by POD/Date		研发确认/日期 Approved by R&D/Date	
客户确认/日期 Approved by Customer/Date		市场确认/日期 Approved by Marketing/Date		LM/RO 法规事务确认/日期 Approved by LM/RO RA/Date	
LM/RO 质量保证确认/日期 Approved by LM/RO QA/Date		备注 Remark			

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.

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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

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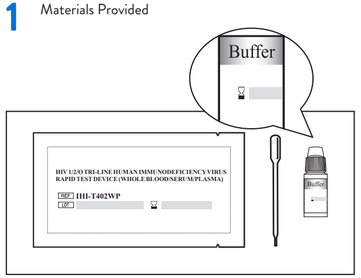
ABON™

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

PREPARATION

1 Materials Provided



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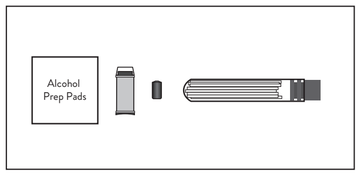
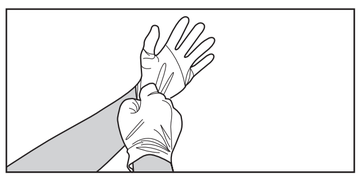
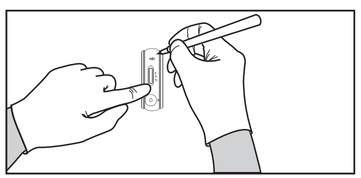


2 Wear gloves

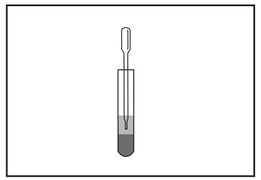


3 Open the pouch, Label with specimen ID.
Use it as soon as possible (within one hour).

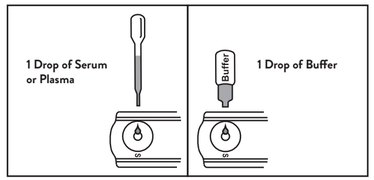


SERUM OR PLASMA SPECIMENS

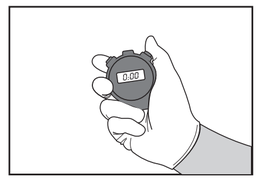
4 Draw the specimen from the specimen tube with a dropper.



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

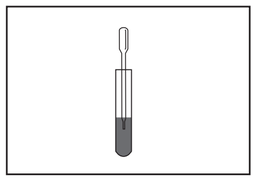


6 Start the timer.

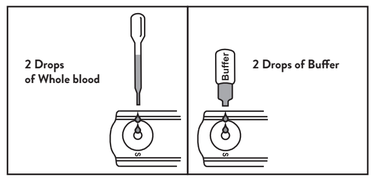


VENIPUNCTURE WHOLE BLOOD SPECIMENS

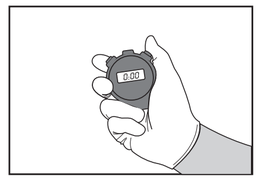
4 Draw the specimen from the specimen tube with a dropper.



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

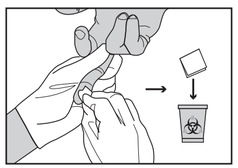


6 Start the timer.

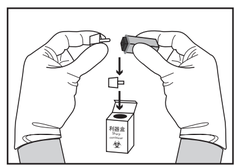


FINGERSTICK WHOLE BLOOD SPECIMENS

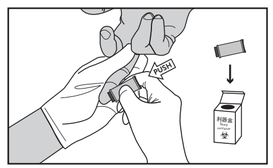
4 Clean entire fingertip (preferable 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



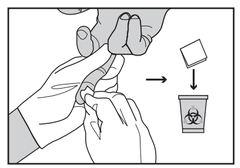
5 Take off the cap of the lancet and dispose the cap in sharps container.



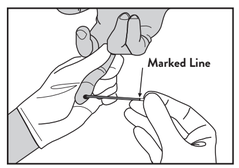
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



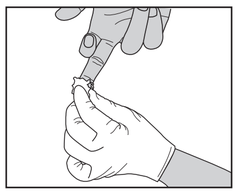
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



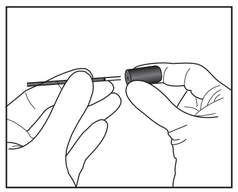
8 Immerse the open end of the capillary tube into the blood drop and allow for the blood to draw into the capillary tube up to marked line.



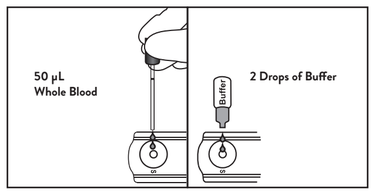
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



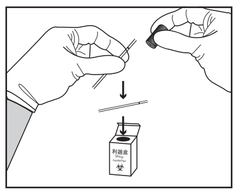
10 Place the bulb onto the top end of the capillary tube.



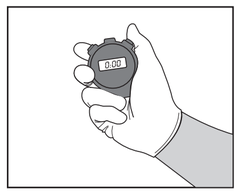
11 Squeeze the bulb to dispense all whole blood on the specimen well (approximately 50 µL) , then add 2 drops of buffer (approximately 80 µL).



12 Dispose the capillary tube in sharps container after testing.

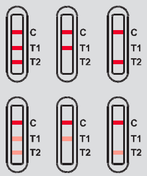


13 Start the timer.



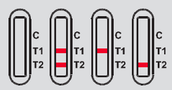
READ RESULTS

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.

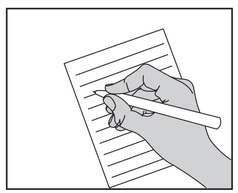
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).



