WHO Prequalification of In Vitro Diagnostics Programme
PUBLIC REPORT

Product: SURE CHECK HIV Self-Test
Number: PQDx 0054-006-01

SURE CHECK HIV Self-Test with product code 60-9508-0, manufactured by Chembio Diagnostic Systems, Inc, Rest-of-World regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 29 November 2019.

Summary of prequalification status for SURE CHECK HIV Self-Test[1]

	Date	Outcome
Prequalification amended for SURE CHECK HIV Self-Test	29-Nov-2019	Listed
Prequalification listing for SURE CHECK HIV 1/2 assay	08-Dec-2014	Listed
Dossier assessment	12-Aug-2014	MR
Site Inspection of quality management system	27-Nov-2014	MR
Product performance evaluation	31-Oct-2014	MR
Labelling accepted	26-Nov-2019	MR
Change reviewed *	01-Nov-2019	MR

MR: Meets Requirements

***Change notification**

In 2019, Chembio Diagnostic Systems, Inc. submitted a change notification for their prequalified product SURE CHECK HIV 1/2 Assay to introduce a new configuration with an intended use specific for HIV self-testing (SURE CHECK HIV Self Test). The new configuration was adapted from the corresponding professional use product (SURE CHECK HIV 1/2 Assay) for which a WHO prequalification assessment has already taken place. Additional data was generated to meet particular requirements for self-testing as set out in the WHO Technical Specifications Series document TSS-1 Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or self-testing.[2]

[1] Dossier assessment and product performance evaluation for the SURE CHECK HIV Self-Test were considered from the previous assessment of professional use product, SURE CHECK HIV 1/2 Assay, which was prequalified in 2014. Based on the product dossier assessment and product performance evaluation, SURE CHECK HIV Self-Test meets WHO prequalification requirements. Please refer to the WHO Prequalification of Diagnostics Programme PUBLIC REPORT for SURE CHECK HIV-1/HIV-2 assay.
https://extranet.who.int/pqweb/content/public-report-sure-check-hiv-1-2-assay-pqdx-0054-006-00

[2] https://apps.who.int/iris/bitstream/handle/10665/251857/9789241511742-eng.pdf?sequence=1

Intended use:[3]

According to the claim of intended use by Chembio Diagnostic Systems, Inc., "*SURE CHECK HIV Self-Test is a qualitative, single-use in-vitro diagnostic self-test for detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV 1/2) in fingerstick whole blood. The SURE CHECK HIV Self-Test is intended for use by untrained lay users in a private setting as a self-test to aid in the diagnosis of HIV infection. The test is intended for people who believe they may have had exposure to the HIV virus or a risk event within the last 3 months period of time, and who are ages 14 and older. Examples of risk events can include sex with multiple partners, sex with someone who is HIV positive or whose status you do not know, using illegal injected drugs or steroids, shared needles or syringes and exchanging sex for money*".

Assay description:

According to the claim of assay description by Chembio Diagnostic Systems, Inc., "*SURE CHECK HIV Self-Test has a test strip inside a plastic tube. The test is performed by mixing one drop of blood with a liquid solution contained in the buffer cap. As the test runs you can see the mixture flowing up the strip. When the test is complete, two lines will be visible if antibodies to HIV are detected (CONTROL and TEST lines). Only the CONTROL line appears if there are no antibodies detected*".

Test kit contents

Component	1 Test kit (product code 60-9508-0)
Contents in the box	
Instructions for use	1
Test stand	1
Alcohol swab	1
Sterile gauze pad	1
Contents in the pouch	
SURE CHECK HIV Self-Test device	1
Buffer cap (attached to the test device)	1
Sterile safety Lancet	1
Bandage	1
Desiccant (discard)	1

Materials required but not provided
Clock, watch or other timing device.

[3] This product is one that uses Protein A to detect human IgG antibodies. Protein A is also able to detect other classes of human antibody (IgA, IgD, IgE and IgM) but not as reliably as it does IgG. This product has been prequalified with respect to its ability to detect human IgG antibodies. Any claim to detect other types of antibodies on this kind of product has not been validated based on WHO prequalification requirements

Storage:
The test kit should be stored between 8 °C to 30 °C.

Shelf-life:
24 months.

Warnings/limitations
Refer to current version of manufacturer's instructions for use.

