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-Test¹

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

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.


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

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

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

Materials required but not provided

Clock, watch or other timing device.

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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
SURE CHECK® HIV Self-Test
One Drop Of Blood Is All You Need

CHEMBIO
DIAGNOSTIC SYSTEMS, INC.

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

1. Prepare
2. Run
3. Read

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

Caution
Do not re-use
Consult instructions for use

In vitro diagnostic medical device

8°C—30°C
Temperature limit

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.

STOCK:.016 SBS C1S
MY-4719 (3 x 1 x 7)
Prints:
Black
PANTONE 293 C Bue
and Spot Aqueous
(void for glue only)
1.2 Foil pouch label (60-9508-0)
1.3 Alcohol swab label

Front

![Alcohol swab label front](image)

Back

![Alcohol swab label back](image)
1.4 Sterile gauze pad
2. Instructions for use\textsuperscript{4}

\textsuperscript{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

•• 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
SURE CHECK® HIV Self-Test (one drop of blood is all you need)
INSTRUCTIONS FOR USE
STERILE GAUZE PAD
TEST STAND
ALCOHOL SWAB

CONTENTS IN THE POUCH
SURE CHECK® HIV Self-Test (one drop of blood is all you need)
STERILE SAFETY LANCET
BUFFER CAP
TEST DEVICE
BANDAGE
DESICCANT (TO DISCARD)

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Run test in a well-lit area.
Use within expiration date.

PREPARE
1
PLACE TEST STAND ON FLAT SURFACE

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

MASSAGE FINGER FOR 5-10 SECONDS

OPEN ALCOHOL SWAB AND STERILE GAUZE PAD

WASH AND DRY YOUR HANDS

MASSAGE FINGER WITH ALCOHOL SWAB AND ALLOW TO DRY

FILL TIP OF TESTING DEVICE WITH BLOOD

CHECK FOR PINK/PURPLE FLOW IN 1 MINUTE

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

POSITION TEST DEVICE VERTICALLY ABOVE TEST STAND

POSITION TEST DEVICE VERTICALLY ABOVE TEST STAND

PUSH HARD THROUGH THE FOIL. YOU WILL FEEL 3 SNAPS

1st SNAP
2nd SNAP
3rd SNAP

CHECK FOR PINK/PURPLE FLOW IN 1 MINUTE

WAIT 15 MINUTES

READ RESULTS BETWEEN 15-20 MINUTES

DO NOT READ THE RESULTS AFTER 20 MINUTES

USE STERILE GAUZE PAD TO CLEAN FINGER AND APPLY BANDAGE

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USE STERILE GAUZE PAD TO CLEAN FINGER AND APPLY BANDAGE
**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 indicates that you have antibodies specific for HIV.

2. **What is a false result?**
   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 is over to be sure.

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 control bar?**
   Do not use the test if it has been exposed to household cleaning products or8.

6. **Which direction should I place the control bar into the test stand?**
   Place the control bar 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 test 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.

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

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 not run correctly, the diagnostic line will appear. If the CONTROL line does not appear, your test has not worked properly. Please discard your test and try again.

14. **What is a false negative result?**
    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 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 should consult the IFU for potential description.

16. **What is a false negative?**
    A false negative result means that the test has detected HIV antibodies in your blood sample.

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

18. **What can cause a false negative result?**
    There are several potential causes that can lead to a false negative result. For example, if a person is negative, or if they did not follow the instructions for use carefully.

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

20. **What can cause a false positive result?**
    There are several potential causes that can lead to a false positive result. For example, if a person is positive, or if they did not follow the instructions for use carefully.

21. **What is a false positive result?**
    A false positive result means that the test has not detected HIV antibodies in your blood sample.

22. **What can cause a false positive result?**
    There are several potential causes that can lead to a false positive result. For example, if a person is positive, or if they did not follow the instructions for use carefully.

23. **What is the procedure for using the test?**
   The procedure for using the test is designed to be easy to follow and requires no special equipment or training.

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.