WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: Panbio HIV Verification Test
WHO reference number: PQDx 0480-032-00

Panbio HIV Verification Test with product codes 29011-W20 and 29011AW20, legal manufacturer **Abbott Rapid Diagnostics Jena GmbH**[1]**,** Rest of World regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 21 November 2022.

Summary of WHO prequalification assessment for Panbio HIV Verification Test

	Date	Outcome
Prequalification listing	21 November 2022	listed
Dossier assessment	12 August 2022	MR
Site inspection(s) of the quality management system	29 December 2018	MR
Product performance evaluation	2nd quarter of 2021	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 summarized in the following table below.

Version	Summary of amendment	Date of report amendment
2.0	Addition of the legal manufacturer and a footnote to include the manufacturing site of the product. Correction to the IFU intended use statement and seroconversion specimen numbers in the performance characteristics section of the IFU.	9 March 2023

[1] The product is manufactured by Abbott, ABON Biopharm (Hangzhou) Co., Ltd. #198, 12th Street East, Hangzhou Economic & Technological Development Area , 310018 Hangzhou, China

	Removal of satisfactorily completed commitment to Prequalification.	

Intended use:

According to the claim of intended use from Abbott Rapid Diagnostics Jena GmbH, *"The Panbio HIV Verification Test is a manual in vitro diagnostic rapid test for the qualitative detection of antibodies to HIV-1 and HIV-2 in human serum, plasma, venous and capillary whole blood. The Panbio HIV Verification Test is for professional use only and is intended for near-patient testing as an aid in the diagnosis of HIV infection. The product may be used in any laboratory and nonlaboratory environment that meets the requirements specified in the Instructions for Use. A reactive result should be confirmed by supplemental testing according to a validated HIV testing algorithm. This test is not intended to be used as an HIV screening test for blood donation and not suitable for testing infants younger than 18 months."*

Assay description:

According to the claim of assay description from Abbott Rapid Diagnostics Jena GmbH, *"HIV is recognized as the virus that causes AIDS (Acquired Immunodeficiency Syndrome). The virus is transmitted by sexual contact, exposure to infected blood, certain body fluids or tissues, and from mother to child during pregnancy. The Panbio HIV Verification Test is an immunochromatographic test based on sandwich principle. It uses recombinant antigens HIV-1 gp41 and HIV-2 gp36 for the qualitative detection of antibodies to HIV-1 and HIV-2. The test contains a membrane strip and a plastic housing. The test device has the letter C, T and S for Control line, Test line and Specimen well on the surface of the plastic device. To use the test, the serum/plasma/whole blood is applied into the specimen well (S) first, and then one drop of buffer is applied. The mixture of specimen and buffer migrates along the membrane strip to the reading window. On the nitrocellulose membrane of the reading window HIV-1 and HIV-2 antigens are precoated at T area and streptavidin is precoated at C area. If the specimen is HIV antibodies positive, the Test line will become visible. If the specimen is HIV antibodies negative, the Test line will not become visible. The Control line should always be visible if the test has been performed correctly. The visible Control line indicates that the result is valid. If the Control line does not appear, the test result is INVALID. When the Control line and Test line are visible this indicates a REACTIVE result. When only the Control line is visible this indicates a NON-REACTIVE result."*

Test kit contents

Component	20 tests (product code 29011-W20)	20 tests (product code 29011AW20)
Test devices individually foil pouched with a desiccant	20	20
Buffer (3 mL/vial)	1	1
Specimen dropper (Serum/Plasma/Venipuncture Whole Blood)	20	20
Instructions for Use	1	1
Sterile single-use lancet	\	20
Sterile alcohol pad	\	20
Fingerstick blood dropper	\	20

Items 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
- Pen/Marker
- Disposable gloves and/or protective clothing

Storage

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

Shelf-life upon manufacture

24 months.

Warnings/limitations:

Refer to the current version of the manufacturer's instructions for use.

Prioritization for prequalification:

Based on the established eligibility criteria, the Panbio HIV Verification Test was given priority for the WHO prequalification assessment.

Dossier assessment

Abbott Rapid Diagnostics Jena GmbH submitted a product dossier for the Panbio HIV Verification Test as per the "*Instructions for compilation of a product dossier*" (PQDx_018 version 3). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

Commitments for prequalification

All dossier commitments to prequalification were considered complete as of 24 February 2023.

Based on the product dossier screening and assessment findings, the product dossier meets WHO prequalification requirements.

