WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: CheckNOW HIV SELF TEST
WHO reference number: PQDx 0481-032-00

CheckNOW HIV SELF TEST with product code 29012-W01, manufactured by Abbott Rapid Diagnostics Jena GmbH (former Alere Technologies GmbH), Rest of World regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 4 April 2022.

Summary of WHO prequalification assessment for CheckNow HIV SELF TEST

<table>
<thead>
<tr>
<th></th>
<th>Date</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prequalification listing</td>
<td>4 April 2022</td>
<td>listed</td>
</tr>
<tr>
<td>Dossier assessment</td>
<td>8 February 2022</td>
<td>MR</td>
</tr>
<tr>
<td>Site inspection(s) of quality management system</td>
<td>16-18 July 2018</td>
<td>MR</td>
</tr>
<tr>
<td>Product performance evaluation</td>
<td>3rd and 4th quarter 2021</td>
<td>MR</td>
</tr>
</tbody>
</table>

MR: Meets Requirements

Report amendments and/or product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table below.

<table>
<thead>
<tr>
<th>Version</th>
<th>Summary of amendment</th>
<th>Date of report amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>Updating of product’s shelf life from 18 to 24 months and updating the zip-lock pouch label with the current version in the public report.</td>
<td>17 June 2022</td>
</tr>
</tbody>
</table>

Intended use

According to the claim of intended use from Abbott Rapid Diagnostics Jena GmbH, “The CheckNOW HIV SELF TEST is a single-use, in vitro (outside the body) visually read rapid immunoassay that uses a blood sample from a finger puncture for the qualitative detection of antibodies to HIV-1 and HIV-2 in blood. The CheckNOW HIV SELF TEST is intended to be used manually by untrained lay users (self testing) who are 14 years older to aid in the
diagnosis of HIV-1 or HIV-2 infection. This test is not intended to be used as an HIV screening test for blood donation.”

Assay description
According to the claim of assay description from Abbott Rapid Diagnostics Jena GmbH, “HIV is recognized as the virus that causes AIDS (Acquired Immunodeficiency Syndrome). The virus is transmitted by sexual contact, exposure to infected blood, certain body fluids or tissues, and from mother to child during pregnancy. The CheckNOW HIV SELF TEST detects the presence of antibodies to HIV-1 and/or HIV-2 in blood. The product includes a Test device and a Buffer. To use the test, two drops of blood sample are collected from the fingerstick in the Basin of the plastic cover. One drop of blood is transferred by a Specimen dropper to the Well. After that, one drop of Buffer is applied. When the test is completed, two lines can appear on the device. The red line in the Control Line (C) area will only become visible if the added blood sample and/or buffer have moved over the T/C Line areas of the reading window. The T line area is precoated with HIV-1 antigen glycoprotein 41 and HIV-2 antigen glycoprotein 36. The red line in the Test Line (T) area will only become visible if the applied sample contains antibodies to HIV-1 or HIV-2.”

Test kit contents

<table>
<thead>
<tr>
<th>Component</th>
<th>1 test (product code 29012-W01)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test device</td>
<td>1</td>
</tr>
<tr>
<td>Alcohol pads (sterile)</td>
<td>2</td>
</tr>
<tr>
<td>Plaster (sterile)</td>
<td>1</td>
</tr>
<tr>
<td>Buffer</td>
<td>1</td>
</tr>
<tr>
<td>Specimen dropper</td>
<td>1</td>
</tr>
<tr>
<td>Sterile lancet</td>
<td>1</td>
</tr>
<tr>
<td>Instructions for use</td>
<td>1</td>
</tr>
</tbody>
</table>

Items required but not provided
- Timer
- Tissue

Storage
The test kit should be stored at 2-30°C.

Shelf-life upon manufacture
24 months.
Warnings/limitations

Refer to current version of manufacturer’s instructions for use.

Prioritization for prequalification

Based on the established eligibility criteria, the CheckNow HIV SELF TEST was given priority for WHO prequalification assessment.

