

## 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 (HIV) types 1 (HIV-1) and type 2 (HIV-2) in whole blood.

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 finger stick blood collection technique. The test result is qualitative and of 2.5µL. The test result is qualitative and binary – either “Your test result is positive” (positive) or “Your test result is negative” (negative).

This test incorporates an in-built sample control mechanism which allows the user to determine that the test has been performed correctly. This 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.

### 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.

- The 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.

### Storage

- 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.

### 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 you have 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).

### 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.

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# Reading your result

Lay your test in the space below and compare it with the pictures.

The lines can only appear in the positions shown in the diagrams below but 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.

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

## 1 LINE

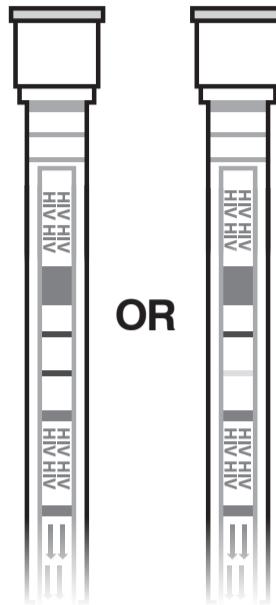


Your test result is **NEGATIVE**

## YOUR TEST



## 2 LINES



OR

Your test result is **POSITIVE**

## NO LINES



Your test did **NOT** work

### BIOLOGICAL PRINCIPLES OF THE TEST

The BioSURE HIV Self Test device is a qualitative rapid test for the detection of antibodies to Human Immunodeficiency Virus. The result of the test is binary, i.e. it can be positive or negative depending on the presence or absence of these antibodies. The result is determined by the appearance of pink/purple colour lines across the test strip.

There are two main types of the virus, HIV-1 and HIV-2 and there are a number of known variants of HIV-1, described as subtypes and/or circulating recombinant forms. The BioSURE HIV Self Test has been shown to effectively detect all types, including subtype O. The BioSURE HIV Self Test cannot detect the presence of HIV until the body has created antibodies.

The BioSURE HIV Self Test contains a solid-phase membrane, test strip, which is pre-coated, in the test line area, with synthetic peptides representing HIV antigens gp120 and gp41 (HIV-1) and gp36 (HIV-2). The test also contains a human protein which binds specifically to human IgG antibodies and is combined with (conjugated to) gold nanoparticles. This conjugated gold is used to label HIV antibodies if present in the sample. Once the sample has been applied to the test device and mixed with the buffer solution (by inserting the tip of the test device into the sealed buffer pot) the antibodies move along the test strip by chromatography. If antibodies to HIV are present in the sample, they are captured by the immobilised HIV-peptides. The newly formed complex of antigen-antibody-gold is visible as a pink/purple line.

The lines can only appear where the pre-coating occurs. The position of the pre-coating is very accurate and, therefore, the lines can only appear in specific places on the test strip. The control line is pre-coated with an IgG antigen peptide which captures protein-gold conjugate particles as the sample/buffer mixture continues to migrate along the test strip. The control line is, therefore, a definitive sample control line which enables the user to determine that the test has been performed correctly and that the sample/buffer mixture has progressed completely through the device. The control line cannot appear if human blood has not been applied to the test in sufficient volume.

The test line and control lines have been carefully optimised such that when the test line intensity increases the control line intensity decreases. The control line is set to create a line of maximum intensity with the application of 2µL of blood.

### PERFORMANCE CHARACTERISTICS

#### DIAGNOSTIC SENSITIVITY:

Diagnostic sensitivity of a qualitative binary test such as the BioSURE HIV Self Test, is a measure of how well the tests correctly detect the presence of the condition or analyte. It is usually given as a percentage and is calculated following one or more performance evaluations and is calculated by dividing the number of positive test results by the total number of analyte true positive samples. The higher the sensitivity the better the test is at correctly identifying persons with a condition. The BioSURE HIV Self Test has an overall diagnostic sensitivity of 99.85% (95% CI 99.2-99.99%). In these studies, "true positive" samples were determined by concordant results of a CE Marked Enzyme Immunoassay and confirmatory testing by Western Blot or line immunoassay.

Sample type	Study ID#	Number of True positive samples (n)	BioSURE HIV Self Test Positive	BioSURE HIV Self Test Negative
HIV-1	1, 2, 4	563	562	1
HIV-2	2, 4	120	120	0
All		683	682	1

#### DIAGNOSTIC SENSITIVITY WITH SEROCONVERSION PANELS:

The BioSURE HIV Self Test cannot detect the presence of HIV until the body has created antibodies to the virus. The process of antibody creation is known as seroconversion. The time from infection to the completion of seroconversion is highly variable by individual and can take from around 4 weeks to 3 months to finish. Sensitivity to early infection an important characteristic HIV tests and the ability of BioSURE HIV Self Test to detect HIV infection before 3 months after infection relative to other testing methods is reported. The sensitivity is given by average delay (in days) between the initial BioSURE HIV Self Test positive result in any one panel and other comparative test methods, including state of the art rapid tests and the most sensitive HIV test methods, antibody/antigen immunoassays. On average, the BioSURE HIV Self Test detected HIV antibodies 2.3 days sooner than the confirmatory test (either Western Blot or Line Immunoassay) but had an average detection 3.9 days later than laboratory (ELISA) tests for HIV antibodies. The device is shown to have state of the performance relative to anti-HIV confirmatory assays.