Manufacturing site inspection

An inspection of Abbott Rapid Diagnostics GmbH located at Orlaweg 1, Jena, Germany, was conducted from 16 to 18 July 2018. At the time of considering the product application for Prequalification, the Manufacturer of the product had a well-established quality management system and manufacturing practices in place that would support the manufacture of a product of consistent quality. Routine inspections of the Manufacturing site will be conducted with copies of the WHO Public Inspection Report (WHOPIR) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. Note that a WHOPIR reflects the information on the most current inspection performed at a manufacturing site for *in vitro* diagnostic products and gives a summary of the inspection findings.

The manufacturer's responses to the nonconformities found at the time of the inspection were accepted on 29 December 2018.

Product performance evaluation

Panbio HIV Verification Test was evaluated by the Kenya Medical Research Institute Centre for Global Health Research, HIV-Research laboratory on behalf of WHO in the 2nd quarter of 2021, according to protocol PQDx_030, version 11.

Clinical performance evaluation

In this limited laboratory-based evaluation of clinical performance characteristics, a panel of 1200 plasma specimens was used. The specimens were characterized using the following algorithm: AiD anti-HIV 1+2 ELISA (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd)

and Murex HIV Ag/Ab Combination (DiaSorin Dartford, United Kingdom) and INNO-LIA HIV I/II Score LIA.

Clinical performance characteristics in comparison with an agreed reference standard	
Sensitivity % (N=470)	100% (95% CI: 99.2-100)
Specificity % (N= 730)	99.7% (95%CI: 99.0-100)
Invalid rate % (N=1200)	0%
Inter-reader variability % (N=1200)	0.1%

Analytical performance evaluation

Analytical performance characteristics	
Sensitivity during seroconversion on five seroconversion panels in comparison with a benchmark assay (Wantai AID anti-HIV 1+2 ELISA)*	Of a total of 34 specimens, 10 were detected by the Panbio HIV Verification Test HIV-1/2 assay; versus 10 specimens detected by the benchmark assay**.
Analytical sensitivity on a mixed titer panel (0800-436)	20 of the 20 specimens were correctly classified.
Analytical sensitivity on WHO reference preparation panel(s) (NIBS Code 02/210)	7 of 7 specimens were detected.
Lot to lot variation on a dilution panel	Lot to lot variation was within +/- 1 two-fold dilutions for all 10 dilution series.

**The seroconversion results are not directly comparable to seroconversion results of HIV tests evaluated before 2020 due to changes in the seroconversion panels and the benchmark assay.*
***Although the number of specimens detected by each test was the same, the specific panel members detected were not the same: panel member PRB953-03 was reactive with the benchmark assay but not with the test under evaluation, while panel member 0600-270-03 was reactive with the test under evaluation but not the benchmark assay. The next bleed in the latter panel, 0600-270-04 was non-reactive both with the test under evaluation and benchmark assay, so a seroconversion index could not be calculated.*

Operational characteristics and ease of use

This assay does not require laboratory equipment and can be performed in laboratories with limited facilities or nonlaboratory settings.
The assay was found easy to use by the operators performing the evaluation.

Key operational characteristics	
Specimen types and volume	1 drop (approximately 25 µL) of serum, plasma (containing anticoagulants such as heparin, EDTA and sodium citrate), venous or capillary whole blood.
Number of steps*	2 steps in total No step with precision pipetting
Time to result	15 minutes
Endpoint stability (interval)	5 minutes (the test can be read between 15 and 20 minutes after the addition of diluent)
Internal QC	Yes, reagent addition control

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

Based on these results, the performance evaluation for the Panbio HIV Verification Test meets the WHO prequalification requirements.

Labelling

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

1. Label

1.1 Labels for product code 29011-W20

1.1.1 Outer Box artwork

Abbott

Panbio™
HIV VERIFICATION TEST

2°C 30°C 20 IVD

Panbio™
HIV VERIFICATION TEST
Abbott

70003298

Panbio™
HIV VERIFICATION TEST
Abbott

Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1, D-07743 Jena, Germany
www.abbott.com/poct

2°C 30°C 20 IVD

Made in China

Panbio™
HIV VERIFICATION TEST
Abbott

EN
Contents:
20 Test Devices for HIV Diagnosis
20 Specimen Droppers
1 Buffer (3 mL/vial)
1 Instructions for Use