Labelling

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

1. Labels

1.1 Kit Box 10-6038-0

PROOF

The Mid-York Press, Inc.
Since 1916

Job# 68039 P.O.# P220384

Company Chembio Diagnostic

Date Submitted 11/20/19 Date Returned

Approved By

Further Changes Necessary

Remarks:

IMPORTANT NOTICE
Final approval is your (you the customer's) responsibility. Please check for all possible errors before signing off on this proof. The Mid-York Press, Inc. will not be responsible for undetected production errors if the work is printed per the customer's approval or if requests for changes are communicated orally.

The Mid-York Press, Inc.

Note: PMS spot colors on color proof may or may not be accurate to Pantone Matching System.

5/18/05

STOCK: .016 SBS C1S
MY-4719 (3 x 1 x 7)
Prints:
Black
PANTONE 293 C Bue
and Spot Aqueous
(void for glue only)

SURE CHECK® HIV Self-Test

One Drop Of Blood Is All You Need

CHEMBIO
DIAGNOSTIC SYSTEMS, INC.

REF 60-9508-0

Chembio Diagnostic Systems, Inc.
3661 Horseblock Rd.
Medford, NY 11763 USA

10-6038-0
Rev. 3

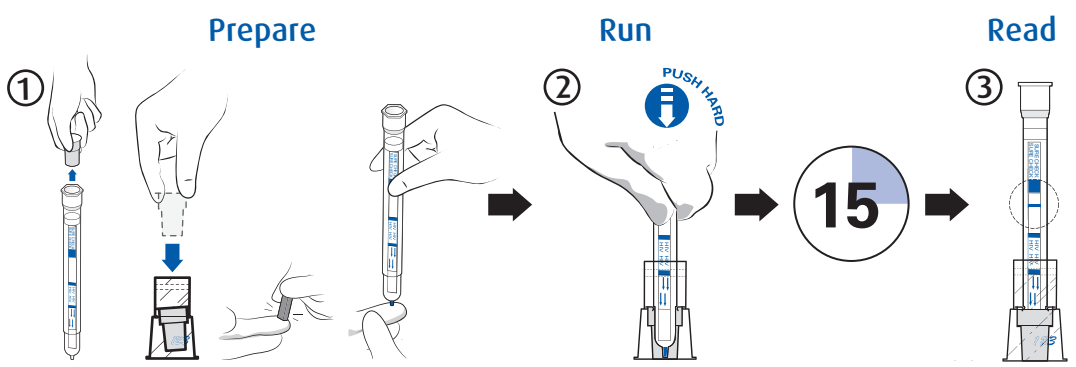
MY

Void Aqueous

Contents:
1 foil pouch containing: 1 test device, 1 buffer cap, 1 sterile safety lancet, 1 bandage, 1 dessicant
1 instructions for use/ product insert
1 sterile gauze pad
1 alcohol swab
1 test stand

