



# Panbio™ HIV Self Test

SPECIMEN TYPE: FINGERSTICK BLOOD

IVD EN  
REF 29012M001



Watch the instructional video:  
<https://alere.wistia.com/medias/eop1k1thk0>

**Before testing you must read all the steps. Conformance with the test procedure is necessary to ensure an accurate result.**

## Precautions

**Do not use**

- If you have a bleeding disorder
- If you are on HIV treatment (ARVs)
- If you are needle-phobic
- If the kit box or components are broken
- If the kit or components have been used

**Do not** eat or drink while you perform the test.

## STEP 1: PREPARATION

**1 PREPARE** a timer and tissue.

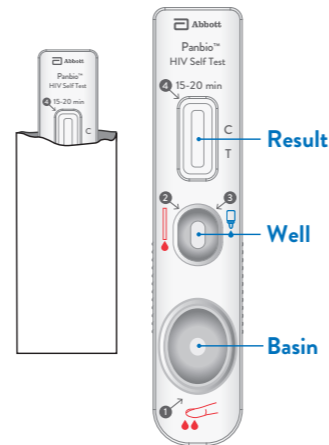
**Materials required but not provided**



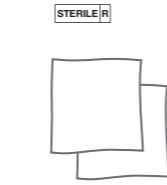
**2 OPEN AND PLACE** all materials on a flat and clean surface.

**Materials provided**

**A** Test device



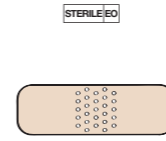
**B** 2 Alcohol pads



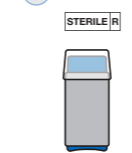
**E** Specimen dropper



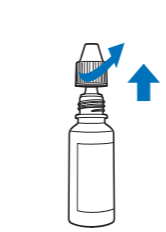
**C** Plaster



**F** Lancet

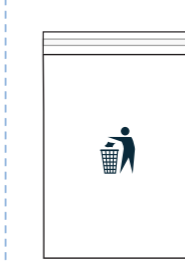


**D** Buffer



**It only pricks once!**

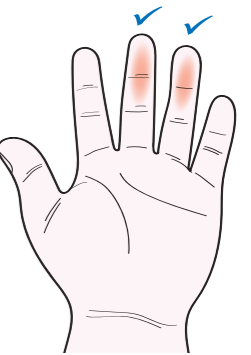
**G** Disposal bag



**3 WASH** hands in warm water and dry. If no warm water is available, rub your hands together.



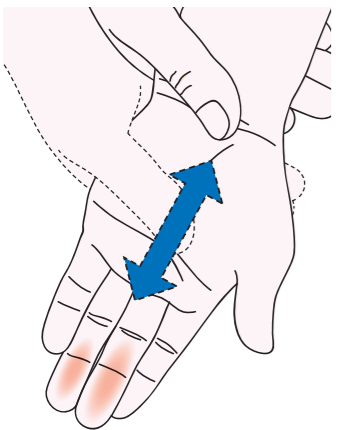
**4 CHOOSE** ring finger or middle finger.



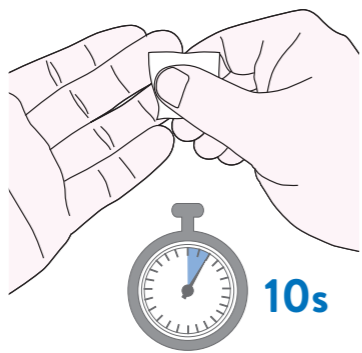
**Avoid dominant hand.**

## STEP 2: COLLECT BLOOD

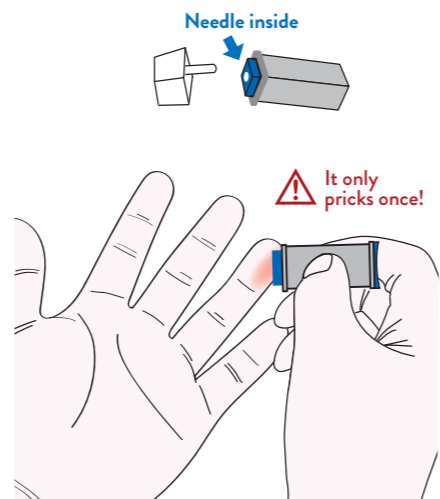
**5 MASSAGE** and rub your hand & finger to increase circulation.