Panbio™
HIV VERIFICATION TEST
Abbott

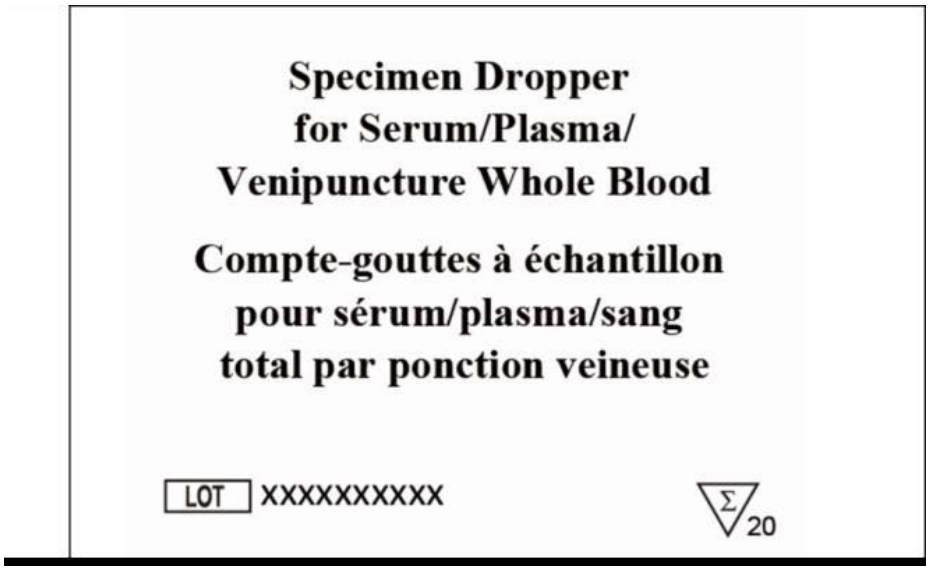
REF 29011-W20
LOT XXXXXXXXXX
YYYY-MM-DD
XXXXXXXXXX NB01652-01

label:66x25mm

1.1.2 Test device pouch

1.1.3 Buffer label

1.1.4 Specimen dropper label



1.2 Labels for product code 29011AW20

1.2.1 Outer Box artwork

Panbio™
HIV VERIFICATION TEST

Abbott

2°C 30°C Σ 20 IVD

70003299

Panbio™
HIV VERIFICATION TEST
Abbott

Panbio™
HIV VERIFICATION TEST
Abbott

Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1, D-07743 Jena, Germany
www.abbott.com/poct

2°C 30°C Σ 20 IVD

Made in China

Panbio™
HIV VERIFICATION TEST
Abbott

EN

Contents:
20 Test Devices for HIV Diagnosis
20 Single-use Lancets
20 Specimen Droppers
20 Alcohol Pads
20 Fingerstick Blood Droppers
1 Buffer (3 mL/vial)
1 Instructions for Use

