











**Meaning of symbols used**

-  CE Mark
-  Legal Manufacturer
-  Store between 8-30°C
-  For in vitro diagnostic use only
-  For single use only
-  Lot Number
-  Catalogue or Part Number
-  Instructions for use provided. Please read carefully.
-  Warnings and Precautions
-  Expiry Date

# BioSURE HIV Self Test

**Product Insert**

Knowing your HIV status is vital for your own and your partner's sexual health.

Worldwide there are nearly 37 million people living with HIV, but nearly 40% remain undiagnosed and do not know they are infected with HIV. HIV can be transmitted through unprotected anal, vaginal and oral sex, by sharing injecting equipment and from a mother to her baby during pregnancy, birth or breastfeeding. There were over 1.8 million new HIV diagnoses in 2016 (approx 5,000 new infections per day) and an estimated 1 million people died from AIDS related illnesses. Many people were diagnosed late, i.e. at a point after which treatment should have started, meaning a greater risk of avoidable morbidities and mortality. (This data is taken from the World Health Organisation).

Advances in anti-retroviral treatments now mean they are so good that if they are started early and taken regularly, the HIV virus in a person's blood can be suppressed to an undetectable level. This means the person's health and immune system are not damaged, they can live a healthy life and very importantly means the virus cannot be passed on.

Your BioSURE HIV Self Test comprises a paper test strip inside a plastic barrel. The test is performed by applying a small drop of blood to the test device and applying a liquid contained in the buffer pot to the test device by inserting the tip of the test device through the sealed top of the buffer pot. The blood sample and the liquid are mixed together. This mixture is absorbed by the paper strip. As the test runs you can see the mixture moving up the paper strip.

The test process does not detect HIV directly but detects antibodies specific to HIV that are part of your body's natural response to infection. The first antibodies take between 4 to 12 weeks to appear.

When the test is completed, two lines can appear on the paper strip. The upper line (the Control Line) will only become visible if you have performed the test correctly. The lower line (the Test Line) will only become visible if you have antibodies to HIV in your blood.

**MATERIALS PROVIDED**

- 1 Box containing:
- 1 x BioSURE HIV Self Test Pouch containing:
  - 1 x BioSURE HIV Self Test
  - 1 x Safety lancet
  - 1 x Plaster
  - 1 x Pack of desiccant
- 1 x Instructions for Use
- 1 x Product Insert (this leaflet)
- 1 x Opaque plastic disposal envelope

**REQUIRED BUT NOT PROVIDED**

- Clock, watch, or other timing device

**Frequently Asked Questions**

**How does the test work?**  
The technology used is very similar to a human pregnancy test. The process detects antibodies in your blood sample that are specific to HIV (not the HIV virus itself) and these antibodies produce the second line (Test Line).

**What is an antibody?**  
When your body detects something harmful (like a bacteria or a virus) your immune system starts to produce antibodies in order to try to defend your body.

**How accurate is the BioSURE HIV Self Test?**  
Extensive research has proven that this test is extremely accurate when performed correctly, with similar accuracy to a pregnancy test.

- It has a proven clinical sensitivity (how reliably the test will give a positive result for people who do have HIV) of 99.7%. This means that on average 997 in every one thousand positive cases will be correctly detected.
- It has a proven clinical specificity (how reliably the test will give a negative result for people who do not have HIV) of 99.9%. This means that on average 999 in every one thousand negative results will be correct.
- If you are at all unsure of your result you must go and see a healthcare professional who will perform another test.

**What is the 'window period'?**  
This is the time between HIV infection and when a test can correctly give a positive result. During this period someone who has been infected with HIV may get a negative test result if they have not produced enough antibodies to HIV.

**Why do I have to wait until 12 weeks after exposure for my negative test result to be reliable?**  
People produce antibodies at different rates and at different times after becoming infected with HIV. Most people have made these antibodies by 4 weeks but some people produce them much later. So although encouraging, a negative test result may not be accurate until 12 weeks after possible infection in case the person has not yet made antibodies.