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.

Pantone 2925C

Pantone 285C

Pantone 285C 40%

Pantone 185C

Pantone 185C 50%

Black

Black 0-100%

Attention/注意:

1. The enclosed design will be applied to manufacture directly. Once approving the enclosed design, customer will accept all responsibility for the accuracy of the design. If an error is detected following the printing or manufacturing of a material, customer will be responsible for the cost of any inventory which is deemed unsuitable for sale. 所附的设计稿会直接应用于生产。客户批准所附的设计稿即代表客户已接受承担设计正确性的所有责任。如物料在随后的印刷和生产过程中发现有任何不适合销售的错误，客户将负责承担任何库存的费用。
2. Regulatory owner must ensure the compliance with all applicable regulations in the distribution territory. The applicable regulation means all federal, state and local laws, ordinances, rules, regulations, and mandatory ISO standards applicable to the design, development, manufacture, control and marketing of the Product in the Territory. 法规所有人必须确保其销售区域适用法规的符合性。适用法规指的是所有联邦/州/地方性法律、法令、条例、规章以及强制的ISO标准，以用于产品在某区域的设计、开发、生产、控制和上市。

Regulatory owner's RA/RR: Regulatory owner's RA/Authorized Regulatory Representative

☐ US ■ OUS ☐ China

Description 描述	ABT WHO ABON IHI-T402WA English PI	***Part Number*** PN 号码	1156212601	***Size*** 尺寸	360x580mm
Printing Contents 印刷内容	/	***L Number*** L 号码	/	***Size*** 尺寸	/
Designer 设计者	Lyn/Sara	***Design Date/Version*** 设计日期/版本	May 18, 2021/A	***Mold Num.*** 模具号	/
Artwork Checked By 设计审核		***Material/ Checked By*** 材质/审核	70g双胶,折法22		
Approved by Regulatory owner's RA/RR / Date 法规所有人**RA/RR** 确认/日期		***Approved by US Customer*** **US** 客户确认/日期			
Approved by Affiliates QA / Date 关联公司**QA**确认/日期		***Approved by Marketing / Date*** 市场部确认/日期			
Approved by ABON RA / Date ***ABON*** 注册部 确认/日期		***Approved by PMT / Date*** 产品管理确认/日期			
Approved By ABON QA/Date ***ABON QA***确认/日期					

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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

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+965 2202 2828
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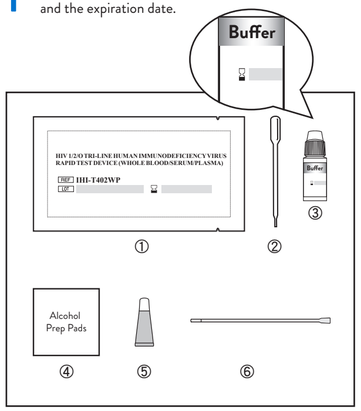
ABON™

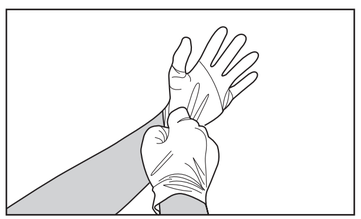
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

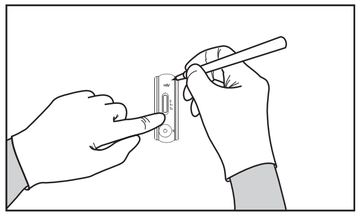
1 Open the package and check the content and the expiration date.



2 Wear gloves

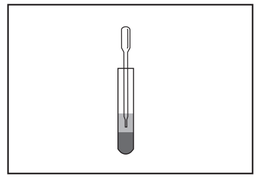


3 Open the pouch, Label with specimen ID. Use it as soon as possible (within one hour).

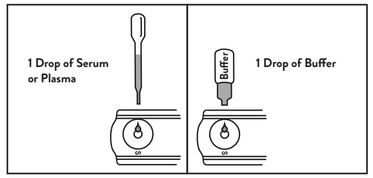


SERUM OR PLASMA SPECIMENS

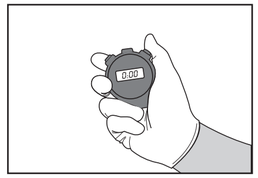
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



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

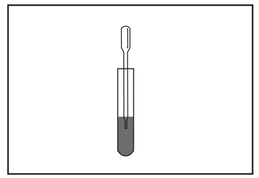


6 Start the timer.

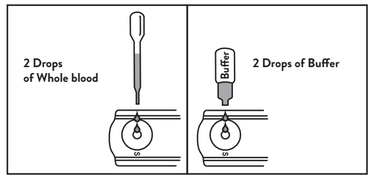


VENIPUNCTURE WHOLE BLOOD SPECIMENS

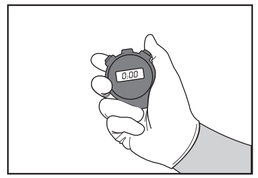
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



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

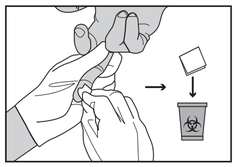


6 Start the timer.

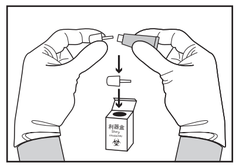


FINGERSTICK WHOLE BLOOD SPECIMENS

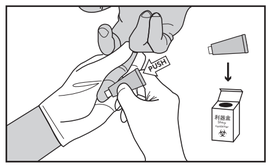
4 Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



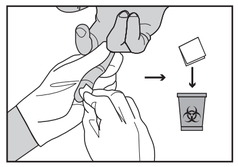
5 Take off the cap of the lancet and dispose the cap in sharps container.