Panbio™
HIV VERIFICATION TEST
Abbott

REF 29011AW20
LOT XXXXXXXXXX
YYYY-MM-DD
XXXXXXXXXX NB01653-01

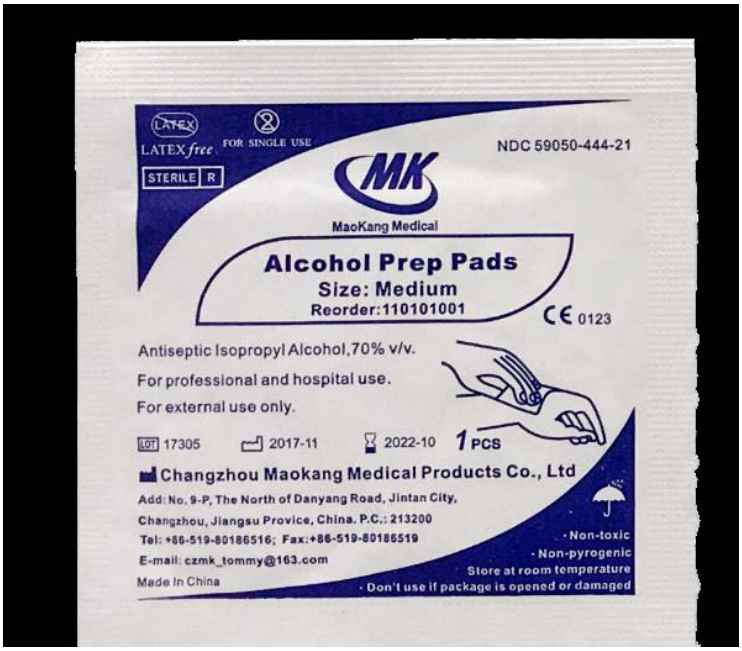
label:66x25mm

1.2.2 Test Device Pouch label

1.2.3 Buffer label

1.2.4 Sterile single-use safety lancet label

1.2.5 Sterile alcohol swab label



1.2.6 Specimen dropper label

2. Instructions for use[2]

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

Panbio™

HIV VERIFICATION TEST

INSTRUCTIONS FOR USE

Catalogue number: 29011-W20 / 29011AW20 EN

Revision date: 2023-02-15 IFU Version 03

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

For professional use only. IVD

INTENDED USE

The Panbio™ HIV Verification Test is a manual *in vitro* diagnostic rapid test for the qualitative detection of antibodies to HIV-1 and HIV-2 in human serum, plasma, venous and capillary whole blood. The Panbio™ HIV Verification Test is for professional use only and is intended for near-patient testing as an aid in the diagnosis of HIV infection. The product may be used in any laboratory and nonlaboratory environment that meets the requirements specified in the Instructions for Use. A reactive result should be confirmed by supplemental testing according to a validated HIV testing algorithm. This test is not intended to be used as an HIV screening test for blood donation and not suitable for testing infants younger than 18 months.

PRINCIPLE

HIV is recognized as the virus that causes AIDS (Acquired Immunodeficiency Syndrome). The virus is transmitted by sexual contact, exposure to infected blood, certain body fluids or tissues, and from mother to child during pregnancy.[1] The Panbio™ HIV Verification Test is an immunochromatographic test based on sandwich principle. It uses recombinant antigens HIV-1 gp41 and HIV-2 gp36 for the qualitative detection of antibodies to HIV-1 and HIV-2. The test contains a membrane strip and a plastic housing. The test device has the letter C, T and S for Control line, Test line and Specimen well on the surface of the plastic device. To use the test, the serum/plasma/whole blood is applied into the specimen well (S) first and then one drop of buffer is applied. The mixture of specimen and buffer migrates along the membrane strip to the reading window. On the nitrocellulose membrane of the reading window HIV-1 and HIV-2 antigens are precoated at T area and streptavidin is precoated at C area. If the specimen is HIV antibodies positive, the Test line will become visible. If the specimen is HIV antibodies negative, the Test line will not become visible. The Control line should always be visible if the test has been performed correctly.

The visible Control line indicates that the result is valid. If the Control line does not appear, the test result is INVALID. When the Control line and Test line are visible this indicates a REACTIVE result. When only the Control line is visible this indicates a NON-REACTIVE result.

MATERIALS

Materials Provided

COMPONENTS	29011-W20	29011AW20
1. Test Devices Individually Foil Pouched with a Desiccant	×20	×20
2. Buffer (3 mL/vial)	×1	×1
3. Specimen Dropper (Serum/Plasma/ Venipuncture Whole Blood)	×20	×20
4. Instructions for Use	×1	×1
5. Sterile single-use Lancet	—	×20
6. Sterile Alcohol Pad	—	×20
7. Fingerstick Blood Dropper	—	×20

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
- Pen/Marker
- Disposable gloves and/or protective clothing

PRECAUTIONS/STORAGE AND STABILITY

1. The test kit should be stored at 2-30°C (storage in refrigerator is permitted). Higher temperatures up to 55°C for a limited period of time (i.e. up to 48 accumulated hours) have no impact on test performance. Do not store the kit in the freezer.
2. The test device and buffer are stable until the expiration date printed on outer package. Do not use it beyond the expiration date.
3. The test device must remain in the sealed pouch until use.
4. Do not use the test device if the pouch is damaged or the seal is broken. Do not use the alcohol pad if the package is opended. Do not use the lancet if the lancet cap is unloaded.
5. The test device is recommended to be used at room temperature (15-30°C).
6. Perform the test as soon as possible after removing the test device from foil pouch (within one hour).
7. After opening of the pouch the test is sensitive to relative humidity above 70%.
8. Do not re-use the test device.
9. EDTA-K_2/EDTA-K_3/Sodium Heparin/Lithium Heparin/Sodium Citrate can be used as anticoagulant. Do not use other anticoagulants.

WARNINGS

1. For *in vitro* diagnostic use only.
2. Do not eat, drink or smoke in the area where handling specimens or test kits.
3. Read the instruction carefully before performing the test.
4. Wear PPE such as gloves, laboratory coats, and eye protection when handling specimens.
5. Avoid splashing or aerosol formation and clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container in accordance with local, state and federal regulations.
7. The buffer contains 0.09% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities of water.

