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

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

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.

Version	Summary of amendment	Date of report amendment
2.0	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.	17 June 2022

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

Component	**1 test (product code 29012-W01)**
Test device	1
Alcohol pads (sterile)	2
Plaster (sterile)	1
Buffer	1
Specimen dropper	1
Sterile lancet	1
Instructions for use	1

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	
Sensitivity* % (N=400)	99.5% (95% CI: 98.2-99.9)
Specificity % (N= 600)	98.5% (95%CI: 97.2-99.3)
Invalid rate % (N= 0)	0
Inter-reader variability % (N= 0)	0

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

Analytical performance evaluation

Analytical performance characteristics	
Sensitivity during seroconversion on 5 seroconversion panels in comparison with a benchmark assay (Wantai AID anti-HIV 1+2 ELISA)	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.
Analytical sensitivity on a mixed titer panel (0800-436)	20 of 20 specimens were correctly classified.
Analytical sensitivity on WHO reference preparation panel(s) (NIBSC Code 02/210)	All 6 types/subtypes included in the panel were detected (although subtype HIV-1 O with a very weak line)
Lot to lot variation on a dilution panel	Lot to lot variation was within +/- 1 two-fold dilutions for 6 dilution series and ≥ 2 two-fold dilution for 4 dilution series.

Operational characteristics and ease of use

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

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

** 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

Front

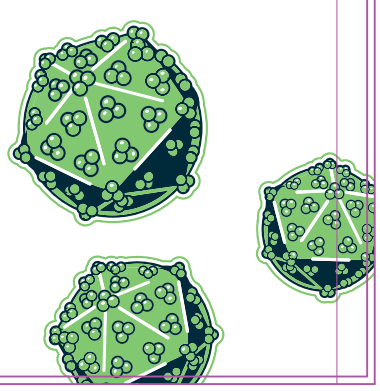
Abbott

CheckNOW™

HIV SELF TEST

Know your HIV status Now

2°C 30°C Σ 1 IVD



Back

LOT XXXXXXXXXX

REF 29012-W01

YYYY-MM-DD

For HIV Self Testing

CONTENTS:

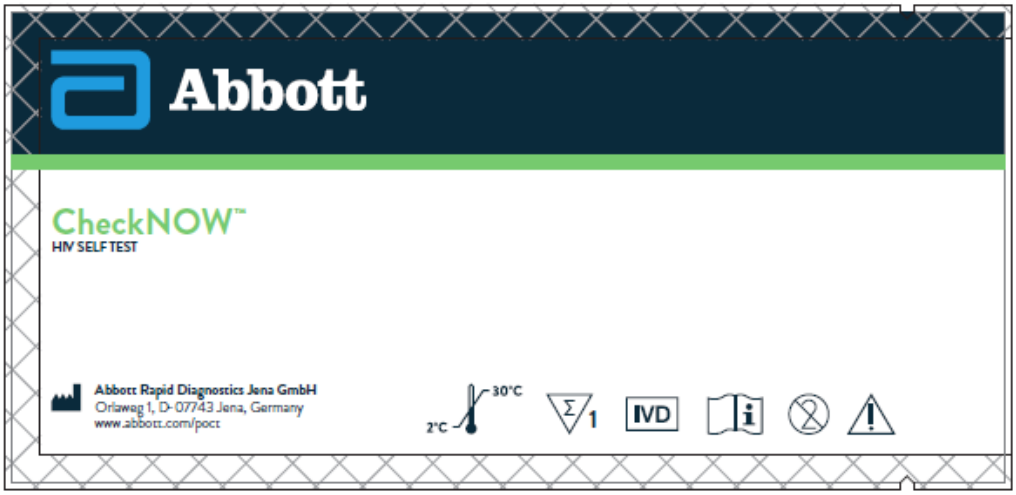
1 Test device
1 Buffer
1 Specimen dropper
1 Lancet
2 Alcohol pads
1 Plaster
1 Instructions for use

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

Made in China

1205802602

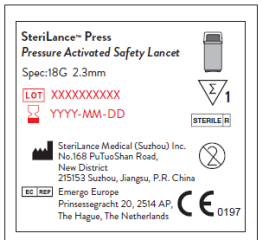
1.2 Test device pouch



1.3 Test device image

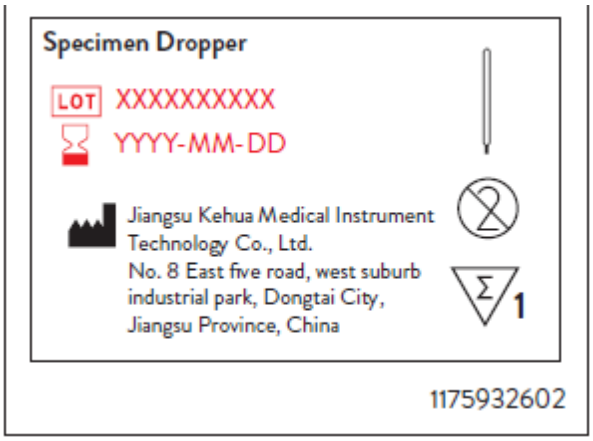
1.4 Buffer label

1.5 Sterile lancet label



1.6 Alcohol swab label

1.7 Specimen dropper label



1.8 Plaster

2. Instructions for use[1]

[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.