Time after exposure	% of people with detectable antibodies
Up to 3 weeks	0%
At 4 weeks	50%
At 6 weeks	95%
At 12 weeks	99.9%

**Why should I test regularly?**  
The main transmission route for HIV is through having unprotected sex and the more sexual partners you have, the more risk you have. Early diagnoses and treatment mean better health outcomes for everyone, so regular testing means new HIV infections are diagnosed earlier.

**I can't find the buffer pot...**  
You will find it at the top of the device, at the other end from the tip. Remove it and place it in the tray.

**The buffer pot won't fit into the hole...**  
It needs to be foil side up to fit in the hole and is a snug fit.

**The lancet won't click...**  
The lancet is designed to only work once. You may have already clicked the lancet by mistake.

**Will using the lancet hurt?**  
Not really. It is best to take the sample from the side of the tip of your finger as there are less nerve endings there.

**Does it matter which finger I take blood from?**  
No, the blood will be the same from whichever finger you get it from.

**How does the tip fill up?**  
The device automatically sucks 2.5µL of blood into the tip by capillary action. You can see when the tip has filled with blood.

**My test hasn't started to run**  
The tip of the device must be fully inserted into the buffer pot for the test to run. Make sure the tip has been pushed right to the bottom of the buffer pot. You may need to push quite hard.

**When will I get my result?**  
You will get your test result in 15 minutes.

**Why does the test have to stand up?**  
Because the buffer has to run up the test strip contained within the device. The test may not run properly if it is run laying down, the Control Line may not appear and the result will not be valid.

**What happens if my test falls over?**  
Stand it up as soon as possible. Your test should still work. You will know that your test has run correctly by the appearance of the Control Line after 15 minutes.

**I can't see any results...?**  
Make sure the blue wording on the test strip is facing towards you when you place the test device into the cut out shape in the box.

**How do I dispose of my test?**  
To dispose of your BioSURE HIV Self Test, place all components back into the box and slip into the opaque disposal bag included. Seal the bag and throw away with your normal household rubbish. Not suitable for recycling.

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## SUMMARY OF THE TEST

### Intended Use

The BioSURE HIV Self Test device is a single-use immunochromatographic in-vitro diagnostic test for the detection of antibodies to Human Immunodeficiency Virus Types 1 (HIV-1) and Type 2 (HIV-2) in whole blood. The BioSURE HIV Self Test is intended to be used by untrained lay users as a self-test to aid in the diagnosis of infection with HIV-1 and HIV-2 from samples of fresh, whole blood obtained through a finger stick blood collection technique. The device requires a sample size of 2.5µL. The test result is qualitative and binary – either "Your test result is positive" (positive) or "Your test result is negative" (negative).

The test incorporates an in built sample control mechanism which allows the user to determine that the test has been performed correctly. This control mechanism takes the form of a line that will only appear on the test device if the correct test procedure has been followed and the correct type of sample has been applied.

### Restrictions on Use

- Not suitable for people with a bleeding disorder.
- Not suitable for use by people under the age of 16 years.
- Not suitable for people receiving any form of antiretroviral treatment for HIV.
- Not suitable for people who have been previously included in an HIV vaccine study.

### Limitations of the test

- The BioSURE HIV Self Test will only indicate the presence of antibodies to HIV and should not be used as the sole criteria for the diagnosis of HIV infection.
- The BioSURE HIV Self Test may not detect HIV infections that have occurred within the last 12 weeks.
- The procedure, precautions and interpretation of results for this test must be followed when testing.
- Positive results **must** be confirmed by a healthcare professional.
- You should not take any decision of medical relevance with regard to your condition without first consulting a healthcare professional.
- If the test result is negative but clinical symptoms are present, additional testing using other clinical methods is recommended. A negative result does not at any time absolutely preclude the possibility of HIV infection.

### Helpful tips

- If you normally wear spectacles to read, you should wear them whilst performing the test and reading the results.
- It is recommended that you perform the test in a well lit area.
- Before starting the test, wash your hands and ensure that they are clean and dry.