SPECIMEN COLLECTION, STORAGE AND PREPARATION

WHOLE BLOOD

Collection by venipuncture

Using venipuncture, collect whole blood into the collection tube (containing anticoagulants such as EDTA-K_2/EDTA-K_3/Sodium Heparin/Lithium Heparin/ Sodium Citrate).

- If the blood specimen is not immediately tested, it should be refrigerated at 2-8° C.
- If stored at 2-8°C, the blood specimen should be tested within 2 days.
- Do not freeze whole blood specimens.

Collection using a sterile lancet

- Clean entire fingertip (3rd or 4th finger from non-dominant hand corresponding to middle or ring finger) with sterile alcohol pad. Allow to dry (about 10 seconds). Refer to Image 5B.
- Puncture the side of the finger with a sterile lancet provided. Refer to Image 7B.
- Using the Fingerstick Blood Dropper provided, immerse the open end into the blood drop and allow the blood to draw into the dropper up to the marked line. Refer to Image 8B.
- After collecting the finger blood specimen, place a gauze pad or cotton ball on the finger until the bleeding stops. Refer to Image 9B.
- Whole blood collected by fingerstick should be tested immediately.

PLASMA OR SERUM

Plasma: Collect the whole blood into the collection tube (containing anticoagulants such as EDTA-K_2/EDTA-K_3/Sodium Heparin/Lithium Heparin/Sodium Citrate) by venipuncture and then centrifuge the blood to get plasma specimen.

Serum: Collect the whole blood into the collection tube (NOT containing anticoagulants) by venipuncture, leave to settle for 30 minutes to allow for blood coagulation and then centrifuge the blood to get serum specimen.

The centrifuge setting 1,000-1,500 g for approximately 5 minutes is required and refrigeration is not required.

- If plasma or serum specimens are not tested immediately, they should be refrigerated at 2-8°C for up to 3 days. If testing is delayed more than 3 days, the specimen can be frozen at -20°C±10°C for up to 7 months. 3 times freeze/thaw cycles show no impact on test result.
- If plasma or serum specimens contain a precipitate or turbidity, such specimens need to be centrifuged at 10,000 g for 5 minutes (no refrigeration required) before testing.

TEST PROCEDURE

1. Allow the test device, buffer and specimen to reach room temperature (15-30°C) prior to testing.
2. Remove the test device from the foil pouch and use it as soon as possible (within one hour).
   Place the test device on a clean and flat surface. Write specimen ID on the test device.
   Serum or plasma or venipuncture whole blood specimens
   Hold the Specimen Dropper vertically and transfer 1 drop of serum or plasma or venipuncture whole blood (approximately 25 µL) to the specimen well (S) of the test device, then add 1 drop (approximately 40 µL) of buffer directly to specimen well by holding the buffer bottle vertically. NOTE: Ensure buffer bottle tip does not touch the specimen. Start the timer and wait for 15 minutes.
   Fingerstick whole blood specimens
   Cover the 2 air holes on the bulb of Fingerstick Blood Dropper and squeeze bulb to dispense all whole blood onto the specimen well (approximately 25 µL). Keep pressure on bulb until all the blood is squeezed to the specimen well (S). Then add 1 drop of buffer into the specimen well (S) (approximately 40 µL). NOTE: Ensure buffer bottle tip does not touch the specimen. Start the timer and wait for 15 minutes
3. As the test begins to work, a red color moves across the reading window of test device.
4. Wait for the red line/lines to appear. Read test results at 15 minutes. NOTE: Do not read results before 15 minutes or after 20 minutes.

INTERPRETATION OF RESULTS

A red line will appear at C area of the reading window to show that the test is working properly. This line is the Control line.

A red line might appear at T area of the reading window. This line is the Test line.

NON-REACTIVE: The presence of only Control line within the reading window indicates a non-reactive result.

REACTIVE: The presence of both Control line and Test line within the reading window indicates a reactive result.

INVALID: No presence of the Control line in the reading window, even if a line appears in the T area, indicates that the result is invalid. If an invalid test result occurs, it is recommended to read the IFU again and re-test the specimen with a new test device. If no migration or incomplete migration or uncleared background occurs in reading window the buffer may not be added. It is recommended to re-test the specimen with a new test device.

QUALITY CONTROL

A control line is visible within the reading window after the test is performed. The control line is used in the test as a procedural control. A visible control line confirms a lateral flow through the membrane but does not confirm appropriate specimen (and buffer) addition. Quality control specimens are not supplied in this kit; however, it is recommended that quality control specimens can be tested as a good laboratory practice.