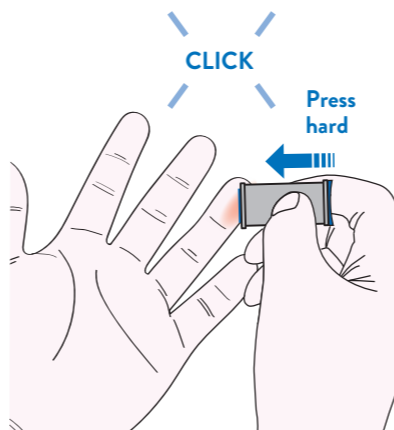
**6 CLEAN** your finger with **B** Alcohol pad. Let it **DRY** for 10 seconds.



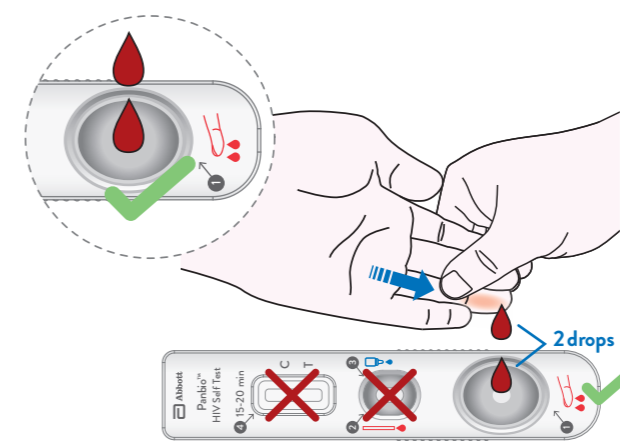
**7 REMOVE** the Lancet cover.



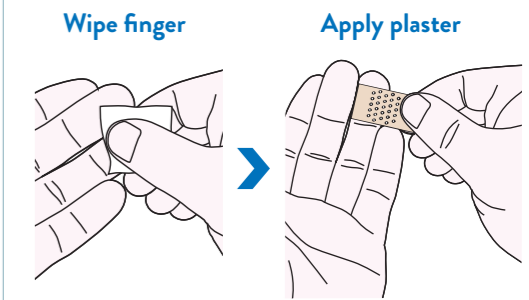
**8 PRESS** the **F** Lancet against the side of the finger until it clicks.



**9 MASSAGE** from the base to the tip, and let **2 DROPS** of blood fall into the Basin **1**. If you are having difficulty, wipe finger clean and squeeze again.

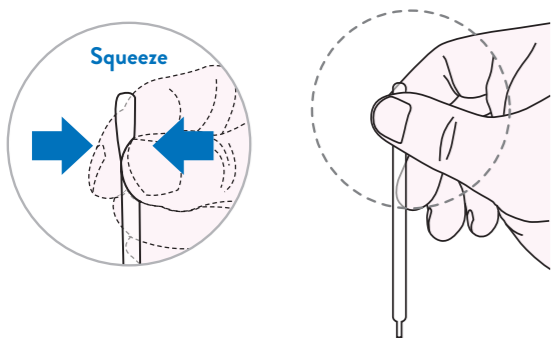


**10 WIPE** finger with a new **B** Alcohol pad and **APPLY** the **C** Plaster. If needed, press on the Plaster to stop bleeding. Start next step immediately to transfer blood.