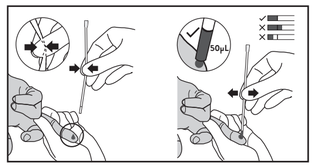
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



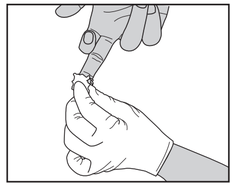
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



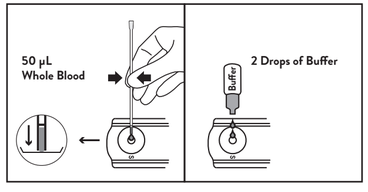
8 Take the provided specimen dropper (for fingerstick whole blood) vertically, squeeze the middle of the dropper, immerse the open end into the blood drop, and then slowly release the pressure to draw blood until mark line. Avoid air bubbles.



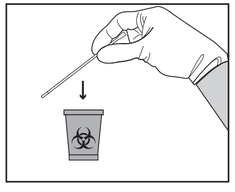
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



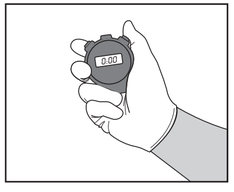
10 Squeeze the specimen dropper and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).



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

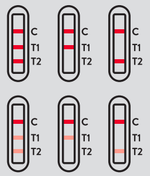


12 Start the timer.



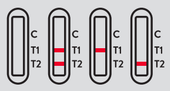
READ RESULTS

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.

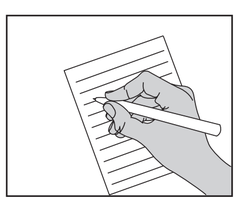
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).



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.

Pantone 2925C

Pantone 285C

Pantone 285C 40%

Pantone 185C

Pantone 185C 50%

Black

Black 0-100%

注意 **Attention**:

1. 所附的设计稿会直接应用于生产。客户批准所附的设计稿即代表客户已接受承担设计正确性的所有责任。如物料在随后的印刷和生产过程中发现有任何不适合销售的错误，客户将负责承担任何库存的费用。
   The enclosed design will be applied to manufacture directly. Once approving the enclosed design, customer will accept all responsibility for the accuracy of the design. If an error is detected following the printing or manufacturing of a material, customer will be responsible for the cost of any inventory which is deemed unsuitable for sale.
2. 法规所有人必须确保其销售区域适用法规的符合性。适用法规指的是所有联邦/州/地方性法律、法令、条例、规章以及强制的ISO标准，以用于产品在某区域的设计、开发、生产、控制和上市。
   Regulatory owner must ensure the compliance with all applicable regulations in the distribution territory. The applicable regulation means all federal, state and local laws, ordinances, rules, regulations, and mandatory ISO standards applicable to the design, development, manufacturer, control and marketing of the Product in the Territory.

美国以外的国际区域OUS　　美国US　　内销China

描述 Description	WHO ABT ABON IHI-T402WG EN PI	物料号 Part Number	1156230401	尺寸 Size	360x580mm
打码号 Ink jetting/ Ink printing No.	/	设计者/日期/版本 Designer/Date/ Version	Zoe Feb.22, 2022/B	复核者/日期 Reviewer/Date	Amy
材质 Material	70g双胶	折法 Folding Method	折法22	尺寸/材质/折法审核/日期 Size/Material/ Folding Method checked by/Date	
模具号 Mold Number	/	模具号审核/日期 Mold Number checked by/Date	/		
生产确认/日期 Approved by Production/Date	/	技术确认/日期 Approved by POD/Date		研发确认/日期 Approved by R&D/Date	
客户确认/日期 Approved by Customer/Date		市场确认/日期 Approved by Marketing/Date		LM/RO 法规事务确认/日期 Approved by LM/RO RA/Date	
LM/RO 质量保证确认/日期 Approved by LM/RO QA/Date		备注 Remark			

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

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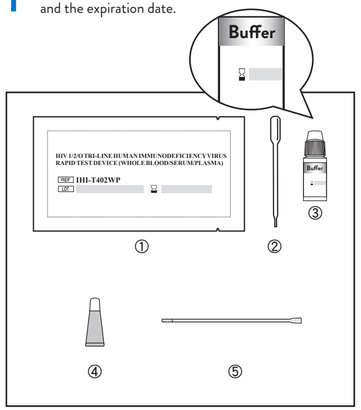
ABON™

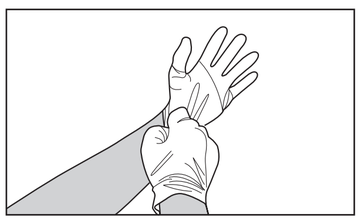
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

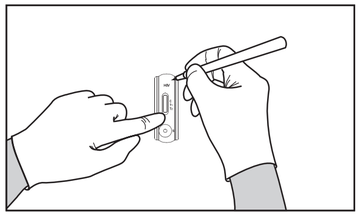
1 Open the package and check the content and the expiration date.