LIMITATION

1. The Panbio™ HIV Verification Test is for *in vitro* diagnostic use only. This test can be used for the detection of antibodies to HIV-1/2 in human serum, plasma and capillary and venipuncture whole blood. Other body fluids or diluted specimens may not give accurate results and should not be used.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the medical doctor.
3. The intensity of a red line at T area does not necessarily correlate to the titer of antibody in the specimen.
4. For venipuncture whole blood and plasma, EDTA-K_2/EDTA-K_3/Sodium Heparin/Lithium Heparin/Sodium Citrate should be used as the anticoagulant. Other anticoagulants have not been validated and may give incorrect results.
5. Reading test results earlier than 15 minutes or later than 20 minutes may give incorrect results.
6. A negative result does not eliminate the possibility of HIV infection. A false negative result can occur in the following circumstances:
   - Recent infection. Antibody response to a recent exposure may take several months to be positive. The specimen collected during this period cannot be recognized as positive by all 3rd generation immunoassays.
   - Individuals who are receiving effective antiretroviral therapy may produce false negative results when tested by rapid diagnostic tests.[2,3,4]
   - The test procedure has not been correctly followed.
   - Improper specimen handling.
   - The presence of bubbles during sample application, in particular in low positive samples.
7. An incorrect positive result may occur in cases of infection with cytomegalovirus (CMV) or vaccine-induced HIV seropositivity.
8. The Panbio™ HIV Verification Test has not been evaluated with pediatric and neonatal specimens. Infants born to HIV-infected mothers may carry maternal antibodies and will test antibody positive until eighteen months of age, which may not necessarily indicate the true infection status of the new born. Definitive diagnosis of HIV infection in early infancy requires other assays, including HIV nucleic acid test or viral culture.[5]
9. Biotin concentrations up to 1,500 ng/mL may lead to decreased Control Line intensity but have no impact on the internal control performance.
10. A reactive (positive) result should be confirmed by a different test method.

PERFORMANCE CHARACTERISTICS

Clinical sensitivity and specificity

2800 specimens were tested with Panbio™ HIV Verification Test. The result shows that Panbio™ HIV Verification Test demonstrates a sensitivity of 100% (600/600) including serum (206/206), plasma (394/394) and venous whole blood (100/100) with 95% confidence interval of [99.5%-100%] and a specificity of 99.9% (2097/2100) including serum (749/750), plasma (598/600) and venous whole blood (750/750) with 95% confidence interval of [99.6%-100%]. Panbio™ HIV Verification Test has been shown to correctly detect common (A1, A, B, C, G, CRF02_AG, CRF01_AE) and less common HIV-1 subtypes (D, F, K, J, H, CRF03_AB, CRF06_cxp, CRF11_cxp, CRF47_BF, BF1; Group O) and HIV-2.

As a result of testing of 30 commercially available seroconversion panels containing a total of 275 samples (including 73 early seroconversion samples and 110 seroconversion samples), the performance of Panbio™ HIV Verification Test was equivalent to that of the tested CE-marked 3rd generation EIA tests.

Specimen types consistency

100 HIV seropositive whole blood and paired plasma specimens were tested with Panbio™ HIV Verification Test. The result of paired whole blood and plasma was identical in all the 100 patients.

25 HIV seropositive capillary whole blood and paired venous whole blood specimens as well as 25 HIV negative capillary whole blood and paired venous whole blood specimens were tested with Panbio™ HIV Verification Test. The result of paired capillary whole blood and venous whole blood was identical in all the 50 subjects.

Precision

The repeatability and reproducibility studies were performed with Panbio™ HIV Verification Test by testing 2 HIV negative plasma and whole blood and 6 positive serum and whole blood specimens containing different concentration of HIV-1 and HIV-2 antibodies. With each specimen the same 100% correctly identified result was obtained with all 4 tested lots, for 2 different runs, on all 10 days, by 3 operators and at 3 different laboratories. The test device showed good reproducibility and repeatability and there was no significant variance on lot-to-lot, operator-to-operator, run-to-run, lab-to-lab and day-to-day.