### Warnings and precautions

- This test is for use only with human whole blood.
- Do not use if the foil pouch is damaged in any way (i.e. seal broken, tears, holes, etc.).
- Do not use if the expiry date printed on the pouch has passed.
- Do not open the pouch until you are ready to perform the test.
- Do not read your result more than 1 hour after performing the test.
- If the buffer solution comes into contact with your eye, wash with a large amount of water. If the eye becomes irritated or painful, contact a healthcare professional.
- If you mistakenly swallow the buffer solution wash your mouth out with a large amount of water. If your mouth becomes irritated or you start to feel unwell, contact a healthcare professional.
- Handle your finished test and the lancet as if they are capable of transmitting infection.

### Storage

- This test can be stored at room temperature (8 to 30°C). It can, but does not need to be, stored in refrigerated conditions (2-8°C).
- Do not freeze
- Do not store above a radiator or in direct sun.
- This test should be performed at room temperature (8 to 30°C).
- The test must be used within 1 hour of opening the pouch.

### TEST METHOD

Tear open the pouch and remove the contents.

Remove the buffer pot from the end of your test device and place it in the hole in the box.

Remove the cap from the end of your lancet and discard. Place the red pad of the lancet against the side of the tip of your finger

Press the lancet down until it clicks (it won't hurt!).

You may need to gently massage your finger to make a round, well formed drop of blood, approximately 2-3mm across

Touch the tip of your test device into the drop of blood. You will see the tip automatically fill with enough blood.

Push the tip of your test device into the buffer pot, through the foil lid. Push it right down to the bottom of the buffer pot until it won't go any further

Start timing 15 minutes

After the 15 minutes, lay your test down in the cut out shape in the tray and read your result

### RESULTS

When the test is completed, two lines can appear on the paper strip. The upper line (the Control Line) will only become visible if you have performed the test correctly. The lower line (the Test Line) will only become visible if you have antibodies to HIV in your blood.

These lines can only appear in the positions shown on the results reading page but the lines can vary in strength or intensity. You should read any line in these positions as a line regardless of the strength or intensity of the line.

### How will I know if my test has run correctly?

The BioSURE HIV Self Test has an inbuilt sample Control Line (the upper line that can appear on the test) to show that the test has been performed correctly. If the Control Line does not appear, your test has not worked. This is known as an "invalid" result. Please discard your test and retest with a new device.

### Reading your result

If only the Control Line is visible this means that your test result is negative. This means it is very likely you DON'T have HIV. (It is possible that a negative test result may be incorrect, this is known as a False Negative. When this occurs the test result is negative but the person has been infected with HIV. Less than 1 in every 1,000 negative results will be False Negatives).

If two lines are visible your test result is positive. This means it is very likely you have HIV. Although your BioSURE HIV Self Test is very accurate, there is a very small chance that a positive result could be incorrect. This is known as a False Positive. When this occurs the test result is positive but the person has not been infected with HIV. The test will detect 997 in every 1,000 positive cases.

If your test result is positive it is really important that you seek medical advice. You MUST have a positive result confirmed by a healthcare professional. You should not take any decision of medical relevance with regard to your condition without first consulting a physician. HIV is a manageable condition. Early diagnosis and treatment mean that people with HIV can live healthy, active lives and have equivalent life expectancy to people without HIV. The earlier that a diagnosis is made and treatment started the better the outcome.

### Warning



You may see a faint red mark appear here.

THIS IS FROM YOUR BLOOD SAMPLE, IT IS NOT A LINE.

**Disclaimer** – Whilst every effort has been taken to ensure the diagnostic ability and accuracy of this product, the product is used beyond the direct control of the Manufacturer or Distributor and as such the result may be affected by environmental factors and / or user error. A person who is the subject of the test should consult a healthcare professional for further confirmation of the result.

**Warning** – The Manufacturer and/or Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect test result, whether positive or negative, as indicated by this product.