CheckNOW™ HIV SELF TEST

Watch the instructional video:
https://alere.wistia.com/medias/guyym62w5j

Revision Date: 2022-03-31

INSTRUCTIONS FOR USE

Catalog Number: 29012-W01 EN

Before testing you must read all the steps. Conformance with the test procedure is necessary to ensure an accurate result.

Precautions

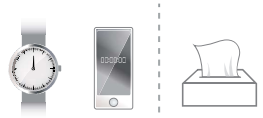
Do not use

- If you have a bleeding disorder
- If you are on HIV treatment (ARVs)
- If you are needle phobic
- If the kit bag or components is 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

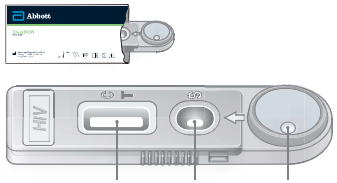
1 Prepare a Timer and Tissue.



⚠ 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 STERILE R

Ⓒ Plaster STERILE EO

Ⓓ Buffer

Ⓔ Specimen Dropper

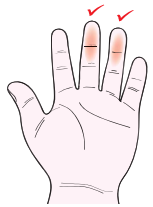
Ⓕ Lancet STERILE R

⚠ It only pricks once!

Ⓖ Use kit bag as disposal bag

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

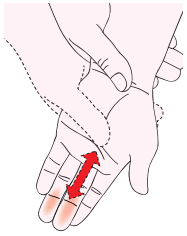
4 Choose ring finger or middle finger.



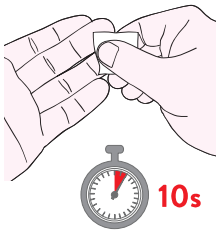
Avoid dominant hand.

STEP 2: COLLECT BLOOD

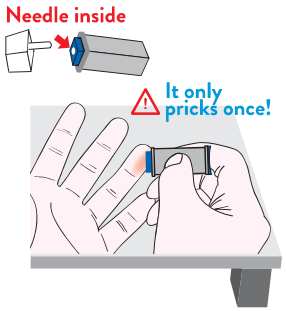
5 Massage and rub your hand & finger to increase circulation.



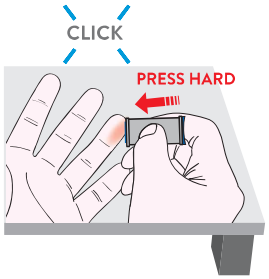
6 Clean your finger with Ⓑ Alcohol Pad. Let it dry for 10 seconds.



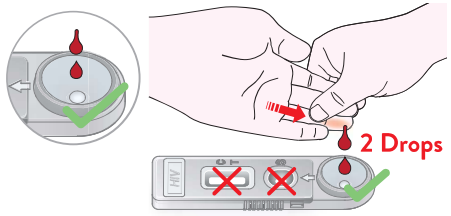
7 Remove the Lancet cover.



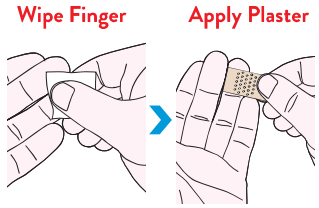
8 Press the Ⓕ Lancet against the finger until it clicks.



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.

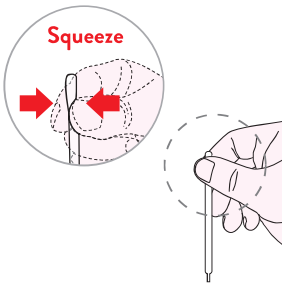


10 Wipe finger with Ⓑ Alcohol Pad and apply the Ⓒ Plaster. If needed, press on the plaster to stop bleeding. Start next step immediately to transfer blood.