The classification between Seroconversion and Early Seroconversion samples used is as follows:

Seroconversion samples: p24 antigen and/or HIV RNA positive and recognised by all HIV antibody rapid tests and positive or indeterminate on confirmatory assays.

Early Seroconversion: p24 antigen and/or HIV RNA positive and not recognised by all equivalent CE Marked Rapid Tests and indeterminate or negative on confirmatory assays.

In all cases confirmatory assay is a CE Marked immunoassay.

Sample type	Study ID#	Number of True positive samples (n)	BioSURE HIV Self Test Positive	BioSURE HIV Self Test Negative
Seroconversion	1, 2, 3	75	75	0
Early seroconversion	1, 2, 3	83	15	68

Evaluation ID#	Testing Site
1	Sanquin Virus Diagnostic Services, Netherlands
2	Abingdon Healthcare Diagnostics Ltd, United Kingdom
3	BioSure (UK) Limited, United Kingdom
4	Sanquin Virus Diagnostic Services, Netherlands
5	Abingdon Healthcare Diagnostics Ltd, United Kingdom
6	Abingdon Healthcare Diagnostics Ltd, United Kingdom

### DIAGNOSTIC SPECIFICITY:

Diagnostic specificity of a qualitative binary test such as the BioSURE HIV Self Test, is a measure of how well the tests correctly detect the absence of the condition or analyte. It is usually given as a percentage and is determined through one or more performance evaluations and is calculated by dividing the number of negative test results by the total number of analyte true negative samples. The higher the specificity the better the test is at correctly identifying persons without a condition. The BioSURE HIV Self Test has an overall diagnostic specificity of 99.99% (95% CI 99.8-100%). In this case "true negative" samples were determined by concordant results of a CE Marked Enzyme Immunoassay and Western Blot or immune-electrophoresis.

In these studies, "true negative" samples were determined by concordant negative results of a CE Marked Enzyme Immunoassay and by confirmatory testing using Western Blot or line immunoassay.

Sample type	Study ID#	Number of true negative samples (n)	BioSURE HIV Self Test Positive	BioSURE HIV Self Test Negative
HIV Negative	1, 2, 5	1,299	0	1,299
Antenatal samples	1, 2, 5	200	0	200
All		1,499	0	1,499

### SPECIFICITY

The ability of a diagnostic test to correctly discriminate between healthy and infected individuals is a function of the ability of the device to not be affected by the presence of analytes unrelated to the test condition. Evaluations have been undertaken with both naturally occurring and contrived samples to ensure that the performance of the test device is not affected by the presence of common possible exogenous and endogenous interferents and potentially cross reacting co-morbidities.

Sample type	Study ID#	No. of negative samples (n)	BioSURE HIVST Negative	No. of positive samples (n)	BioSURE HIVST Positive
Clinical samples	1	191	191	9	9
Pregnant women	1, 2, 5	200	200	0	0
Possible interferents	5, 6	130	130	130	130

Possible interferents	HIV Positive samples	BioSURE HIVST Positive	HIV Negative samples	BioSURE HIVST Negative
Haemolysis	5	5	5	5
Hyperlipidaemia	5	5	5	5
Bilirubin	5	5	5	5
Hyperproteinaemia	5	5	5	5
Raised Ig	5	5	5	5
Rheumatoid factor	5	5	5	5
Biotin	5	5	5	5
Antiretroviral (HIV) drugs	5	5	5	5
Aspirin	5	5	5	5
Paracetamol	5	5	5	5
Ibuprofen	5	5	5	5
Ethanol	5	5	5	5
Caffeine	5	5	5	5
Anti-malarial drugs	10	10	10	10
Anti-TB Drugs	5	5	5	5

Cross Reactivity	HIV Positive samples	BioSURE HIVST Positive	HIV Negative samples	BioSURE HIVST Negative
Sickle cell disease	5	5	5	5
SLE (Lupus)	5	5	5	5
HCV	5	5	5	5
HBV	5	5	5	5
CMV	5	5	5	5
EBV	5	5	5	5
HTLV (I & II)	5	5	5	5
Influenza	5	5	5	5
Influenza vaccine	5	5	5	5
Syphilis	5	5	5	5