## BIOLOGICAL PRINCIPLES OF THE TEST

The BioSURE HIV Self Test contains a unique combination of a specific antibody binding protein which is conjugated to gold nanoparticles and HIV-1/2 antigens which are held in a test membrane. The whole blood sample is applied to the capillary tip of the tube, which draws a tiny amount (2.5µl) into the test device. The tube tip is then inserted into the Buffer solution, which is provided in a sealed vial (Buffer Pot). The buffer combines with the sample and the test reagents. The blood/buffer mixture migrates along the test strip. If the sample contains antibodies to HIV, the antibody/gold conjugate particles are captured and immobilised by the antigens already in the test strip and this produces a line (the TEST line). In a non-reactive (negative) sample there are no antibody proteins present and there is nothing for the antigens to capture, therefore this test line is not produced. There is a control line on each test strip to make sure the sample and reagents have been properly applied and have migrated up the test strip. The control line will always be produced if the test has run correctly.

## PERFORMANCE CHARACTERISTICS

### DIAGNOSTIC SENSITIVITY:

Diagnostic sensitivity of a binary test such as the BioSURE HIV Self Test, is a measure of how well the tests detects the presence of the condition. It is usually given as a percentage and is calculated following a clinical trial or a performance evaluation. The sensitivity is calculated by dividing the number of positive test results by the total number of condition positive samples. The higher the sensitivity the better the test is at correctly identifying persons with a condition. The BioSURE HIV Self Test has a sensitivity of 99.7%.

### STUDIES TO CALCULATE THE SENSITIVITY OF THE BIOSURE HIV SELF TEST

The sensitivity of the BioSURE HIV Self Test to detect infection with HIV-1 was evaluated using 614 specimens from individuals known to be infected with HIV-1 and from 776 individuals at high risk for infection with HIV-1 (Table 1). 648 individuals were identified as positive for infection with HIV-1 using a licensed confirmatory assay, and/or FDA approved NAT assay. Of these, 646 specimens tested reactive on the BioSURE HIV Self Test. The calculated sensitivity of BioSURE HIV Self Test in these studies was 99.7% (646/648 = 99.7% with 95% CI = 98.9% - 100%).

Study population	Number of Samples (n)	BioSURE HIV Self Test Positive	FDA Licenced EIA Positive	Licensed WB Reactive	True Positive <sup>1</sup>
Known Positive	614	610	612	612	612
High Risk	776	36	41	35 <sup>2</sup>	36 <sup>3</sup>
Total	1390	646	653	647	648

<sup>1</sup>Based on licensed WB and NAT assay results (when positive and EIA is repeatedly reactive).

<sup>2</sup>Two specimens were indeterminate by Western Blot.

<sup>3</sup>One specimen was repeatedly reactive on EIA and reactive on BioSURE HIV Self Test, indeterminate on WB, and positive on NAT.

The sensitivity of the BioSURE HIV Self Test to detect HIV-2 antibodies was determined by simultaneously testing 202 serum/plasma specimens that were positive for HIV-2 antibodies only. These specimens were obtained from repository sources. A total of 488 specimens from an area endemic for HIV-2 infection were also tested (Table 2). All specimens reactive with the BioSURE HIV Self Test in these studies were also reactive by a licensed anti-HIV-1/2 EIA. The sensitivity of the BioSURE HIV Self Test for the detection of antibodies to HIV-2 in these studies was calculated to be 100% (203/203 = 100% with 95% CI = 98.2% - 100%).

### DETECTION OF ANTIBODY TO HIV-2 IN KNOWN HIV-2 REACTIVE SPECIMENS AND ENDEMIC SAMPLES

Study population	Samples (n)	BioSURE <sup>®</sup> HIV Self Test Positive	True Positive <sup>1</sup>
Known Positive	202	202	202
Endemic Samples	488	27	1
Total	690	229	203

### DIAGNOSTIC SPECIFICITY:

Diagnostic specificity of a binary test such as the BioSURE HIV Self Test, is a measure of how well the tests detects healthy patients when testing for a condition. It is usually given as a percentage and is calculated following a clinical trial or a performance evaluation. The specificity is calculated by dividing the number of negative test results by the total number of condition negative samples. The higher the specificity the better the test is at correctly identifying healthy persons when testing for a condition. The BioSURE HIV Self Test has a specificity of 99.9%. This means that 999 in every 1000 negative results will be correct.