2 Wear gloves

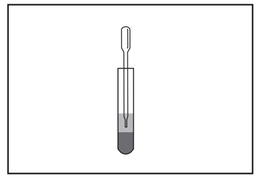


3 Open the pouch, Label with specimen ID. Use it as soon as possible (within one hour).

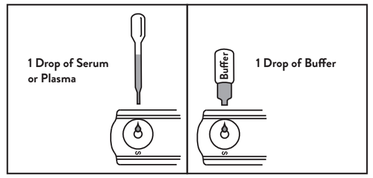


SERUM OR PLASMA SPECIMENS

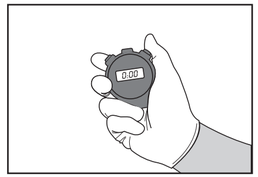
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



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

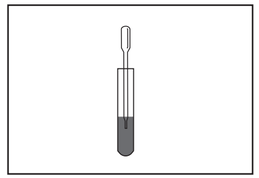


6 Start the timer.

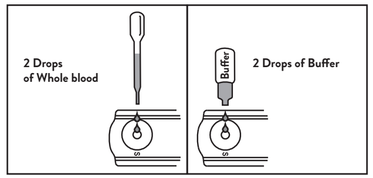


VENIPUNCTURE WHOLE BLOOD SPECIMENS

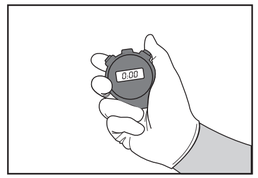
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



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

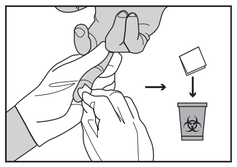


6 Start the timer.

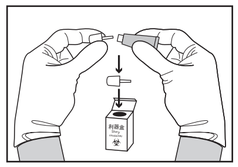


FINGERSTICK WHOLE BLOOD SPECIMENS

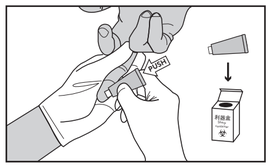
4 Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



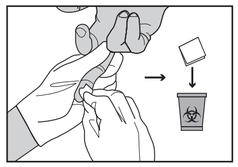
5 Take off the cap of the lancet and dispose the cap in sharps container.



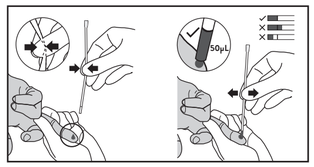
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



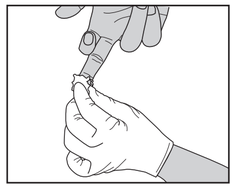
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



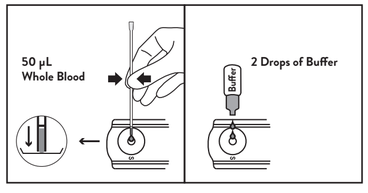
8 Take the provided specimen dropper (for fingerstick whole blood) vertically, squeeze the middle of the dropper, immerse the open end into the blood drop, and then slowly release the pressure to draw blood until mark line. Avoid air bubbles.



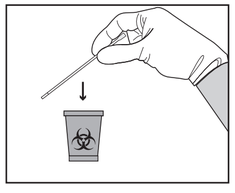
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



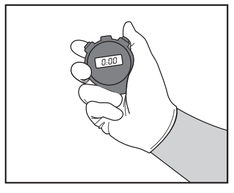
10 Squeeze the specimen dropper and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).



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



12 Start the timer.

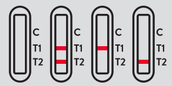


READ RESULTS

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.

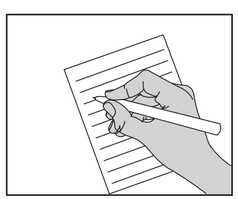
NON-REACTIVE: One colored line appears in the control region (C). No colored lines appear in the test line regions (T1 and/or T2).



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.

Pantone 2925C

Pantone 285C

Pantone 285C 40%

Pantone 185C

Pantone 185C 50%

Black

Black 0-100%

注意 **Attention**:

1. 所附的设计稿会直接应用于生产。客户批准所附的设计稿即代表客户已接受承担设计正确性的所有责任。如物料在随后的印刷和生产过程中发现有任何不适合销售的错误，客户将负责承担任何库存的费用。
   The enclosed design will be applied to manufacture directly. Once approving the enclosed design, customer will accept all responsibility for the accuracy of the design. If an error is detected following the printing or manufacturing of a material, customer will be responsible for the cost of any inventory which is deemed unsuitable for sale.
2. 法规所有人必须确保其销售区域适用法规的符合性。适用法规指的是所有联邦/州/地方性法律、法令、条例、规章以及强制的ISO标准，以用于产品在某区域的设计、开发、生产、控制和上市。
   Regulatory owner must ensure the compliance with all applicable regulations in the distribution territory. The applicable regulation means all federal, state and local laws, ordinances, rules, regulations, and mandatory ISO standards applicable to the design, development, manufacturer, control and marketing of the Product in the Territory.

☐ 美国以外的国际区域OUS　　☐ 美国US　　☐ 内销China

描述 Description	WHO ABT ABON IHI-T402WB EN PI	物料号 Part Number	1156230601	尺寸 Size	360x580mm
打码号 Ink jetting/ Ink printing No.	/	设计者/日期/版本 Designer/Date/ Version	Zoe Feb.22, 2022/B	复核者/日期 Reviewer/Date	Amy
材质 Material	70g双胶	折法 Folding Method	折法22	尺寸/材质/折法审核/日期 Size/Material/ Folding Method checked by/Date	
模具号 Mold Number	/	模具号审核/日期 Mold Number checked by/Date	/		
生产确认/日期 Approved by Production/Date	/	技术确认/日期 Approved by POD/Date		研发确认/日期 Approved by R&D/Date	
客户确认/日期 Approved by Customer/Date		市场确认/日期 Approved by Marketing/Date		LM/RO 法规事务确认/日期 Approved by LM/RO RA/Date	
LM/RO 质量保证确认/日期 Approved by LM/RO QA/Date		备注 Remark			