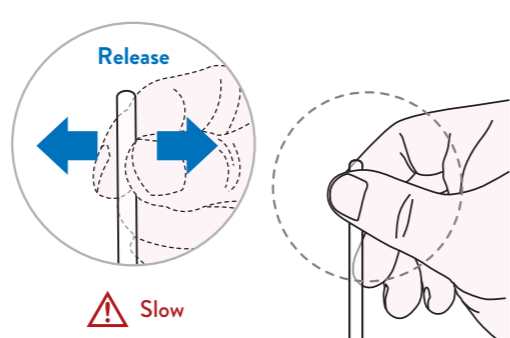


## STEP 3: TEST

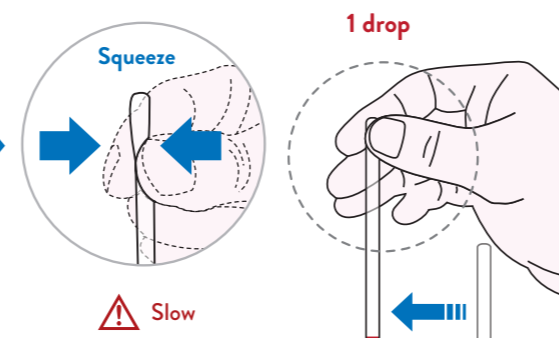
**11 SQUEEZE** the top of the **E** Specimen dropper.



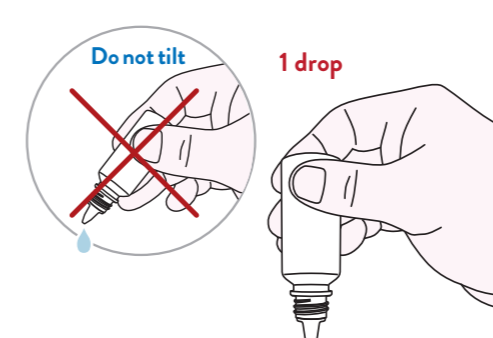
**DIP** the dropper into the blood in Basin and **RELEASE** slowly to draw blood into the dropper.



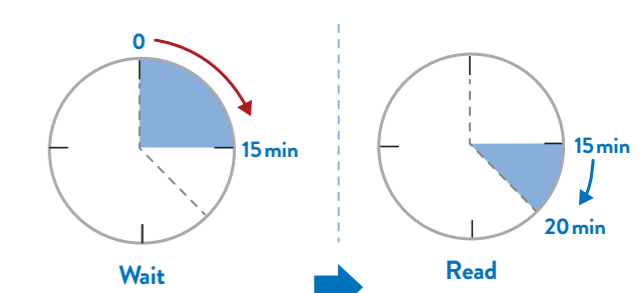
**PLACE** dropper over the Well. **SQUEEZE** the top of the dropper to apply **1 DROP** of blood into the Well **2**.



**12 HOLD** the **D** Buffer bottle vertically and apply **1 DROP** of buffer into the Well **3**.



**13 START** the timer. **READ** the result in 15-20 minutes **4**. Do not read past 20 minutes.



**See flip side for STEP 4: READ RESULT**

# STEP 4: READ RESULT

**14** READ test result in 15-20 minutes.

**Read result in a well-lit area.**

Control Line

Test Line

Place your test device here



**NON-REACTIVE (=Negative)**



A line appears only in the C area. There is no line in the T area. The test did not detect the presence of HIV, however very recent exposure cannot be excluded.

**It is recommended to conduct a retest after 3 months from latest risk of exposure to HIV.**

**REACTIVE (=Positive)**



One line in the C area, together with one line in the T area, no matter how faint, indicates the potential to be HIV positive.

**Consult a health care provider.**

A reactive result must be confirmed by a lab test. Protect yourself and others! Avoid any activity that could transmit HIV to others.

**TEST DID NOT WORK (=Invalid)**



If no line appears in the C area, even if a line appears in the T area, the test did not work.

**Test again using a new kit or consult a health care provider.**

# STEP 5: DISPOSAL

**15** PLACE all used components into the Disposal bag.



**17** THROW AWAY the Disposal bag in waste bin.



**16** SEAL the Disposal bag tightly.



**Blood can transmit infectious diseases. Clean up spills.**

Dispose in accordance with local regulations. Avoid release to the environment.