Self-test for the detection of HIV

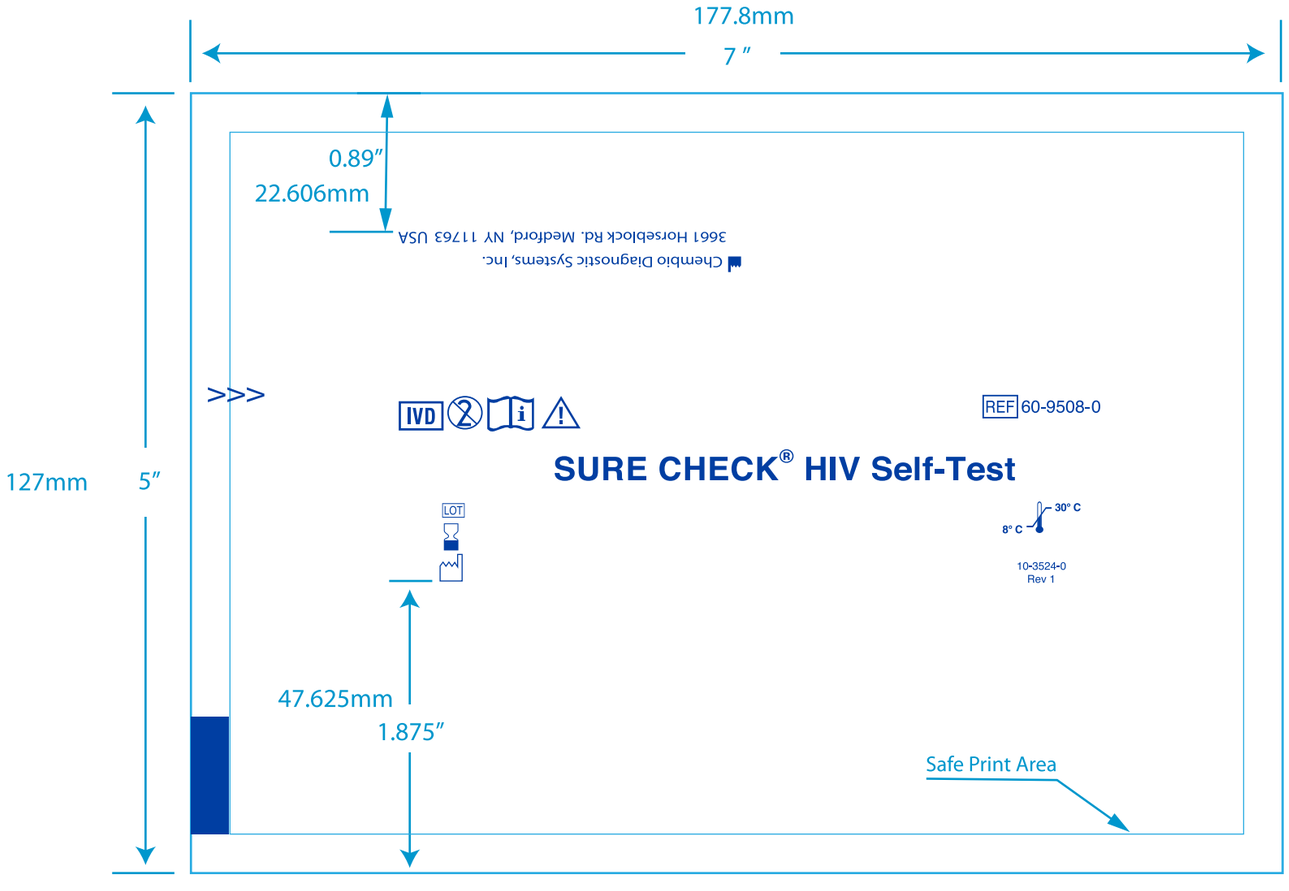
Know Your Status In 3 Easy Steps



Refer to the product insert for detailed test procedure information.
For technical assistance, email customerservice@chembio.com
www.chembio.com
+1 (631) 924-1135

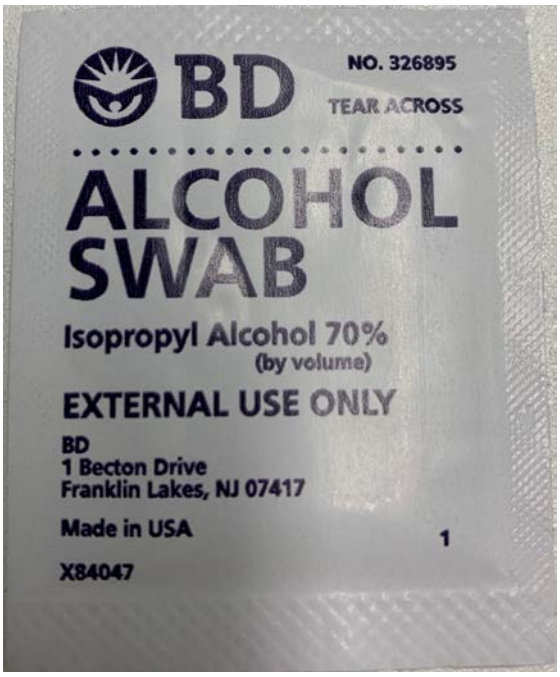
IVD *In vitro* diagnostic medical device
Do not re-use
Consult instructions for use
Caution
30°C 8°C Temperature limit