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

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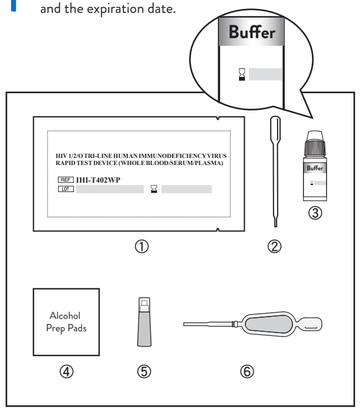
Abbott

ABON™

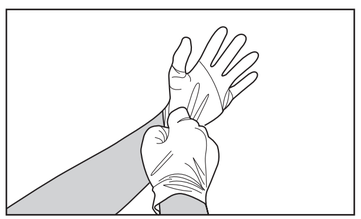
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

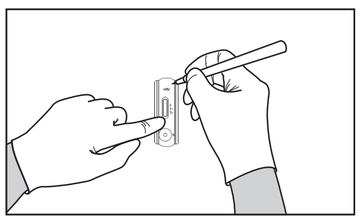
1 Open the package and check the content and the expiration date.



2 Wear gloves

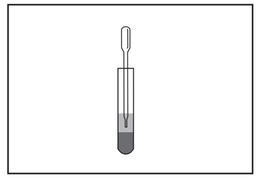


3 Open the pouch, Label with specimen ID. Use it as soon as possible (within one hour).

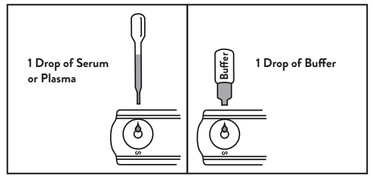


SERUM OR PLASMA SPECIMENS

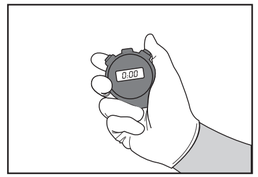
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



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

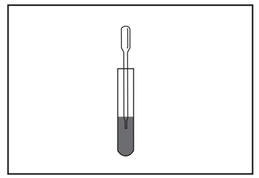


6 Start the timer.

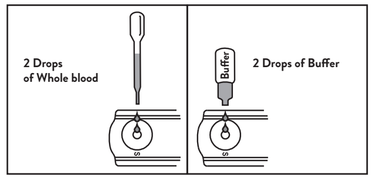


VENIPUNCTURE WHOLE BLOOD SPECIMENS

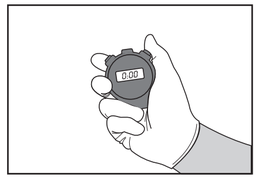
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



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

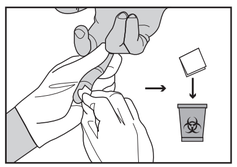


6 Start the timer.

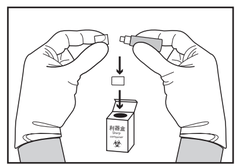


FINGERSTICK WHOLE BLOOD SPECIMENS

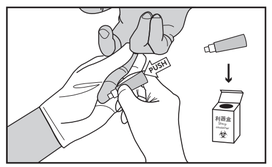
4 Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



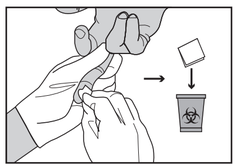
5 Take off the cap of the lancet and dispose the cap in sharps container.



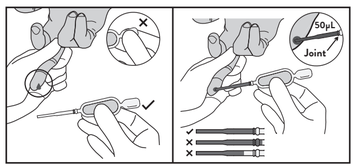
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



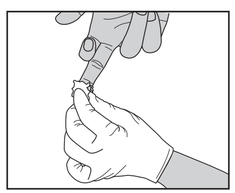
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



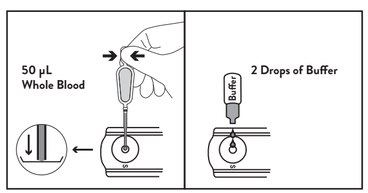
8 Hold the provided capillary tube (for fingerstick whole blood) horizontally below the bulb. DO NOT TOUCH OR SQUEEZE BULB. Immerse the open end of the capillary tube into the blood drop and let the blood rise by capillarity to the **joint** (volume position). Avoid air bubbles.



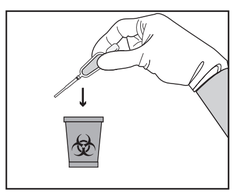
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



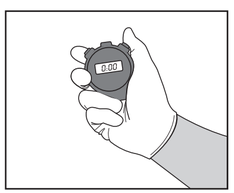
10 Squeeze the bulb and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).



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

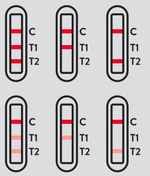


12 Start the timer.



READ RESULTS

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



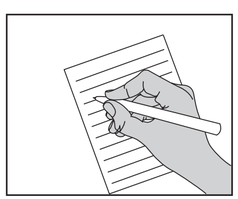
REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 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.

Pantone 2925C

Pantone 285C

Pantone 285C 40%

Pantone 185C

Pantone 185C 50%

Black

Black 0-100%

注意 **Attention**:

1. 所附的设计稿会直接应用于生产。客户批准所附的设计稿即代表客户已接受承担设计正确性的所有责任。如物料在随后的印刷和生产过程中发现有任何不适合销售的错误，客户将负责承担任何库存的费用。
   The enclosed design will be applied to manufacture directly. Once approving the enclosed design, customer will accept all responsibility for the accuracy of the design. If an error is detected following the printing or manufacturing of a material, customer will be responsible for the cost of any inventory which is deemed unsuitable for sale.
2. 法规所有人必须确保其销售区域适用法规的符合性。适用法规指的是所有联邦/州/地方性法律、法令、条例、规章以及强制的ISO标准，以用于产品在某区域的设计、开发、生产、控制和上市。
   Regulatory owner must ensure the compliance with all applicable regulations in the distribution territory. The applicable regulation means all federal, state and local laws, ordinances, rules, regulations, and mandatory ISO standards applicable to the design, development, manufacturer, control and marketing of the Product in the Territory.