Interference studies

To ensure that other medical conditions (potentially interfering substances) do not affect the performance of the Panbio™ HIV Verification Test, samples of HIV negative blood were tested from people who had other conditions. These included 250 specimens from pregnant women and 342 other specimens as follows:

HAMA; Multiparous woman; Elevated IgG; Elevated IgM; Systemic lupus erythematosus; Hemolytic; Lipemic; Icteric; Rheumatoid Factor; ANA; Anti-E. coli positive specimens; Sickle-cell disease specimens; Blood from recipients of multiple blood transfusions; HBsAg; EBV; CMV; Malaria; Measles; Tuberculosis; Varicella zoster virus; Influenza A and B; Tick borne encephalitis; Influenza vaccine recipient; Human African trypanosomiasis; Yellow fever virus; Post-immunization measles; Vaccine-induced HIV seropositivity; Yellow fever vaccine recipient, Leishmaniasis positive; Syphilis; Toxoplasmosis; H. pylori; HSV; anti-HCV, anti-HBs, anti-HBc; anti-HTLV-1/2; anti-HEV, anti-HAV. These non-HIV medical conditions did not affect the performance of Panbio™ HIV Verification Test with exception of the observed cross-reactivity seen with 2 out of 21 tested CMV specimens.

The Panbio™ HIV Verification Test was also evaluated with 23 interfering substances which include relevant blood analytes and drugs. These substances were spiked with HIV-1 antibody positive samples and HIV negative samples. The test results indicated these interference substances did not affect the performance of Panbio™ HIV Verification Test at the indicated tested concentrations: Hemoglobin (10 mg/mL); Uric Acid (0.6 mg/mL); Bilirubin (10 mg/mL); Triglyceride (50 mg/mL); Human Serum Albumin (60 mg/mL), Creatine (1 mg/mL); Ascorbic Acid (20 mg/mL); Gentistic Acid (0.2 mg/mL); Acetaminophen (1 mg/mL); Acetylsalicylic Acid (0.2 mg/mL); Caffeine (0.2 mg/mL); Oxalic Acid (0.6 mg/mL); Cyclobenzaprine (250 µg/mL), Ibuprofen (250 µg/mL); Naproxen (250 µg/mL); Salicylic Acid (250 µg/mL); Metronidazole (0.12 mg/mL); Chloroquine (0.2 mg/mL); Efavirenz (0.12 mg/mL); Rifampicin (50 µg/mL); Albendazole (0.75 µg/mL); Ethanol (1%); Biotin (1500 ng/mL).

BIBLIOGRAPHY

1. Blattner, W., Gallo, R., & Temin, H. HIV causes AIDS. Science. 1988; 241(4865), 515-515.
2. 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.
3. 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
4. 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.
5. CDC: 2008 Case Definition; Human Immunodeficiency Virus Infection.

40002957

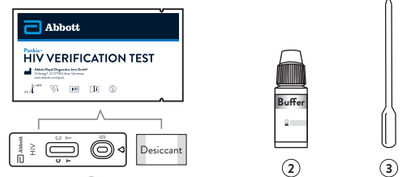
Panbio™ HIV VERIFICATION TEST

TECHNICAL SUPPORT

Europe	Tel. +44 161 483 9032 Option 3	Email: EME.TechSupport@abbott.com
Middle East	Tel. +965-2202 2828	Email: EME.TechSupport@abbott.com
Africa	Tel. +27 10 500 9700 Option 3	Email: arcis.techsupport@abbott.com
APAC (Asia-Pacific)	Tel. +61 7 3363 7711	Email: AP.TechSupport@abbott.com
LATAM (Latin-America)	Tel. +57-601-4824033	Email: LA.TechSupport@abbott.com
RCIS	Tel. +7-499-403 9512	Email: arcis.techsupport@abbott.com

PREPARATION

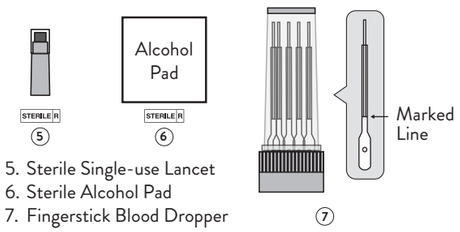
1 Open the package and check the contents and the expiration date.



Contents:

1. Test devices individually foil pouched with a desiccant
2. Buffer (3 mL/vial)
3. Specimen Dropper (Serum/ Plasma/Venipuncture Whole Blood)
4. Instructions for Use

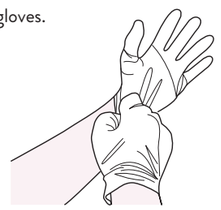
Included only for Cat. No. 29011AW20



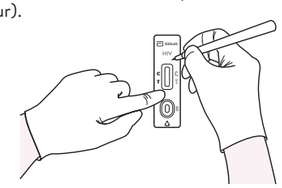
5. Sterile Single-use Lancet
6. Sterile Alcohol Pad
7. Fingerstick Blood Dropper

2 Before testing read the Instructions for Use carefully.

3 Wear gloves.



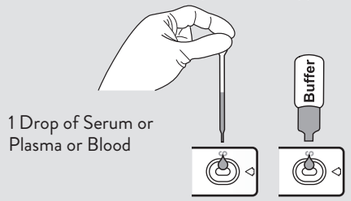
4 Open the pouch. Write specimen ID on the test device. Use it as soon as possible (within one hour).