## INTENDED PURPOSE

The Panbio™ HIV Self Test is a single-use, visually read, rapid *in vitro* diagnostic immunochromatographic assay for the qualitative detection of antibodies to HIV-1 and HIV-2 in a blood sample from finger puncture. The Panbio™ HIV Self Test is a manual test and is intended to be used by untrained adult lay users in a home setting. It is intended for use as an aid in the diagnosis of HIV-1 or HIV-2 infection in individuals with symptoms of HIV infection and in individuals at risk of HIV infection, with or without symptoms.

The Panbio™ HIV Self Test is a preliminary test, and a positive result must be confirmed by a healthcare professional using laboratory confirmatory testing.

## INTRODUCTION

There are two main types of the human immunodeficiency virus (HIV) known as HIV-1 and HIV-2. Both HIV-1 and HIV-2 target the immune system and weaken people's defence against many infections. If left untreated, HIV infection can progress over the years to the most advanced stage, known as acquired immunodeficiency syndrome (AIDS) <sup>1</sup>.

HIV transmission takes place through the mixing of bodily fluids from sexual activity, blood contact via open wounds, syringes or exposure to contaminated blood or blood products, or mother to baby transmission <sup>2</sup>.

The Panbio™ HIV Self Test detects the presence of antibodies to HIV-1 and/or HIV-2 in blood. It may take between 6 to 12 weeks for the body to develop antibodies following exposure to HIV virus. This window between exposure to the HIV virus and antibodies being detected is known as the 'window period' <sup>3</sup>. UNAIDS considers gay men, adolescents and young people (15-24 years), sex workers, transgender people, people who inject drugs and prisoners/incarcerated people as being most vulnerable to contracting HIV <sup>4</sup>. These individuals may be considered to be in a high risk category <sup>5</sup>. Individuals within the high risk category should test frequently if there is an ongoing risk for contracting HIV.

Behaviours and conditions that put people at greater risk of contracting HIV include: having anal or vaginal sex without a condom; having another sexually transmitted infection (STI) such as syphilis, herpes, chlamydia, gonorrhoea and bacterial vaginosis; harmful use of alcohol or drugs in the context of sexual behaviour; sharing contaminated needles, syringes and other injecting equipment, or drug solutions when injecting drugs; receiving unsafe injections, blood transfusions, or tissue transplantation; and medical procedures that involve unsterile cutting or piercing; or accidental needle stick injuries, including among health workers <sup>6</sup>. Safe sex is protected sex during every sexual encounter. It includes: Oral sex with a condom, a dental dam, or plastic wrap; Vaginal sex with a male or female condom; Anal sex with a male or female condom <sup>7</sup>.

## TEST PRINCIPLE

The Panbio™ HIV Self Test detects the presence of antibodies to HIV-1 and/or HIV-2 in whole blood. The product includes a test device, a buffer and tools to transfer the blood sample. To use the test, two drops of blood sample are collected via fingerstick in the basin of the plastic cover. One drop of blood is transferred by a specimen dropper to the sample well. After which, one drop of buffer is applied. When the test is complete, two lines may appear on the device. The red line in the Control (C) line area will only become visible if the added blood sample and buffer have moved over the T/C line areas of the reading window and only after the internal control reaction has taken place. The Test (T) line area is pre-coated with HIV-1 antigen glycoprotein 41 and HIV-2 antigen glycoprotein 36. The red line in the "T" line area will only become visible if the applied blood sample contains antibodies to HIV-1 or HIV-2.