### STUDIES TO CALCULATE THE SPECIFICITY OF THE BIOSURE HIV SELF TEST

Study population	Samples (n)	BioSURE <sup>®</sup> HIV Self Test Negative	FDA Licenced EIA Negative	True Negative <sup>1</sup>
Low risk	691	690	687 <sup>2</sup>	691
High Risk	776	740	735 <sup>3</sup>	740
Total	1467	1430	1422	1431

<sup>1</sup>Confirmation performed by licensed HIV-1 Western Blot, IFA or NAT. One specimen was EIA repeatedly reactive, WB indeterminate, and NAT positive. One specimen was EIA repeatedly reactive and WB indeterminate. These two specimens were not included in the specificity calculations.

<sup>2</sup>Four specimens were repeatedly reactive on EIA and nonreactive on BioSURE HIV Self Test and Western Blot.

<sup>3</sup>Five specimens were repeatedly reactive on EIA and nonreactive on BioSURE HIV Self Test and Western Blot.

Based on these studies, the specificity of the BioSURE HIV Self Test in these studies was calculated to be 99.9% (1430/1431 = 99.9% with 95% CI = 99.6% - 100%)

## EFFECT OF POTENTIALLY INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS

To evaluate the influence of unrelated medical conditions or interfering substance on the specificity and sensitivity of the BioSURE HIV Self Test, 208 specimens representing unrelated medical conditions, and 110 specimens representing potential interfering substances were tested (Table 7). The specimens were spiked with either saline (Nonreactive) or an HIV-1 reactive serum specimen to a low level of reactivity.

All HIV-1 spiked specimens gave reactive results while all unspiked samples, with the exception of one elevated albumin specimen and 14 syphilis specimens, gave nonreactive results. The one elevated albumin specimen and all of the 14 unspiked syphilis specimens with reactive results were subsequently confirmed as infected with HIV-1 using a licensed Western Blot assay. An additional ten known HIV-1 nonreactive, syphilis reactive specimens were tested and yielded expected results.

## BIOSURE HIV SELF TEST REACTIVITY AGAINST SPECIMENS FROM UNRELATED MEDICAL CONDITIONS OR CONTAINING POTENTIAL INTERFERING SUBSTANCES

Description	Saline (Nonreactive)	HIV-1/2 (Weak reactive)
Cirrhosis	20 / 20	20 / 20
CMV IgM	20 / 20	20 / 20
Recent flu vaccination <sup>1</sup>	11 / 11	11 / 11
HBV	21 / 21	21 / 21
HCV	19 / 19	19 / 19
HTLV-I	11 / 11	11 / 11
HTLV-II	10 / 10	10 / 10
Multiparous	9 / 9	9 / 9
Myeloma	10 / 10	10 / 10
Rheumatoid Factor	10 / 10	10 / 10
Syphilis <sup>2</sup>	15 / 29	29 / 29
Tuberculosis	38 / 38	38 / 38
Elevated Albumin <sup>3</sup>	9 / 10	10 / 10
Elevated Bilirubin	10 / 10	10 / 10
Citrate	10 / 10	10 / 10
DNA	10 / 10	10 / 10
EDTA	10 / 10	10 / 10
Hemolyzed	10 / 10	10 / 10
Heparin	10 / 10	10 / 10
Icteric	10 / 10	10 / 10
Lipemic	10 / 10	10 / 10
Elevated Protein	10 / 10	10 / 10
Elevated Triglycerides	10 / 10	10 / 10

<sup>1</sup>Collected within 6 months of vaccination.

<sup>2</sup>Fourteen samples were confirmed reactive, using a licensed WB assay.