■ 美国以外的国际区域OUS　　□ 美国US　　□ 内销China

描述 Description	WHO ABT ABON IHI-T402WE EN PI	物料号 Part Number	1156230801	尺寸 Size	360x580mm
打码号 Ink jetting/ Ink printing No.	/	设计者/日期/版本 Designer/Date/ Version	Zoe Feb.22, 2022/B	复核者/日期 Reviewer/Date	Amy
材质 Material	70g双胶	折法 Folding Method	折法22	尺寸/材质/折法审核/日期 Size/Material/ Folding Method checked by/Date	
模具号 Mold Number	/	模具号审核/日期 Mold Number checked by/Date	/		
生产确认/日期 Approved by Production/Date	/	技术确认/日期 Approved by POD/Date		研发确认/日期 Approved by R&D/Date	
客户确认/日期 Approved by Customer/Date		市场确认/日期 Approved by Marketing/Date		LM/RO 法规事务确认/日期 Approved by LM/RO RA/Date	
LM/RO 质量保证确认/日期 Approved by LM/RO QA/Date		备注 Remark			

Abbott

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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

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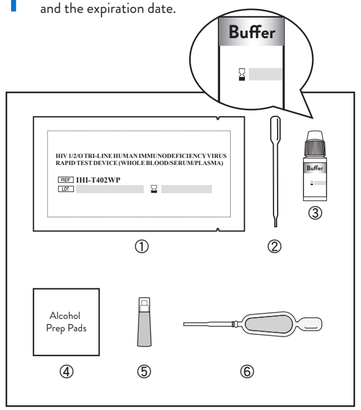
ABON™

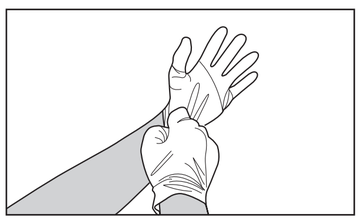
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

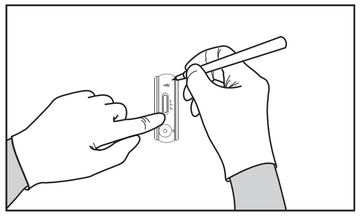
1 Open the package and check the content and the expiration date.



2 Wear gloves

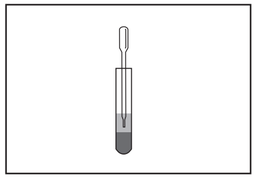


3 Open the pouch, Label with specimen ID. Use it as soon as possible (within one hour).

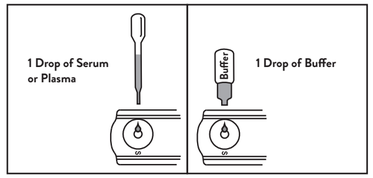


SERUM OR PLASMA SPECIMENS

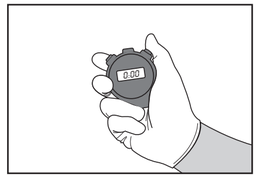
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



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

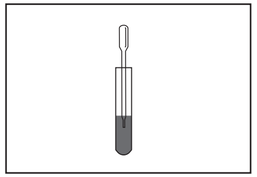


6 Start the timer.

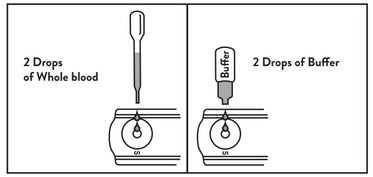


VENIPUNCTURE WHOLE BLOOD SPECIMENS

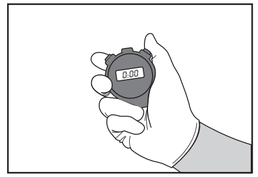
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



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

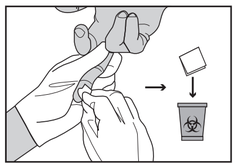


6 Start the timer.

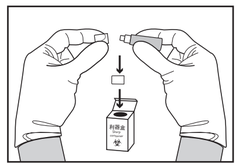


FINGERSTICK WHOLE BLOOD SPECIMENS

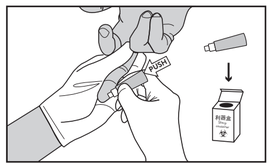
4 Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



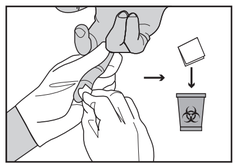
5 Take off the cap of the lancet and dispose the cap in sharps container.



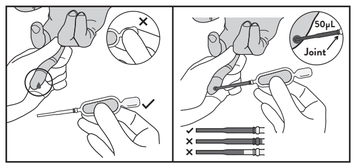
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



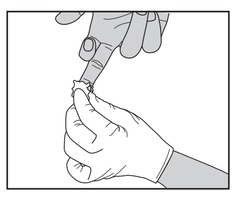
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



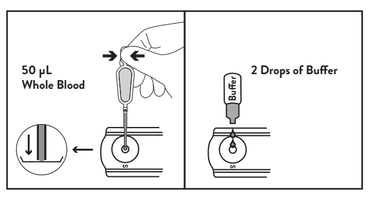
8 Hold the provided capillary tube (for fingerstick whole blood) horizontally below the bulb. DO NOT TOUCH OR SQUEEZE BULB. Immerse the open end of the capillary tube into the blood drop and let the blood rise by capillarity to the **joint** (volume position). Avoid air bubbles.