## MATERIALS

### Materials Provided

COMPONENTS	
1 Test Device Foil Pouched with a Desiccant	1 Plaster
2 Sterile Alcohol Pads	1 Sterile Single-use Lancet
1 Specimen Dropper (Fingerstick Blood)	1 Instructions for Use
1 Buffer (1 mL/vial)	1 Disposal Bag

### Active Ingredients of Main Components

Test Device	
Red Latex Conjugate	Recombinant HIV-1 antigen, Recombinant HIV-2 antigen, Biotin, BSA (Total weight: 0.372 µg)
Test Line	Recombinant HIV-1 antigen (gp 41), Recombinant HIV-2 antigen (gp36) (Total weight: 0.209 µg)
Control Line	Streptavidin (0.177 µg)
Sample Pad	Mab RBC (0.149 µL)

Buffer	
Extraction buffer	Sodium Azide (< 0.1 %)

## STORAGE AND STABILITY

- Store the test kit at 2 °C to 30 °C (36 °F to 86 °F) until the expiry date. Do not freeze.
- Do not use the test after expiry date printed on the test pouch.
- Do not open the sealed foil test pouch until you are ready to use the test. Test device should be used within one hour after the pouch has been opened.
- The buffer is for single-use, and should be used within one hour after cap is opened.

## WARNINGS AND PRECAUTIONS

- This test may give an unexpected positive result.
- Whether the result is positive or negative, you should consult with your doctor before making medical decisions.
- For *in vitro* diagnostic use only.
- Perform test only by using a fresh blood sample. Not to be used with serum or plasma sample.
- The test device is recommended to be used at room temperature (15 °C to 30 °C).
- Lancet and Specimen dropper are for single-use only. Do not reuse.
- If you do not understand the Instructions for Use please reach out to the provided Technical Service contact.
- If your test is working, you will see a line in the Control Line area on your test device. If there is no line in the Control Line area, your test did not work, and the test result is invalid. To ensure there is enough of the blood sample for the test to work, you must transfer exactly one drop of blood to the Well before adding buffer (see Step 11 on page 1 of these instructions).
- Keep the device and the components out of the reach of children.
- If the buffer comes into contact with skin, wash skin thoroughly with mild soap and water. Take off contaminated clothing and wash it before reuse. Get medical attention if symptoms occur. If the buffer comes into contact with eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention if you feel unwell.
- If your finger is still bleeding after specimen collection, use tissue or wipes. Protect yourself and others.
- Finger prick blood should be transferred from Basin to Well immediately to avoid blood clotting (within 2 minutes).
- If you receive a negative result within 3 months of a high risk event, you should repeat testing 3 months after the high risk event.
- A negative result does not indicate that engaging in high risk behaviour is safe.

## LIMITATION

- The Panbio™ HIV Self Test is designed to be used with a finger puncture blood sample. Other body fluids must not be used.
- Not suitable for testing any user younger than 15 years <sup>8,9,10</sup>.
- A NON-REACTIVE (Negative) result does not absolutely rule out the possibility of HIV infection.
- A REACTIVE (Positive) result must be confirmed by a health care provider using appropriate confirmatory testing.
- The intensity of the Test Line for a REACTIVE (Positive) result does not reflect how much HIV antibody is present in the blood sample.
- Although it's rare, false results may occur. If you have concerns that your result may be false, please contact your health care provider.
- Levels of biotin (vitamin B7) up to 1500 ng/mL may result in the Control Line appearing more faint, but do not have an impact on whether the test works. If you have concerns about the test's validity, test again with a new kit or consult a healthcare provider.
- An incorrect or "false" NON-REACTIVE (Negative) result can occur for any of the following reasons: Incorrectly reading test result; Not following the Instructions for Use carefully; If you are on HIV treatment (ARV); If you are within the window period between infection and development of antibodies; The presence of bubbles during sample application, in particular in low positive samples.
- An incorrect or "false" REACTIVE (Positive) result can occur for any of the following reasons: Incorrectly reading test result; Not following the Instructions for Use carefully; In cases of infection with cytomegalovirus.

## PERFORMANCE CHARACTERISTICS

### How did the test perform in clinical evaluations?

The test has been shown in clinical evaluations performed by professional health care persons to correctly identify 99.9% (2097 out of 2100) of HIV negative samples (known as the test specificity) with a 95% confidence interval\* of 99.6% to 100%. Further "in field" clinical evaluations conducted in South Africa, Congo, Vietnam and Spain demonstrated that the test correctly identified 99.6%

(1824 out of 1831) of HIV negative samples when performed by first time self test users with a 95% confidence interval\* of 99.2% to 99.8%.