A. SERUM OR PLASMA OR VENIPUNCTURE WHOLE BLOOD SPECIMENS

5A Draw the specimen from the specimen tube with a Specimen Dropper.

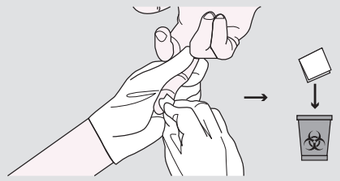
6A Transfer 1 drop of serum or plasma or venipuncture whole blood (approximately 25 µL) to the specimen well (S), then add 1 drop of Buffer (approximately 40 µL).



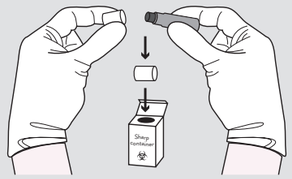
7A Start the timer and wait for 15 minutes.

B. FINGERSTICK WHOLE BLOOD SPECIMENS

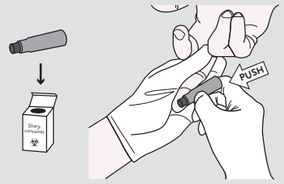
5B Clean entire fingertip (3rd or 4th finger from non-dominant hand corresponding to middle or ring finger) with sterile Alcohol Pad. Dispose the Alcohol Pad in a proper biohazard waste container.



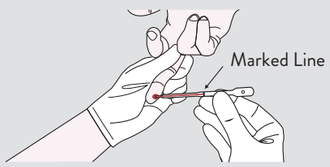
6B Take off the cap of the sterile Single-use Lancet and dispose the cap in sharp container.



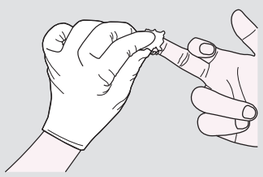
7B Puncture the side of the finger. Dispose the Single-use Lancet in sharp container immediately after using it.



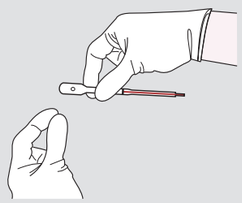
8B Hold the Fingerstick Blood Dropper. DO NOT TOUCH OR SQUEEZE BULB. Immerse the open end of the Fingerstick Blood Dropper into the blood drop and allow the blood to draw into the Fingerstick Blood Dropper up to marked line.



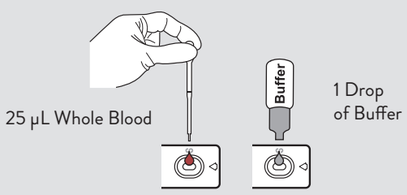
9B After collecting the blood, place a gauze pad or cotton wool on the finger to stop bleeding.



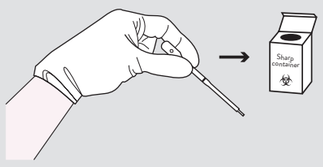
10B Cover the 2 air holes.



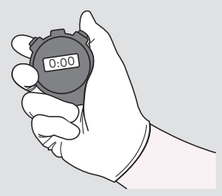
11B Squeeze bulb to dispense all blood (approximately 25 µL) to the specimen well (S) . Then add 1 drop of Buffer (approximately 40 µL) into the specimen well (S).



12B Dispose the Fingerstick Blood Dropper in sharp container after testing.



13B Start the timer and wait for 15 minutes.

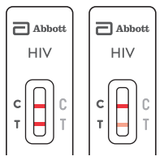


READ RESULTS

Wait for the red line(s) to appear.
Read results at **15-20 minutes.**

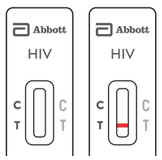
NON-REACTIVE (=Negative)

One red line appears at C area.
No red line appear at T area.



REACTIVE (=Positive)

Two red lines appear. If both C line and T line appear, it should be interpreted as reactive. Any visible line at T area, no matter how faint, means reactive.



INVALID

No line appears at C area. If this occurs, read the test procedure again and repeat the test with a new test device.

CLEAR UP/RECORD

Dispose devices, gloves in a proper biohazard waste container.

Record the test results.

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

Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1, D-07743 Jena, Germany
www.abbott.com/poct