1.2 Foil pouch label (60-9508-0)

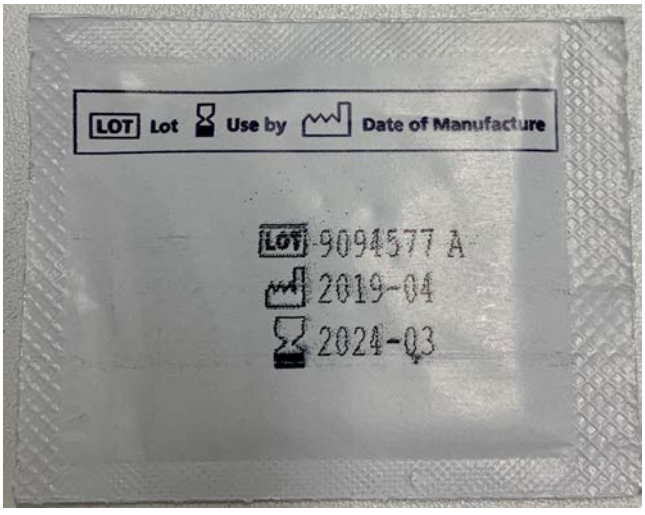

177.8mm
7 ″
0.89″
22.606mm
Chembio Diagnostic Systems, Inc.
3661 Horseblock Rd. Medford, NY 11763 USA
>>>
IVD
REF 60-9508-0
SURE CHECK® HIV Self-Test
LOT
8° C
30° C
10-3524-0
Rev 1
127mm
5″
47.625mm
1.875″
Safe Print Area

1.3 Alcohol swab label

Front



Back



1.4 Sterile gauze pad

2. Instructions for use[4]

[4] 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

SURE CHECK® HIV Self-Test

One Drop of Blood Is All You Need

INSTRUCTIONS FOR USE

PREPARE - RUN - READ

CHEMBIO
DIAGNOSTIC SYSTEMS, INC.

•• READ ME NOW ••

SURE CHECK HIV Self-Test is a screening test for HIV (the virus responsible for AIDS).

SURE CHECK HIV Self-Test is intended for use by untrained lay users in a private setting. Please ensure you visit an HIV testing center, health facility or healthcare professional when your result is positive or invalid (see step 11).

For single-use only. Do not open foil pouch containing device until ready to test.

Please carefully read all of the following instructions prior to using the test.

You will need a watch, clock, or other timing device.

Wash hands prior to running test.

Run test in a well-lit area.

Use within expiration date.

CONTENTS IN THE BOX

STERILE GAUZE PAD

INSTRUCTIONS FOR USE

TEST STAND

ALCOHOL SWAB

CONTENTS IN THE POUCH

DESICCANT (TO DISCARD)

STERILE SAFETY LANCET

BUFFER CAP

TEST DEVICE

BANDAGE

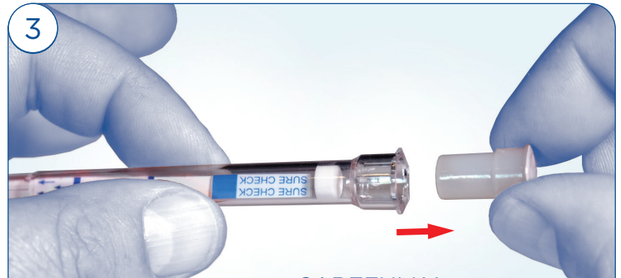
1 PREPARE

PLACE TEST STAND ON FLAT SURFACE

2

TEAR OPEN FOIL POUCH AT TEAR POINT (>>>)