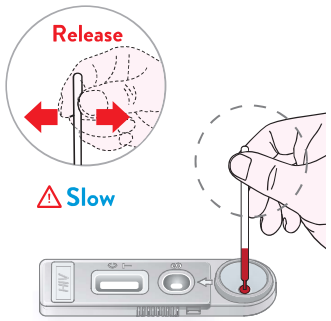


STEP 3: TEST

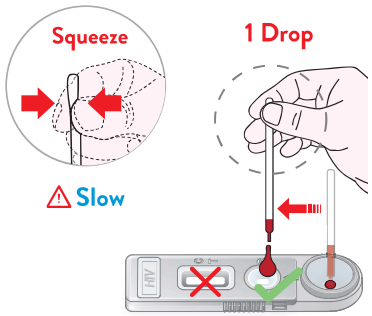
11 Squeeze the top of the Ⓔ Specimen Dropper all the way down and hold while dipping into the blood sample.



Dip the dropper into the blood in Basin and release slowly to draw blood into the dropper.
⚠ Avoid bubbles when drawing blood.

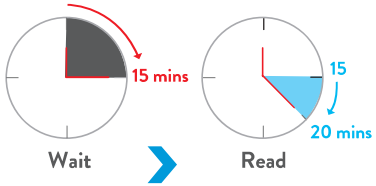


Place dropper over the Well labelled S. Squeeze the top of the dropper to apply **1 drop** of blood into the Well labelled S.



12 Hold Ⓓ 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

Number: 1156182105

STEP 4: READ RESULT

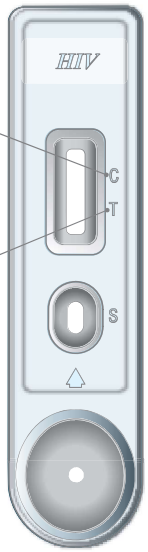
14 Read test result in 15-20 minutes.

Read result in a well lit area

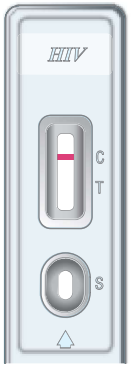
Control Line

Test Line

PLACE YOUR SELF-TEST HERE



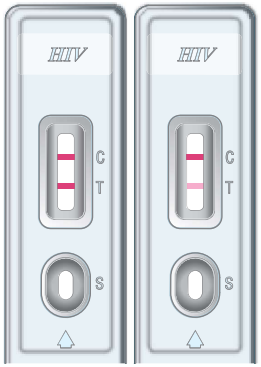
NON-REACTIVE (=Negative)



A line appears only in the C area. There is no line in the T area. The test did not detect the presence of HIV, however very recent exposure cannot be excluded.

It is recommended to conduct a retest after 6 weeks from latest risk of exposure to HIV.

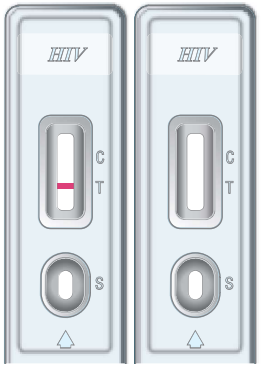
REACTIVE (=Positive)



One line in the C area, together with one line in the T area, no matter how faint, indicates the potential to be HIV positive.

Consult a health care provider.
A reactive result must be confirmed by a lab test. Protect yourself and others! Avoid any activity that could transmit HIV to others.

TEST DID NOT WORK (=Invalid)

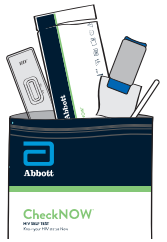


If no line appears in the C area, even if a line appears in the T area, the test did not work.

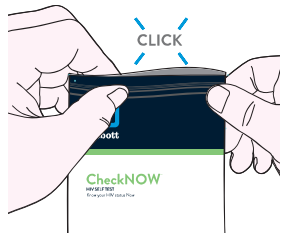
Test again using a new kit or consult a health care provider.

STEP 5: DISPOSAL

15 Place all used components back into the kit bag.



16 Seal the kit bag tightly.



17 Throw away the kit bag in waste bin or household rubbish.

Blood can transmit infectious diseases
Clean up spills

Dispose in accordance to local regulations

INTENDED USE

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 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[1]. 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.

STORAGE

- Store the test kit at 2-30°C (36-86° F) until the expiry date. Do not freeze.
- Do not use the test kit after expiry date printed on the test pouch.
- Do not open the sealed foil test pouch until you are ready to use the test. Test device should be used within one hour after the pouch has been opened.
- The buffer is for single-use, and should be used within one hour after cap open.