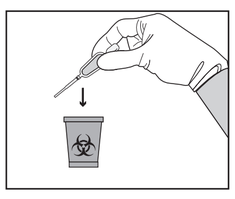
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



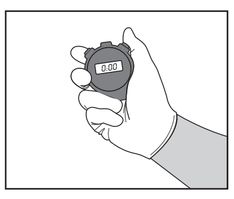
10 Squeeze the bulb and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).



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

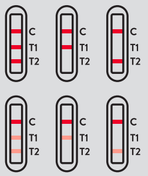


12 Start the timer.



READ RESULTS

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



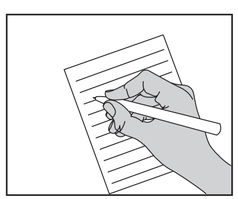
REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 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.

Pantone 2925C

Pantone 285C

Pantone 285C 40%

Pantone 185C

Pantone 185C 50%

Black

Black 0-100%

注意 **Attention**:

1. 所附的设计稿会直接应用于生产。客户批准所附的设计稿即代表客户已接受承担设计正确性的所有责任。如物料在随后的印刷和生产过程中发现有任何不适合销售的错误，客户将负责承担任何库存的费用。
   The enclosed design will be applied to manufacture directly. Once approving the enclosed design, customer will accept all responsibility for the accuracy of the design. If an error is detected following the printing or manufacturing of a material, customer will be responsible for the cost of any inventory which is deemed unsuitable for sale.
2. 法规所有人必须确保其销售区域适用法规的符合性。适用法规指的是所有联邦/州/地方性法律、法令、条例、规章以及强制的ISO标准，以用于产品在某区域的设计、开发、生产、控制和上市。
   Regulatory owner must ensure the compliance with all applicable regulations in the distribution territory. The applicable regulation means all federal, state and local laws, ordinances, rules, regulations, and mandatory ISO standards applicable to the design, development, manufacturer, control and marketing of the Product in the Territory.

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描述 Description	WHO ABT ABON IHI-T402WF EN PI	物料号 Part Number	1156231101	尺寸 Size	360x580mm
打码号 Ink jetting/ Ink printing No.	/	设计者/日期/版本 Designer/Date/ Version	Zoe Feb.22, 2022/B	复核者/日期 Reviewer/Date	Amy
材质 Material	70g双胶	折法 Folding Method	折法22	尺寸/材质/折法审核/日期 Size/Material/ Folding Method checked by/Date	
模具号 Mold Number	/	模具号审核/日期 Mold Number checked by/Date	/		
生产确认/日期 Approved by Production/Date	/	技术确认/日期 Approved by POD/Date		研发确认/日期 Approved by R&D/Date	
客户确认/日期 Approved by Customer/Date		市场确认/日期 Approved by Marketing/Date		LM/RO 法规事务确认/日期 Approved by LM/RO RA/Date	
LM/RO 质量保证确认/日期 Approved by LM/RO QA/Date		备注 Remark			

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

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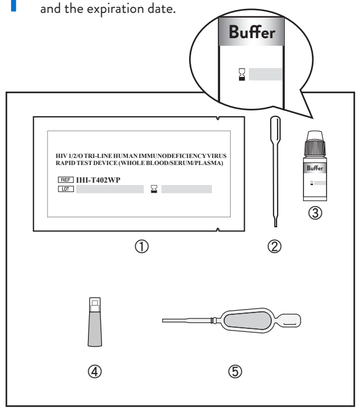
ABON™

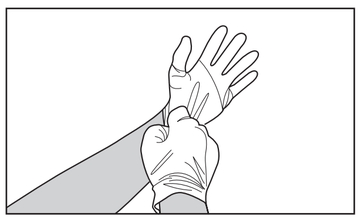
HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE
(WHOLE BLOOD/SERUM/PLASMA)

PREPARATION

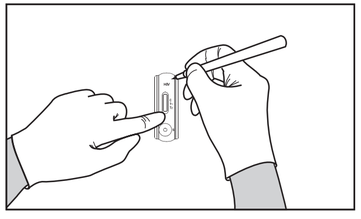
1 Open the package and check the content and the expiration date.



2 Wear gloves

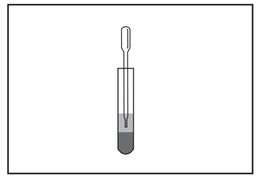


3 Open the pouch, Label with specimen ID. Use it as soon as possible (within one hour).

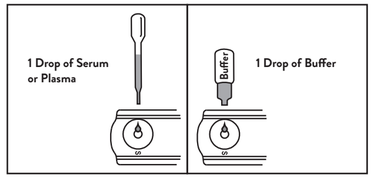


SERUM OR PLASMA SPECIMENS

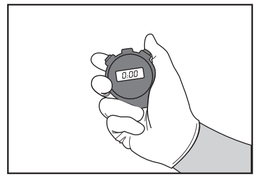
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



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

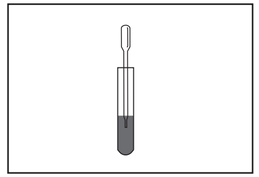


6 Start the timer.

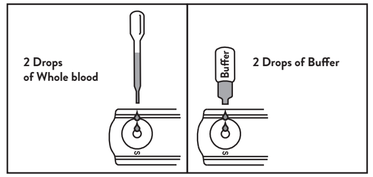


VENIPUNCTURE WHOLE BLOOD SPECIMENS

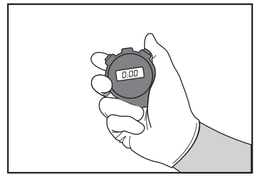
4 Draw the specimen from the specimen tube with a dropper (for serum/plasma/venipuncture whole blood).