3



CAREFULLY REMOVE BUFFER CAP

4

5a

WASH AND DRY YOUR HANDS

6a

MASSAGE FINGER FOR **5-10** SECONDS

5b

OPEN ALCOHOL SWAB AND STERILE GAUZE PAD

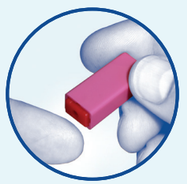
6b

CLEAN FINGER WITH ALCOHOL SWAB AND ALLOW TO DRY

7

UNCAP SAFETY LANCET

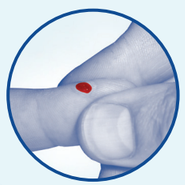
PLACE RED (OPENED) END OF LANCET ON THE SIDE OF YOUR SWABBED FINGERTIP



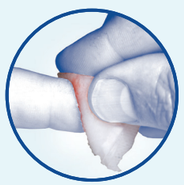
PRESS DOWN FIRMLY TO PRICK YOUR SKIN

8

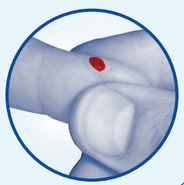
SQUEEZE OUT FIRST BLOOD DROP



WIPE BLOOD WITH STERILE GAUZE PAD

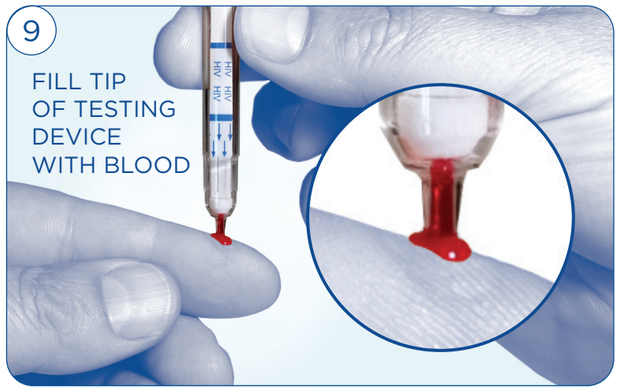


SQUEEZE OUT SECOND BLOOD DROP



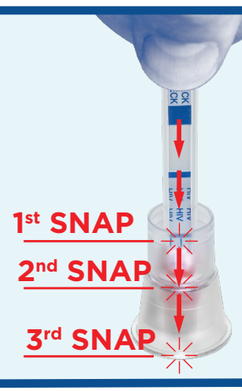
9

FILL TIP OF TESTING DEVICE WITH BLOOD



10 RUN

POSITION TEST DEVICE VERTICALLY ABOVE TEST STAND



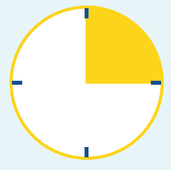
PUSH HARD THROUGH THE FOIL. YOU WILL FEEL **3 SNAPS**

11

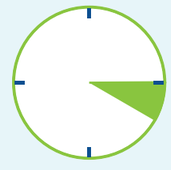
CHECK FOR PINK/ PURPLE FLOW IN **1** MINUTE

IF NO PINK/PURPLE FLOW, PUSH TEST DEVICE FURTHER DOWN

12



WAIT **15** MINUTES



READ RESULTS BETWEEN **15-20** MINUTES

DO NOT READ THE RESULTS AFTER 20 MINUTES

13

USE STERILE GAUZE PAD TO CLEAN FINGER AND APPLY BANDAGE

14 READ RESULTS

14

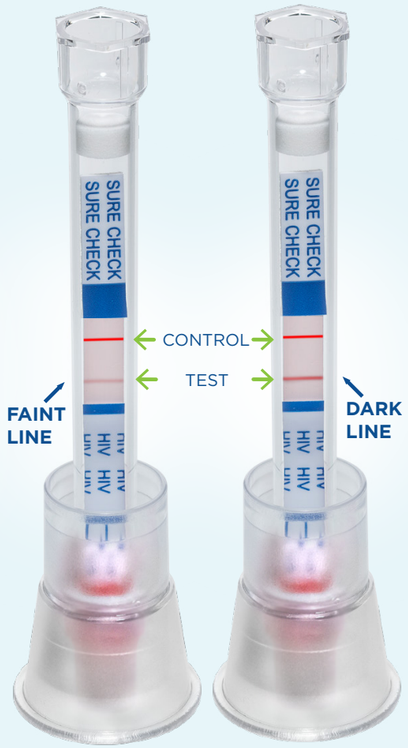
READ RESULTS

NEGATIVE RESULTS

If test shows ONLY the Control Line, your test result is NEGATIVE.

Test again in 3 months.

POSITIVE RESULTS



If test shows BOTH the Control Line AND Test Line, your test result is POSITIVE.

Visit your nearest HIV Testing Center or Health Care Professional.

INVALID RESULTS

If your results do not match negative or positive, the result is INVALID. It is necessary to run another test.

Visit your nearest HIV Testing Center or Health Care Professional.

DISPOSAL
- **To dispose of your test, place all of the components back into the box.**
- **Close the box to help protect your privacy and throw away with normal rubbish.**

For further information on HIV Self-Testing visit *www.HIVST.org*

Manufactured by
CHEMBIO DIAGNOSTIC SYSTEMS, INC.
3661 HORSEBLOCK RD.
MEDFORD, NY 11763 USA
www.chembio.com
Phone: (+1) 631-924-1135
Email: customerservice@chembio.com

•• LEGEND OF SYMBOLS ••

Consult Instructions for Use	Batch Code
Caution	Product catalog number
Do not re-use	Manufacturers identification
For use within temperature limits	Date of manufacture
In vitro diagnostic medical device	Use by date