The test has also been shown in clinical evaluations performed by professional health care persons to correctly identify 100% (700 out of 700) of HIV positive samples (known as the test sensitivity) with a 95% confidence interval\* of 99.5% to 100%. Further "in field" clinical evaluations conducted in South Africa, Congo, Vietnam and Spain demonstrated that the test correctly identified 95.1% (270\*\* out of 284) of HIV positive samples when performed by first time self test users with a 95% confidence interval\* of 91.9% to 97.0%.

\*Note: A 95% confidence interval indicates that 95 out of 100 times the mean value for performance will be in the range specified by the confidence interval.

\*\*Note: A total of 6 first time Panbio™ HIV Self Test users needed to be excluded from this analysis as they were observed to deny an unexpected result. Refer also to warnings and precautions about the use of this test.

### Which possible cross-reactions can occur?

The following cross-reactants and other microorganisms had no impact on the performance of the Panbio™ HIV Self Test: HBsAg, anti-EBV, Malaria, anti-Measles, anti-Tuberculosis, anti-VZV(-Varicella zoster virus), anti-TP(Treponema pallidum), anti-influenza A and B, anti-TBE(Tick borne encephalitis), Influenza Vaccine Recipient, Yellow Fever Virus, Human African Trypanosomiasis, Vaccine-Induced HIV Seropositivity, Post Immunization Measles, Yellow Fever Vaccine Recipient, anti-Leishmaniasis, Syphilis, anti-Toxo, Helicobacter pylori, HSV, anti-HCV, anti-HBs, anti-HBc, anti-HTLV-1/2, anti-HEV and anti-HAV. However, cross reactivity was observed for 2 out of 21 cytomegalovirus (CMV) patient samples that were tested.

### Which possible interferences can occur?

The following potentially interfering substances / factors had no impact on the performance of the Panbio™ HIV Self Test: Ascorbic Acid (20 mg/mL), Hemoglobin (10 mg/mL), Gentisic Acid (0.2 mg/mL), Paracetamol (Acetaminophen, 1 mg/mL), Acetylsalicylic Acid (Aspirin; 0.2 mg/mL), Caffeine (0.2 mg/mL), Oxalic Acid (0.6 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), 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), Ethanol (1%), Biotin (1500 ng/mL), Albendazole (750 ng/mL), HAMA specimens, Icteric panel, specimens from Pregnant Women, Rheumatoid Factor specimens, Sickle-Cell disease, Hemolytic Panel, Recipients of multiple blood transfusions, Multiparous Women, elevated Immunoglobulin G (IgG) specimens, elevated Immunoglobulin M (IgM) specimens, Systemic Lupus Erythematosus, anti-Nuclear Antibodies (ANA) specimens, Lipemic panel and anti-Escherichia coli antibody specimens.

**To report performance or usability issues contact either Abbott Technical Support or the Therapeutic Goods Administration (TGA) via the Users Medical Device Incident Report at [apps.tga.gov.au/prod/mdir](https://apps.tga.gov.au/prod/mdir) or by emailing [iris@health.gov.au](mailto:iris@health.gov.au) or calling 1800 809 361.**