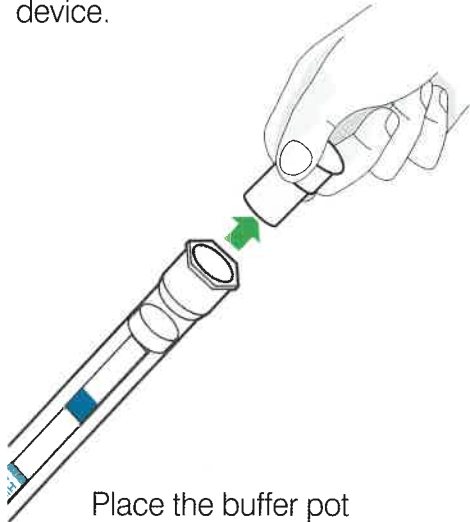
<sup>3</sup>One sample was confirmed as containing HIV antibodies by using a licensed WB assay.

## REPRODUCIBILITY STUDIES

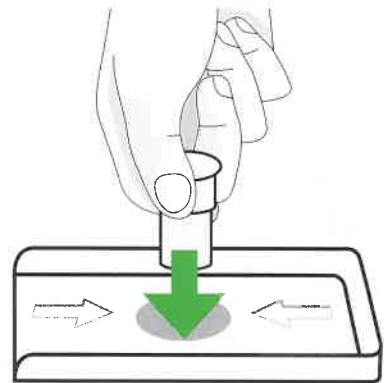
Reproducibility was tested at three independent sites using three lots of BioSURE HIV Self Test. A panel of five blinded samples representing nonreactive, low reactive HIV-1, low reactive HIV-2, high reactive HIV-1 and high reactive HIV-2 were run on three separate days by three separate technicians at each site. Testing was performed according to the Product Insert of the BioSURE HIV Self Test. Results were read at 15 minutes. Results were read semi-quantitatively using a common strip evaluation scale. A total of 405 data points was taken. There was 100% reproducibility (405/405) across all parameters.

## 1. Prepare

Find and remove the buffer pot from the end of the test device.



Place the buffer pot in the hole in the tray.

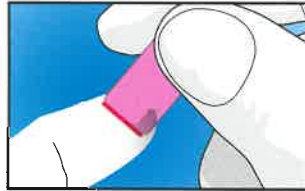


## 2. Sample

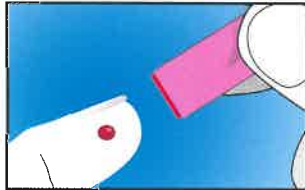
Remove cover.



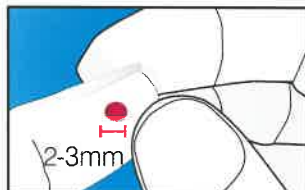
Place the red pad of lancet on side of finger.



Push the lancet down until it "clicks".

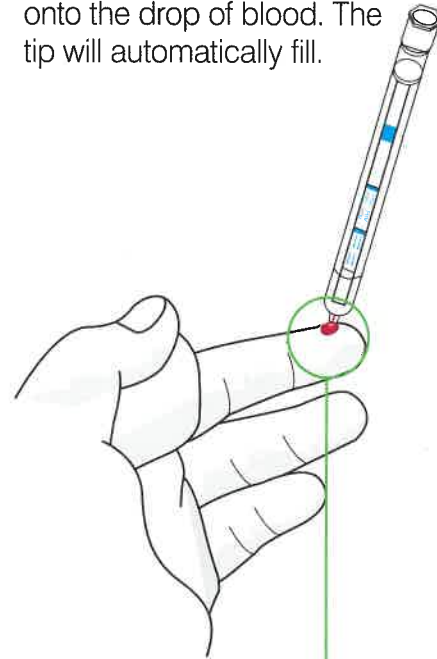


You can squeeze to make the drop bigger.



## 3. Collect

Touch the tip of your test onto the drop of blood. The tip will automatically fill.