•• PRODUCT INSERT ••

INTENDED USE AND SUMMARY

The SURE CHECK® HIV Self-Test is a qualitative, single-use in-vitro diagnostic self-test for detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV 1/2) in fingerstick whole blood. The SURE CHECK® HIV Self-Test is intended for use by untrained lay users in a private setting as a self-test to aid in the diagnosis of HIV infection. The test is intended for people who believe they may have had exposure to the HIV virus or a risk event within the last 3 months period of time, and who are ages 14 and older. Examples of risk events can include sex with multiple partners, sex with someone who is HIV positive or whose status you do not know, using illegal injected drugs or steroids, shared needles or syringes and exchanging sex for money. The SURE CHECK® HIV Self-Test has a test strip inside a plastic tube. The test is performed by mixing one drop of blood with a liquid solution contained in the buffer cap. As the test runs you can see the mixture flowing up the strip. When the test is complete, two lines will be visible if antibodies to HIV are detected (CONTROL and TEST lines). Only the CONTROL line appears if there are no antibodies detected.

KIT CONTENTS

- Each kit contains components to perform 1 test:
  - Instructions for Use (IFU)/Product Insert
  - Test Stand
  - Alcohol Swab
  - Sterile Gauze Pad
  - Pouch, containing: SURE CHECK® HIV Self-Test Device, Buffer Cap (attached to the test device), Sterile Safety Lancet, Bandage, Desiccant (discard)
- Materials required but not provided: Clock, watch, or other timing device

STORAGE

- Store the test in its unopened pouch at 8° to 30°C (46° to 86°F).
- This test must be performed at room temperature, 18° to 30°C (64° to 86°F)
- DO NOT use this test if it has been stored outside the acceptable temperature of 8° to 30°C (46° to 86°F). DO NOT freeze.
- When stored as indicated, test devices are stable until the expiration date (YYYY-MM-DD) marked on the pouch.

WARNINGS & PRECAUTIONS

- DO NOT use this test if you are HIV positive.
- If you are on treatment or preventive treatment for HIV, the test is not meant for you.
- An individual infected with HIV-1 and/or HIV-2 who is receiving highly active antiretroviral therapy (HAART) may produce false negative results.
- The test is for single, in-vitro diagnostic use by a self-tester.
- Use with fingerstick whole blood only. The test is not for use with serum, plasma, oral fluid, breast milk, urine, vaginal fluid or sweat.
- Wash your hands and ensure that they are clean and dry before starting test.
- Adequate lighting is required to read the test results.
- DO NOT use this test if you are age 13 or younger.
- DO NOT eat, drink, or smoke in the area while performing the test.
- DO NOT use if the foil pouch is damaged in any way or has any holes. Contact the health facility or HIV testing center to be issued a new test.
- DO NOT use if the desiccant is missing.
- DO NOT use if the expiration date (YYYY-MM-DD) printed on the pouch has passed.
- DO NOT open the pouch until you are ready to perform the test.
- DO NOT read the result more than 20 minutes after performing the test.
- DO NOT store above the radiator or in direct sunlight.
- DO NOT use the test if it has been exposed to household cleaning products (i.e. bleach).

LIMITATIONS OF THE TEST

- The SURE CHECK® HIV Self-Test Instructions for Use must be followed carefully to get an accurate result.
- The SURE CHECK® HIV Self-Test will only indicate the presence of antibodies to HIV and is not used as the only criteria for the diagnosis of HIV infection.
- The SURE CHECK® HIV Self-Test may not detect HIV infections that have occurred within the last 3 months.
- A positive result must be confirmed by a health care professional.
- If you have participated in a HIV vaccine trial, you may get a positive result using this test, but it may not mean that you are infected with HIV. You should seek follow-up with the research group.
- For a positive result, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.

TEST PERFORMANCE

In a clinical study, 1500 people who were unaware of their HIV status were given the SURE CHECK® HIV Self-Test to use. The results were compared to a 4th generation laboratory test. The laboratory results show that a total of 169 people were HIV positive and 1167 people were HIV negative. The comparison of results was as follows:

- 97% of people (164 out of 169) correctly reported their result as positive. This means that 164 people infected with HIV correctly interpreted the results as HIV positive and 5 out of 169 people infected with HIV reported a negative test result. This is called false negative.
- 100% of people (1167 out of 1167) correctly reported their result as negative. This means that 1167 people not infected with HIV correctly interpreted the results as HIV negative.
- In addition, only 10.5% of study subjects (157 out of 1500) failed to obtain a test result.

INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS

In addition to the clinical studies, twenty-two (22) unrelated medical conditions, interfering substances and non-HIV viral infections were tested. These tests were shown to have no effect on test specificity.

QUESTIONS & ANSWERS

1. How does the test work?
The test detects antibodies in your blood sample that are specific for HIV (not the HIV virus itself) and these antibodies produce the TEST line. A positive result is preliminary and must be confirmed by a healthcare professional.

2. What is a risk event?
Examples of risk events can include sex with multiple partners, sex with someone who is HIV positive or whose status you do not know, using illegal injected drugs or steroids, shared needles or syringes and exchanging sex for money.

3. How soon after a risk exposure can I test myself?
You can test yourself at any time. If you are using this test earlier than 3 months since a risk event and your test is negative, your result may not be accurate. You should test again 3 months after the risk event to be sure. You can also receive testing at your local healthcare facility.

4. How accurate is the test?
Please refer to the Test Performance section for more details. If you are unsure of your test result, please see a healthcare professional to perform another test.

5. Where is the buffer cap?
It is found in the top of the test device. You will need to remove it and place it in the test stand. Please refer to the instructions for use for a pictorial description.

6. Which direction should I place the buffer cap into the test stand?
Place the buffer cap with the foil side up so that it fits in the test stand.

7. How many times can I use the safety lancet?
The safety lancet is designed for one time use only.

8. Does it matter which finger I get the blood from?
No, you can use any finger.

9. How does the tip automatically fill up with blood?
The design allows the blood to be naturally drawn into the tip by capillary action.

10. When will the test start to run?
The test will start to run when the test device tip is fully pushed into the buffer cap. Confirm pink/purple flow on the test strip. Please refer to the IFU for pictorial description.

11. Why does the test have to stand up?
This is because the buffer has to run up the test strip contained within the test device.

12. What happens if my test falls over while it is running?
Stand it up as soon as possible. Verify that the CONTROL line is present after 15 minutes.

13. How will I know if my test has run correctly?
If the test has run correctly, the CONTROL line will appear. If the CONTROL line does not appear, your test has not worked properly. Please discard your test and retest with a new device.

14. What does a negative result mean?
A negative result means that the test has not detected HIV antibodies in the blood sample; however it may take up to 3 months from a risk event for the test to detect HIV.

15. What should I do if I get a negative result?
If you have not had any risk events within the past 3 months, and you followed the instructions for use carefully, then you are most likely HIV negative. If you did not follow the instructions for use carefully, you should perform another test to be sure your result is correct. If you had any risk events in the past 3 months, you could be in the 'window period'. The window period is when a person has been infected with HIV, but their body has not made antibodies yet. If you think you may have been exposed to HIV within the past 3 months, you should retest for HIV 3 months following the risk event. If you continue to engage in risk events that could put you at risk for HIV, you should test on a regular basis.

16. What is a false negative?
When a person reads their test result as negative, but the true HIV status of the person is positive.

17. What can cause a false negative result?
This can occur if you have had a risk event less than 3 months prior to taking the test, having infection with an HIV-1 or HIV-2 variant that does not elicit antibodies recognized by the test, if you incorrectly read the test result as negative, or if you did not follow the instructions for use carefully.

18. What does a positive result mean?
A positive result means you may have been exposed to HIV.

19. What should I do if I get a positive result?
You need to follow up with a healthcare professional to confirm the test result. At that time your healthcare professional will discuss the next steps that need to be taken.

20. What is a false positive result?
When a person reads their test result as positive and the true HIV status of the person is negative.

21. What can cause a false positive result?
This can occur for any of the following reasons: Incorrectly reading test result as positive, not following the instructions for use carefully, or if you have participated in a HIV vaccine clinical trial.

22. Can I get HIV from using the test?
No, you cannot get HIV from using the test.

23. Where can I get additional help or care for HIV?
At your local clinic, doctor or healthcare professional.

24. Can I use this test if I am taking medicine to prevent HIV (oral PrEP)?
If you are taking oral PrEP for HIV, you may get a false result.

25. Can I use this test if I am pregnant?
Yes, even if you are pregnant you can test with the SURE CHECK HIV Self-Test.