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

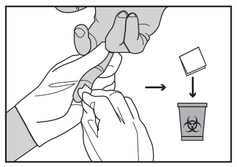


6 Start the timer.

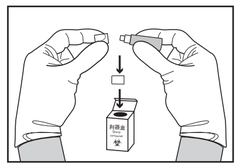


FINGERSTICK WHOLE BLOOD SPECIMENS

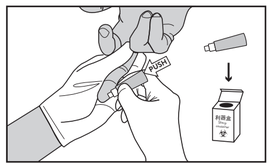
4 Clean entire fingertip (preferably 3rd or 4th finger from non-dominant hand) with alcohol swab. Dispose the alcohol swab.



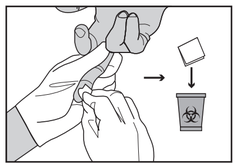
5 Take off the cap of the lancet and dispose the cap in sharps container.



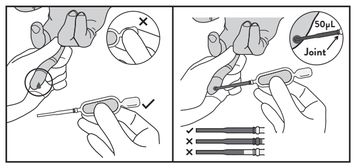
6 Puncture the side of the finger. Dispose the lancet in sharps container immediately after using it.



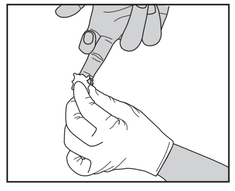
7 Wipe away the first blood drop with a sterile gauze pad or cotton wool.



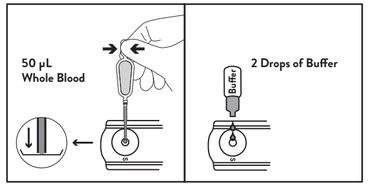
8 Hold the provided capillary tube (for fingerstick whole blood) horizontally below the bulb. DO NOT TOUCH OR SQUEEZE BULB. Immerse the open end of the capillary tube into the blood drop and let the blood rise by capillarity to the **joint** (volume position). Avoid air bubbles.



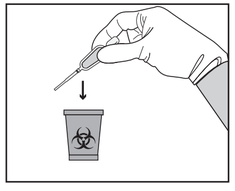
9 After collecting the sample, place a gauze pad or cotton wool on the finger until the bleeding stops.



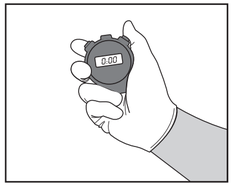
10 Squeeze the bulb and add **all the whole blood** (approximately 50 µL) into the specimen well (S) of the test device. MAKE SURE TO TOUCH THE BOTTOM. Then add 2 drops of buffer (approximately 80 µL) into the specimen well (S).



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

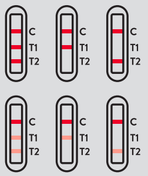


12 Start the timer.



READ RESULTS

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



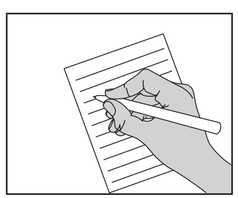
REACTIVE: Two or three distinct colored lines appear.* One line should always appear in the control line region (C), and another one or two colored line(s) should appear in the test line region(s) (T1 and/or T2).
HIV-1 REACTIVE: When C line and T1 line appear, this indicates a reactive result for HIV-1 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.

Pantone 2925C

Pantone 285C

Pantone 285C 40%

Pantone 185C

Pantone 185C 50%

Black

Black 0-100%

注意 **Attention**:

1. 所附的设计稿会直接应用于生产。客户批准所附的设计稿即代表客户已接受承担设计正确性的所有责任。如物料在随后的印刷和生产过程中发现有任何不适合销售的错误，客户将负责承担任何库存的费用。
   The enclosed design will be applied to manufacture directly. Once approving the enclosed design, customer will accept all responsibility for the accuracy of the design. If an error is detected following the printing or manufacturing of a material, customer will be responsible for the cost of any inventory which is deemed unsuitable for sale.
2. 法规所有人必须确保其销售区域适用法规的符合性。适用法规指的是所有联邦/州/地方性法律、法令、条例、规章以及强制的ISO标准，以用于产品在某区域的设计、开发、生产、控制和上市。
   Regulatory owner must ensure the compliance with all applicable regulations in the distribution territory. The applicable regulation means all federal, state and local laws, ordinances, rules, regulations, and mandatory ISO standards applicable to the design, development, manufacturer, control and marketing of the Product in the Territory.

☐ 美国以外的国际区域OUS　☐ 美国US　☐ 内销China

描述 Description	WHO ABT ABON IHI-T402WI EN PI	物料号 Part Number	1156231001	尺寸 Size	360x580mm
打码号 Ink jetting/ Ink printing No.	/	设计者/日期/版本 Designer/Date/ Version	Zoe Feb.22, 2022/B	复核者/日期 Reviewer/Date	Amy
材质 Material	70g双胶	折法 Folding Method	折法22	尺寸/材质/折法审核/日期 Size/Material/ Folding Method checked by/Date	
模具号 Mold Number	/	模具号审核/日期 Mold Number checked by/Date	/		
生产确认/日期 Approved by Production/Date	/	技术确认/日期 Approved by POD/Date		研发确认/日期 Approved by R&D/Date	
客户确认/日期 Approved by Customer/Date		市场确认/日期 Approved by Marketing/Date		LM/RO 法规事务确认/日期 Approved by LM/RO RA/Date	
LM/RO 质量保证确认/日期 Approved by LM/RO QA/Date		备注 Remark			