**Dossier assessment**

Abbott Rapid Diagnostics Jena GmbH submitted a product dossier for CheckNow HIV SELF TEST as per the “Instructions for compilation of a product dossier” (PQDx_018 version 3). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 8 February 2022.

**Commitment for prequalification**

Commitment to Prequalification 1: Please provide real-time stability study final report TR20077 by 31 August 2022. Commitment was fulfilled. Issue closed.

Based on the product dossier screening and assessment findings, the product dossier for CheckNow HIV SELF TEST meets WHO prequalification requirements.

**Manufacturing site inspection**

An inspection of Abbott Rapid Diagnostics Jena GmbH (former Alere Technologies GmbH) located at Loebstedter Str. 103-105, Jena, Germany was conducted from 16th to 18th of July 2018. At the time of considering the product application for Prequalification, the Manufacturer of the product had a well-established quality management system and manufacturing practices in place that would support the manufacture of a product of consistent quality. Routine inspections of the Manufacturing site will be conducted with copies of the WHO Public Inspection Report (WHOPIR) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. Note that a WHOPIR reflects the information on the most current inspection performed at a manufacturing site for *in vitro* diagnostic products and gives a summary of the inspection findings.

The manufacturer's responses to the nonconformities found at the time of the inspection were accepted on 20th of December 2018.
Product performance evaluation

CheckNOW HIV SELF TEST was evaluated by the KEMRI CGHR HIV Research laboratory, Kenya, on behalf of WHO in the 3rd and 4th quarter of 2021, according to protocol PQDx_241, version 5.

Clinical performance evaluation

In this limited laboratory-based evaluation of clinical performance characteristics, a panel of 1000 capillary blood specimens was used. Plasma specimens collected simultaneously were characterized using the following reference algorithm: AiD anti-HIV 1+2 ELISA (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd) and Murex HIV Ag/Ab Combination (DiaSorin Dartford, United Kingdom); followed by INNO-LIA HIV I/II Score (Fujirebio).

### Clinical performance characteristics in comparison with an agreed reference standard

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity* % (N=400)</td>
<td>99.5% (95% CI: 98.2-99.9)</td>
</tr>
<tr>
<td>Specificity % (N= 600)</td>
<td>98.5% (95%CI: 97.2-99.3)</td>
</tr>
<tr>
<td>Invalid rate % (N= 0)</td>
<td>0</td>
</tr>
<tr>
<td>Inter-reader variability % (N= 0)</td>
<td>0</td>
</tr>
</tbody>
</table>

* Seven of the 398 (1.8%) reactive results on the HIV-positive clinical panel were graded as very weak lines.

Analytical performance evaluation

<table>
<thead>
<tr>
<th>Analytical performance characteristics</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity during seroconversion on 5 seroconversion panels in comparison with a benchmark assay (Wantai AID anti-HIV 1+2 ELISA)</td>
<td>Of a total of 34 specimens, 13 were detected by the CheckNOW™ HIV SELF TEST; versus 10 specimens detected by Wantai AID anti-HIV 1+2 ELISA. Seroconversion sensitivity index of -0.6, therefore detection is -0.6 specimens earlier than Wantai AID anti-HIV 1+2 ELISA.</td>
</tr>
<tr>
<td>Analytical sensitivity on a mixed titer panel (0800-436)</td>
<td>20 of 20 specimens were correctly classified.</td>
</tr>
<tr>
<td>Analytical sensitivity on WHO reference preparation panel(s) (NIBSC Code 02/210)</td>
<td>All 6 types/subtypes included in the panel were detected (although subtype HIV-1 O with a very weak line)</td>
</tr>
<tr>
<td>Lot to lot variation on a dilution panel</td>
<td>Lot to lot variation was within +/- 1 two-fold dilutions for 6 dilution series and ≥ 2 two-fold dilution for 4 dilution series.</td>
</tr>
</tbody>
</table>
Operational characteristics and ease of use

The assay was found easy to use by the operators performing the evaluation.

<table>
<thead>
<tr>
<th>Key operational characteristics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen type and volume</td>
<td>One drop of capillary whole blood is needed for the test, but 2 drops are collected for the procedure</td>
</tr>
<tr>
<td>Number of steps*</td>
<td>3 steps in total</td>
</tr>
<tr>
<td></td>
<td>0 steps with precision pipetting</td>
</tr>
<tr>
<td>Time to result</td>
<td>15 minutes</td>
</tr>
<tr>
<td>Endpoint stability (interval)</td>
<td>5 minutes (the test can be read between 15 and 20 minutes after addition of diluent)</td>
</tr>
<tr>
<td>Internal QC</td>
<td>Yes – reagent addition control</td>
</tr>
</tbody>
</table>

* Definition: each action required to obtain a result (excluding specimen collection, device preparation – opening the pouch), e.g. for RDTs: add specimen, add buffer (2 steps).

Based on these results, the performance evaluation for CheckNOW HIV SELF TEST meets the WHO prequalification requirements.

Limitations of the performance evaluation:
1. All specimens used in the performance evaluation were from the same geographical area.
2. All positive specimens in the performance evaluation were positive for HIV-1, so the sensitivity of CheckNOW HIV SELF TEST for the detection of HIV-2 could not be assessed.
Labelling

1. Labels
2. Instructions for use
1. Labels

1.1 Zip-lock pouch label
CheckNOW™
HIV SELF TEST
Know your HIV status Now

CONTENTS:
1 Test device
1 Buffer
1 Specimen dropper
1 Lancet
2 Alcohol pads
1 Plaster
1 Instructions for use

For HIV Self Testing

Abbott Rapid Diagnostics Jena GmbH
Orlauer Str. 1, D-07743 Jena, Germany
www.abbott.com/poct

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Made in China 1205802602
1.2 Test device pouch
1.3 Test device image

![Test device image]

1.4 Buffer label

![Buffer label]

1.5 Sterile lancet label

![Sterile lancet label]
1.6 Alcohol swab label

1.7 Specimen dropper label

1.8 Plaster
2. Instructions for use

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1 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.
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 bag or components are broken
- If the kit or components have been used
- If your area is under poor lighting
Do not eat or drink while you perform the test

**STEP 1: PREPARATION**

1. Prepare a Timer and Tissue.
   - Not included in the kit, but needed.

2. Open and place all materials on a flat and clean surface with bright light.
   - Test device
   - 2 Alcohol Pads
   - Specimen Dropper
   - 1 Buffer
   - Plaster
   - Use kit bag as disposal bag
   - Result
   - Well
   - Basin
   - Is only pricks once!

3. Wash hands in warm water and dry. If no warm water is available, rub your hands together.
   - Avoid dominant hand.

4. Choose ring finger or middle finger.

**STEP 2: COLLECT BLOOD**

5. Massage and rub your hand & finger to increase circulation.

6. Clean your finger with 1 Alcohol Pad. Let it dry for 10 seconds.
   - Needle inside
   - Is only pricks once!

7. Remove the Lancet cover.

8. Press the 3 Lancet against the finger until it clicks.
   - CLICK
   - PRESS HARD

9. Massage from the base to the tip, let 2 drops of blood fall into the Basin. If you are having difficulty, wipe finger clean and squeeze again.
   - 2 Drops

10. Wipe finger with 2 Alcohol Pad and apply the 4 Plaster. If needed, press on the plaster to stop bleeding. Start next step immediately to transfer blood.

11. Squeeze the top of the 5 Specimen Dropper all the way down and hold while dipping into the blood sample.

12. Hold 6 Buffer bottle vertically and apply 1 drop of Buffer into the Well labelled S.

13. Start the Timer. Read the result in 15-20 minutes, do not read past 20 minutes.

See flip side for **STEP 4: Read Result**
INTENDED USE
The CheckMARK HIV SELF TEST is a single-use, in vitro (outside the body) visually read rapid immunoassay that uses a blood sample from a finger-prick for the qualitative detection of antibodies to HIV-1 and HIV-2 in blood. The CheckMARK HIV SELF TEST is intended to be used manually by untrained lay users (self-testing) who are 18 years and older to aid in the diagnosis of HIV-1 or HIV-2 infection. This test is not intended to be used as an HIV screening test for blood donation.

SUMMARY
HIV is recognized as the virus that causes AIDS (Acquired Immunodeficiency Syndrome). The virus is transmitted by sexual contact, exposure to infected blood, certain body fluids or tissues, and from mother to child during pregnancy. The CheckMARK HIV SELF TEST detects the presence of antibodies to HIV-1 and/or HIV-2 in blood. The product includes a Test device and a Buffer. To use the test, two drops of blood sample are collected from the fingerstick on the whole blood. One drop of blood is transferred by a Spermatozoon to the well after. After 15 minutes, the result can be read.

PERFORMANCE
The CheckMARK HIV SELF TEST is designed to be used by a finger-prick blood sample. Other body fluids must not be used.

LIMITATIONS OF THE TEST
- The CheckMARK HIV SELF TEST detects antibodies to HIV-1 and/or HIV-2, but it may not detect infection at the earliest stage of the disease.
- This test may not be suitable for small children, pregnant women, or individuals with blood disorders.

TEST PROCEDURE
1. Sample Collection
- Use a finger-prick device to collect a blood sample.
- Place the device on a flat surface, and use a sterile needle or lancet to prick the finger.
- Collect at least 2 drops of blood.

2. Add Buffer
- Add 2 drops of Buffer to the well of the Test device.

3. Read the Result
- After 15 minutes, read the result.

RESULT INTERPRETATION
- Non-reactive (Negative): No visible bands in the T line and/or C line.
- Reactive (Positive): A visible band in the T line and a visible band in the C line.

TEST RESULT INTERPRETATION
- 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 (ART) and you were treated recently; If you are on HIV treatment (ART) and you were treated recently.
- Reactive (Positive) result can occur for any of the following reasons: Incorrectly reading test result; Not following the instructions for Use carefully; Having been treated with an HIV vaccine; In cases of infection with syphilis.

TEST PERFORMANCE
The test has been shown in clinical evaluations performed by professional health care personnel to correctly identify 99.9% (2097 of 2100) with a confidence interval of 99.6% to 100.2% of HIV-negative samples (known as the test’s sensitivity), 99.9% (2097 of 2100) with a confidence interval of 99.6% to 100.2% of HIV-positive samples (known as the test’s specificity). Further field clinical evaluations conducted in South Africa, Congo, Vietnam, and Spain, the test correctly identified 99.6% (1934 of 1935) with a confidence interval of 99.2% to 99.9% of HIV-negative samples when performed by first-time self-test users. The test has also been shown in clinical evaluations performed by professional health care personnel to correctly identify 100% (600 out of 600) with a confidence interval of 99.9% to 100% of HIV-positive samples (known as the test’s sensitivity), 99.9% (600 out of 600) with a confidence interval of 99.9% to 100% of HIV-positive samples when performed by first-time self-test users. *Note: A test of 6 time failed tests CheckMARK HIV SELF TEST users needed to be excluded from this analysis as they were observed to deny an unexpected result.

TESTING GUIDANCE
To ensure that other medical conditions (potential cross-reactants) do not affect the performance of the CheckMARK HIV SELF TEST, samples of HIV-1 negative blood were tested from people who had other conditions. These included 250 samples from pregnant women and 842 other samples as follows:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number of Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>100</td>
</tr>
<tr>
<td>Hypertension</td>
<td>50</td>
</tr>
<tr>
<td>Smoking</td>
<td>100</td>
</tr>
<tr>
<td>Alcohol</td>
<td>50</td>
</tr>
</tbody>
</table>

DISPOSAL
- Place all used components back into the kit bag.
- Seal the kit bag tightly.
- Throw away the kit bag in waste bin or household rubbish.

REFERENCE