## REFERENCES

- Hoffmann. HIV 2015/2016. Medizin Fokus Verlag. (2015).
- WHO. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring. (2021).
- ASHM. Types of HIV Testing. Available at: [testingportal.ashm.org.au/national-hiv-testing-policy/types-of-hiv-testing](https://testingportal.ashm.org.au/national-hiv-testing-policy/types-of-hiv-testing)
- WHO. Consolidated guidelines on differentiated HIV testing services. (2024).
- UNAIDS. Key Populations. Available at: [www.unaids.org/en/topic/key-populations](https://www.unaids.org/en/topic/key-populations)
- WHO HIV and AIDS Fact Sheet, 22 July 2024. Available at: [www.who.int/news-room/fact-sheets/detail/hiv-aids](https://www.who.int/news-room/fact-sheets/detail/hiv-aids)
- WebMD. Safe sex. Available at: [www.webmd.com/sex/safe-sex-preventing-hiv-aids-stds](https://www.webmd.com/sex/safe-sex-preventing-hiv-aids-stds)
- Tonen-Wolyc. Acceptability, feasibility, and individual preferences of blood-based HIV self-testing in a population-based sample of adolescents in Kisangani, Democratic Republic of the Congo. (2019).
- Phongphiew. Acceptability of blood-based HIV self-testing among adolescents aged 15-19 years at risk of HIV acquisition in Bangkok. (2021).
- Smith. Adolescents' experience of a rapid HIV self-testing device in youth-friendly clinic settings in Cape Town South Africa: a cross-sectional community based usability study. (2016).

## GLOSSARY OF SYMBOLS

	Temperature limitation		Consult instructions for use		Single Use only
	Manufacturer		Medical device		Catalogue number
	Use-by date		Batch code		Sterilized using irradiation
	Caution		In vitro diagnostic medical device		Sterilized using ethylene oxide
	Patient information website		Authorized representative in the European Community / EU		Contains sufficient for <n> tests
	Unique device identifier		Keep away from sunlight		Do not use if package is damaged and consult instructions for use
	Keep dry		Contains biological material of animal origin		Date of manufacture
	CE Mark				

## TECHNICAL SUPPORT

APAC (Asia-Pacific) Tel. +617 3363 7711 Email: [AP.TechSupport@abbott.com](mailto:AP.TechSupport@abbott.com)

## HIV SUPPORT SERVICES

State	Service	Website	Phone number
N/A	General health advice is available 24 hours a day with Health Direct	N/A	1800 022 222
N/A	24 hour crisis support is available at Lifeline	N/A	13 11 14
ACT	Canberra Sexual Health Centre	<a href="http://www.health.act.gov.au/cshc">www.health.act.gov.au/cshc</a>	(02) 5124 2184
NSW	Sexual Health Info Link	<a href="http://www.shil.nsw.gov.au">www.shil.nsw.gov.au</a>	1800 451 624
NT	Clinic 34	<a href="http://www.nt.gov.au/wellbeing/hospitals-health-services/sexual-health-services/clinic-34">www.nt.gov.au/wellbeing/hospitals-health-services/sexual-health-services/clinic-34</a>	(08) 8999 2678 Darwin
QLD	Sexual Health and HIV Service at Metro North	<a href="http://www.metro.north.health.qld.gov.au">www.metro.north.health.qld.gov.au</a>	(07) 3837 5611
SA	SHINE SA	<a href="http://www.shinesa.org.au">www.shinesa.org.au</a>	(08) 8300 5300
TAS	Sexual Health Service Tasmania	<a href="https://www.health.tas.gov.au/health-topics/sexual-and-reproductive-health/sexual-health-services">https://www.health.tas.gov.au/health-topics/sexual-and-reproductive-health/sexual-health-services</a>	(03) 6166 2672 Hobart
VIC	Thorne Harbour Health	<a href="http://www.thorneharbour.org">www.thorneharbour.org</a>	(03) 9865 6700
WA	SHQ (Sexual Health Quarters)	<a href="http://www.shq.org.au">www.shq.org.au</a>	(08) 9227 6177

**Note: See component labels and separate insert "Panbio™ HIV Self Test Kit Component Information" for further details on Single-Use Lancet, Alcohol Pad and Plaster.**

Abbott Rapid Dx Galway Parkmore East Business Park, Ballybrit, Galway, Ireland [www.globalpointofcare.abbott](http://www.globalpointofcare.abbott)

Australian Sponsor: Abbott Rapid Diagnostics PTY Ltd. 12 Mowbray Tce East Brisbane, QLD, 4169