WARNINGS AND PRECAUTIONS

- This test may give an unexpected positive result. Whether the result is positive or negative, you should consult with your doctor before making medical decisions.
- For *in vitro* diagnostic use only.
- Perform test only by using a fresh blood sample. Not to be used with serum or plasma sample.
- The test device is recommended to be used at room temperature (15-30°C).
- Lancet and Specimen dropper are for single-use only. Do not reuse.
- If you do not understand the IFU please reach out to provided Technical Service contact.
- If your test is working, you will see a line in the Control Line area on your test device. If there is no line in the Control Line area, your test did not work, and the test result is invalid. However, the presence of a line in the Control Line area does not confirm sufficient specimen addition. You must transfer exactly 1 drop of blood to the Well before adding Buffer.
- Keep the SELF TEST and the components out of the reach of children.
- The buffer contains 0.09% sodium azide as a preservative, which may be toxic if ingested. If you get contaminated to your eyes rinse with running water for at least 15 minutes. If irritation persists, get medical attention.
- If your finger is still bleeding, use tissue or wipes. Protect yourself and others.
- Finger prick blood should be transferred from Basin to Well immediately to avoid blood clotting (within 2 minutes).

LIMITATIONS OF THE TEST

- The CheckNOW™ HIV SELF TEST is designed to be used with a finger puncture blood sample. Other body fluids must not be used.
- Not suitable for testing infant younger than 18 months[2].
- A NON-REACTIVE (Negative) result does not absolutely rule out the possibility of HIV infection.
- A REACTIVE (Positive) result must be confirmed by a health care provider using appropriate confirmatory testing.
- The intensity of the Test Line for a REACTIVE (Positive) result does not reflect how much HIV antibody is present in the blood sample.
- Although it's rare, false results may occur. If you have concerns that your result may be false, please contact your health care provider.
- Biotin concentrations up to 1500 ng/mL may lead to decreased Control Line intensity but have no impact on the internal control performance.
- An incorrect or "false" 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 (ARV)[3,4,5]; If you were very recently infected; The presence of bubbles during sample application, in particular in low positive samples.
- An incorrect or "false" REACTIVE (Positive) result can occur for any of the following reasons: Incorrectly reading test result; Not following the Instructions for Use carefully; Having received an HIV vaccine; In cases of infection with cytomegalovirus.

TEST PERFORMANCE

The test has been shown in clinical evaluations performed by professional health care persons to correctly identify 99.9% (2097 out of 2100) with a confidence interval of 99.6% to 100% of HIV negative samples (known as the test's specificity). Further in field clinical evaluations conducted in South Africa, Congo, Vietnam and Spain, the test correctly identified 99.6% (1824 out of 1831) 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 persons to correctly identify 100% (600 out of 600) with a confidence interval of 99.5% to 100% of HIV positive samples (known as the test's sensitivity). Further in field clinical evaluations conducted in South Africa, Congo, Vietnam and Spain, the test correctly identified 95.1% (270* out of 284) with a confidence interval of 91.9% to 97.3% of HIV positive samples when performed by first time self test users.

*Note: A total of 6 first time CheckNOW™ HIV SELF TEST users needed to be excluded from this analysis as they were observed to deny an unexpected result. Refer also to warnings and precautions about the use of this test.

To ensure that other medical conditions (potential cross-reactants) do not affect the performance of the CheckNOW™ HIV SELF TEST, samples of HIV negative blood were tested from people who had other conditions. These included 250 specimens from pregnant women and 342 other specimens as follows:

HAMA; Multiparous woman; Elevated IgG; Elevated IgM; Systemic lupus erythematosus; Hemolytic; Lipemic; Icteric; Rheumatoid Factor; ANA; Anti-E. coli positive specimens; Sickle-cell disease specimens; Blood from recipients of multiple blood transfusions; HBsAg; EBV; CMV; Malaria; Measles; Tuberculosis; Varicella zoster virus; Influenza A and B; Tick borne encephalitis; Influenza vaccine recipient; Human African trypanosomiasis; Yellow fever virus; Post-immunization measles; Vaccine-induced HIV seropositivity; Yellow fever vaccine recipient, Leishmaniasis positive; Syphilis; Toxoplasmosis; Helicobacter pylori; HSV; anti-HCV, anti-HBs, anti-HBc; anti-HTLV-1/2; anti-HEV, anti-HAV. These non-HIV medical conditions did not affect the performance of CheckNOW™ HIV SELF TEST with exception of the observed cross-reactivity seen with 2 out of 21 tested cytomegalovirus (CMV) specimens.

The CheckNOW™ HIV SELF TEST was also evaluated with 23 interfering substances which include medicine and blood analyte. These substances were spiked with HIV-1 Antibody positive plasma and the test results indicated these interference substances did not affect the performance of the CheckNOW™ HIV SELF TEST.

LITERATURE REFERENCES

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2°C 30°C	Store between 2-30°C		Consult instructions for use		Do not reuse		Manufacturer
REF	Catalogue number		Use-by date	LOT	Batch code	STERILE R	Sterilized using irradiation
IVD	*In vitro* diagnostic medical device	Σ	Contains sufficient for <n> tests		Caution	STERILE EO	Sterilized using ethylene oxide

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