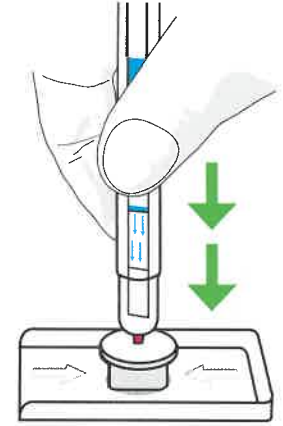


This is all you need...

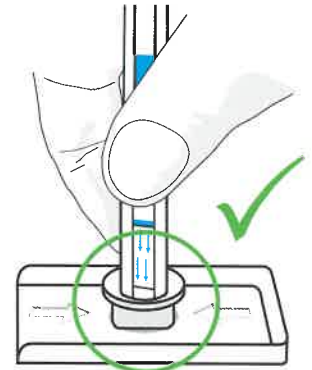


## 4. Test

Push the tip of your test through the foil lid into the buffer pot: **PUSH DOWN HARD.**



You **must** make sure that you **push completely down to the bottom of the buffer pot.**



## Now wait...



Start your timer.  
You need to time  
**15 minutes.**



After about **3 minutes**,  
**CHECK** to make sure  
your test is running.



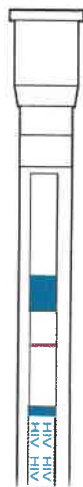
If your test is running,  
you will see colour  
moving up the test  
strip.

**If not**, push the test  
down to the bottom of  
the buffer pot.

## 5. Result

### My test has...

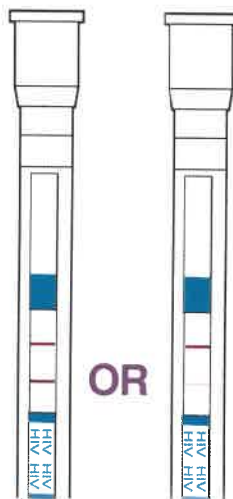
#### 1 LINE



My test result  
is **NEGATIVE**

**OPEN  
HERE**

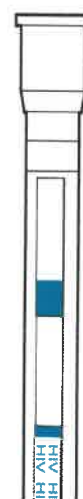
#### 2 LINES



My test result is  
**POSITIVE**

You must have a positive  
test result confirmed by a  
healthcare professional.

#### NO LINES



My test did  
**NOT** work.

**LAY YOUR TEST HERE.**

**BioSURE**  
HIV Self Test

## Before you start

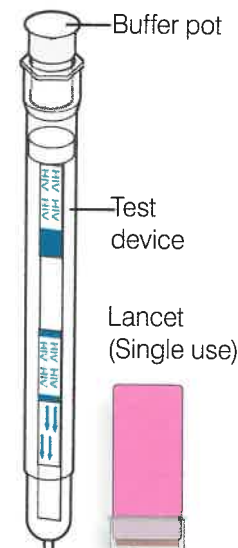
You can watch our short  
instruction video.



## When you are ready

Make sure your hands are clean  
and dry. Open the pouch by  
tearing here

Your pouch  
contains:



## Now wait...

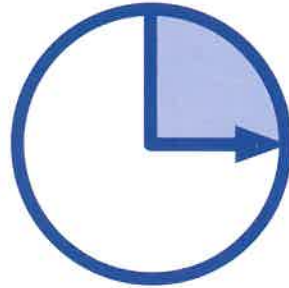


Start your timer.  
You need to time  
**15 minutes.**



After about **3 minutes**,  
**CHECK** to make sure  
your test is running.

## 5. Results



### Wait 15 minutes for your test to run...

Then turn this page and  
read your test result.

You **MUST** have a positive  
test result confirmed by a  
healthcare professional.

If your test is running,  
you will see colour  
moving up the test  
strip.

**If not**, push the test  
down to the bottom of  
the buffer pot.

**OPEN  
HERE**

### For more information:

Visit [www.hivselftest.com](http://www.hivselftest.com)  
where you can also view our  
short instruction video.

### Before you start

You can watch our short  
instruction video.



### When you are ready

Make sure your hands are clean  
and dry. Open the pouch by  
tearing here

Your pouch  
contains:

