THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR (CheckNow™, *HIV Self-Test*)

Version number 2.0, 29/03/2024

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Toll free: 0800110084

Introduction

CheckNow™,, *HIV Self-Test is* a class *D in-vitro diagnostic medical device* belonging to the *Clinical laboratory* specialty category. CheckNow™, *HIV Self-Test* > is approved in Tanzania as a *kit* by *general public*.

1.1. Administrative Information

Registration number	TAN 22 MDR 0130
Brand Name (if relevant)	CheckNow™,, *HIV Self-Test*
Common name	CheckNow™, *HIV Self-Test*
Class of the device and rule applied	Class D according to Rule No 1 of Classification for In Vitro Diagnostics Medical Devices.
GMDN code and term	65848 HIV1/HIV2 antibody IVD, kit, rapid ICT, self-testing.
Name and complete address of the Market Authorization Holder	**Name:** Abbott Rapid Diagnostic Jena GmbH, **Address:** Orlaweg 1, 07743 Jena, Germany, **Post code:** 07743 **Country:** Germany. **Tel No:** +49-3641-3111-203. **Fax No:** +49 364-3111-120. **Email:** atj.info@abbott.com, **Website:** www.globalpointofcare.abbott.com,
Name and address(es) of local responsible person (LRP).	**Name:** Bahari Pharmacy Ltd, **Address:** Block 05 Industrial Area, Nyerere Road, P. O. Box 40591, Dar es Salaam, **Tanzania** **Tel No:** +255 784 564 338 or +255 754 264 153 **Email:** davidlutabana@ticc.co.tz,

1.2. Assessment Procedure

The application for registration of CheckNow™, *HIV Self-Test* was submitted on 17/02/2022. The product underwent abridged procedure assessment. Assessment was completed in 01 rounds of evaluation. CheckNow™, *HIV Self-Test* was registered on 09/06/2022.

2. Technical information

2.1. Intended use

The intended use of CheckNow™, *HIV Self-Test* as declared by the manufacturer and approved by TMDA 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. CheckNow™, *HIV Self-Test* is approved for use by laypersons (self-testing).

2.2. Device details and features

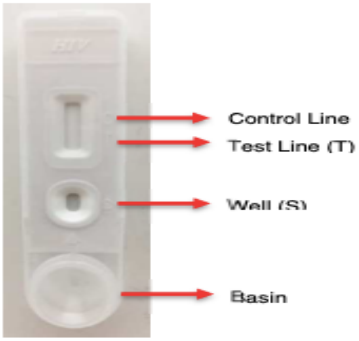
CheckNow™, *HIV Self-Test* is a single device with additional accessories. CheckNow™, *HIV Self-Test* has been registered as a kit which consists of Alcohol pads (Sterile – 2), Single use safety Lancet (Sterile – 1), Plaster (1), Specimen dropper (1) and Buffer (3ml bottle). It is a closed system.

CheckNow™, *HIV Self-Test* is a manually operated device. It is used for screening of HIV-1 or HIV-2 infection. CheckNow™, *HIV Self-Test* operates by immunochromatographic principle. The test output is qualitative.

The type of specimen used is whole blood and is collected by pricking one's finger with a lancet provided in the test kit to obtain a drop of blood.

CheckNow™, *HIV Self-Test* is an immunochromatographic rapid diagnostic test for the qualitative detection of antibodies to HIV-1 and HIV-2 in human capillary whole blood.

The test contains the a membrane strip with immobilized HIV-1 and HIV-2 antigens, internal control (streptavidin) and a plastic housing with a well for sample and buffer application (S). The housed test strip is surrounded by an outer transparent plastic cover that contains an inbuilt additional basin to receive blood sample. This outer cover also contains a window at the position of the well. Its transparent plastic cover also overlays the reading window of the test device, consequently preventing users to mistakenly apply sample on the reading window which would otherwise lead to test failure. The transparent plastic cover does not touch the test strip or interfere with any test reaction on the strip.



Primary package

2.3. Commercial presentation

There is *01* approved commercial presentations as follows: One test in a pouch as the primary pack and additional contents in secondary packaging material.

Additional contents include.

i. Sterile alcohol pads (2),
ii. Plaster (1),
iii. Buffer, 3ml bottle,
iv. Specimen dropper (1),
v. Sterile lancet (1).

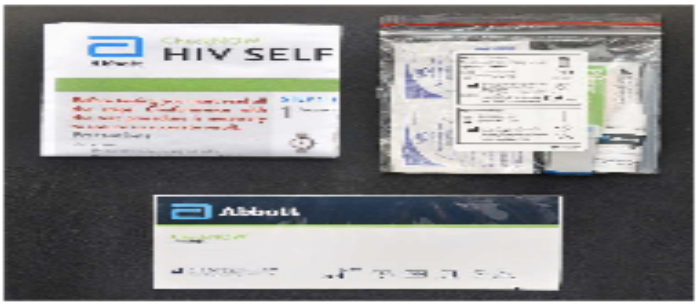


Figure 6: Kit content (representative)

1.16. Accessories

1.16.1. Accessories Provided within the Kit

Table 2: Accessories provided within the kit

Accessory	Content
Alcohol Pads	1 Bag containing 2 Alcohol Pads (sterile)
Single-use Safety Lancet	1 Single-use Safety Lancet (sterile)
Plaster	1 Sterile plaster
Specimen Dropper	1 Specimen Dropper for transfer of capillary (fingerstick) whole blood from the Basin into the Well of the device
Buffer	1 Bottle containing 3 mL of Buffer

Figure 7: Accessories provided within the kit

2.4. Items required but not submitted.

i. Timer
ii. Tissue

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life is 24 months.

3.1.2. Storage conditions

The recommended storage conditions is at 2-30°C (36-86° F) until the expiry date and do not freeze.

3.1.3. Shipping conditions

The recommended shipping conditions is 45°C for 79 days which indicates that product performance is acceptable after a storage period of 13 months at 30°C.

4. Manufacturing site audit

The manufacturing site of the device is,
Abon Biopharm (Hangzhou)Co., LTD,
#19812th Street East,
Hangzhou Economic &Technological Development Area,
Hangzhou, Zhejiang,
310018 P.R. China.

Quality audit of the manufacturing facility was conducted through site visit on 3 – 4 April 2023. The site was found to be a complaint to ISO 13485 requirements.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters: Accuracy {trueness, precision (repeatability and reproducibility)}, analytical sensitivity, analytical specificity.Parameters were tested for analytical specificity and sensitivity.

5.2. Clinical Performance

Clinical performance was conducted at,

Abon Biopharm (Hangzhou)Co., LTD,
#19812th Street East,
Hangzhou Economic &Technological Development Area,
Hangzhou, Zhejiang,
310018 P.R. China.

Based on results of the performance studies done by professional healthcare persons, it was concluded that the test sensitivity and specificity is 100% and 99.9% respectively. The studies further concluded that CheckNow™*,HIV Self-Test* is capable of consistently producing accurate and reliable test output.

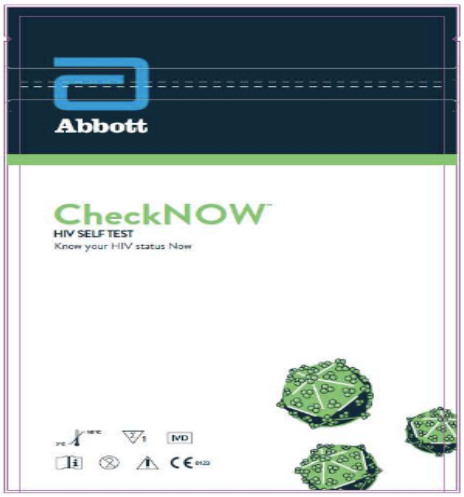
6. Product label and instructions for use

The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product.

The instruction for use includes all the relevant information to ensure correct and safe use of the device by general public.

6.1. Primary pack

6.2. Secondary pack



6.3 Instructions for use/Package insert (here).

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and compliance of the manufacturer to ISO 13485, the benefit of the product outweighs the risks associated with its use when used in accordance to the manufacturer's instruction. CheckNow™*,HIV Self-Test* was recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
NA				

8.2. Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
No recorded Adverse Events	NA	

8.3. Re-registration applications

NA

CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date

CheckNOW™ HIV SELF TEST

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

Revision Date: 2021-06-17 IFU Version 02

INSTRUCTIONS FOR USE

Catalog Number: 290120001 EN

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

Precautions

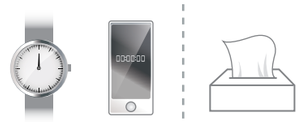
Do not use

- 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

Do not eat or drink while you perform the test

STEP 1: PREPARATION

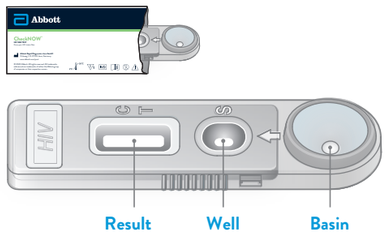
1 Prepare a Timer and Tissue.



⚠ **Not included in the kit, but needed.**

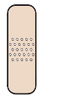
2 Open and place all materials on a flat and clean surface.

Ⓐ Test device



Ⓑ 2 Alcohol Pads

Ⓒ Plaster



Ⓓ Buffer

Ⓔ Specimen Dropper

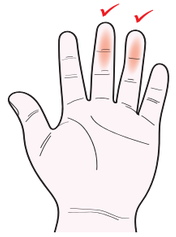
Ⓕ Lancet STERILE R

⚠ **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.

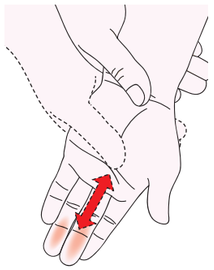
4 Choose ring finger or middle finger.



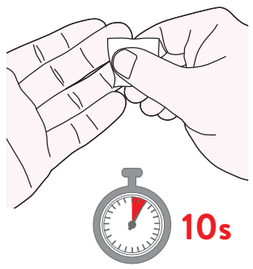
Avoid dominant hand.

STEP 2: COLLECT BLOOD

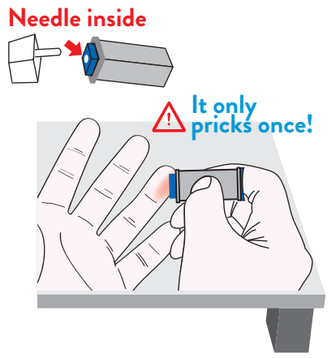
5 Massage and rub your hand & finger to increase circulation.



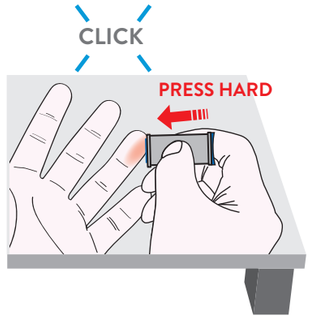
6 Clean your finger with Ⓑ Alcohol Pad. Let it dry for 10 seconds.



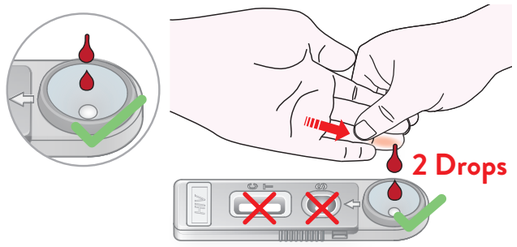
7 Remove the Lancet cover.



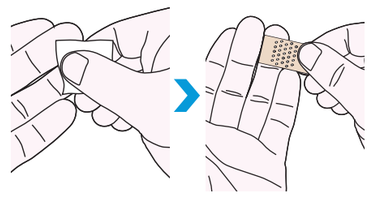
8 Press the Ⓕ Lancet against the finger until it clicks.



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.

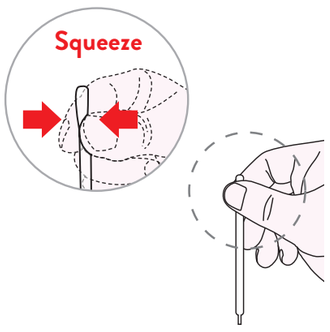


10 Wipe finger with Ⓑ Alcohol Pad and apply the Ⓒ Plaster. If needed, press on the plaster to stop bleeding.
Start next step immediately to transfer blood.

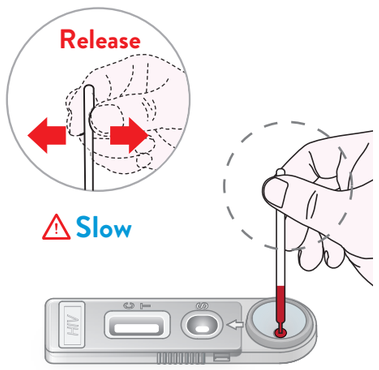


STEP 3: TEST

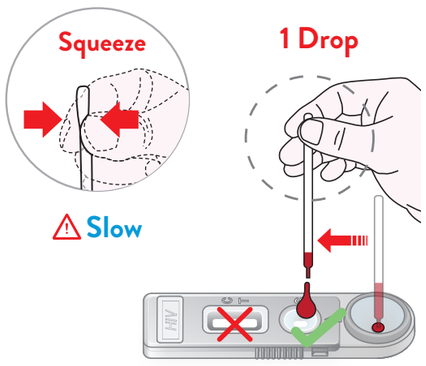
11 Squeeze the top of the Ⓔ Specimen Dropper.



Dip the dropper into the blood in Basin and release slowly to draw blood into the dropper.



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



12 Hold Ⓓ Buffer bottle vertically and apply **1 drop** of Buffer into the **Well.**

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

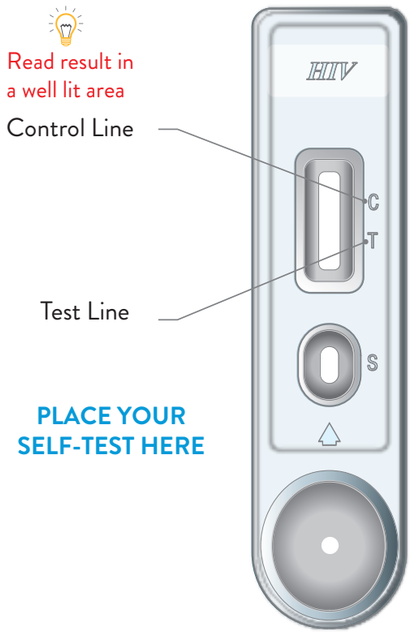
See flip side for STEP 4: Read Result

Number: 1156183602

STEP 4: READ RESULT

14 Read test result in 15-20 minutes.

Read result in a well lit area



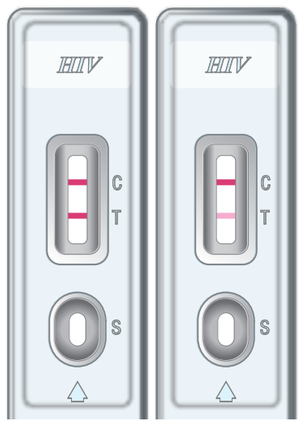
PLACE YOUR SELF-TEST HERE

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.

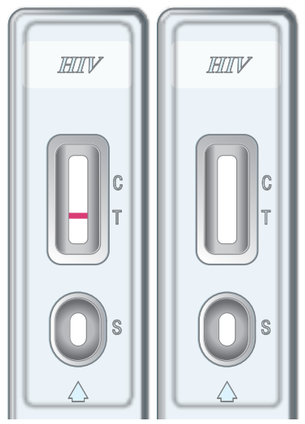
REACTIVE (=Positive)



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)



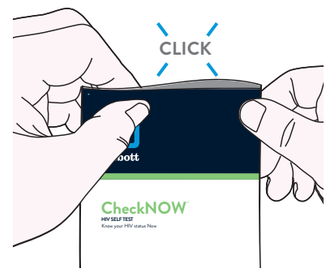
If no line appears in the C area, even if a line appears in the T area, the test did not work.

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.

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) 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.
- Note 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 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

1. Blattner, W., Gallo, R., & Temin, H. HIV causes AIDS. Science. 1988; 241(4865), 515-515.
2. CDC: 2008 Case Definition; Human Immunodeficiency Virus Infection.
3. Delaney KP, Branson BM, Uniyal A, et al. Evaluation of the Performance Characteristics of 6 Rapid HIV Antibody Tests. Clinical Infectious Diseases. 2011; 52(2): 257-263.
4. O'Connell RJ, Merritt TM, Malia JA, et al. Performance of the OraQuick Rapid Antibody Test for Diagnosis of Human Immunodeficiency Virus Type 1 Infection in Patients with Various Levels of Exposure to Highly Active Antiretroviral Therapy. Journal of Clinical Microbiology. 2003; 41(5): 2153-2155.
5. O'Connell RJ, Agan BK, Anderson SA, et al. Sensitivity of the Multispot HIV-1/HIV-2 Rapid Test Using Samples from Human Immunodeficiency Virus Type 1-Positive Individuals with Various Levels of Exposure to Highly Active Antiretroviral Therapy. Journal of Clinical Microbiology.

Note: **See component labels and separate insert "CheckNOW™ HIV SELF TEST Kit Component Information" for further details on Single-Use Lancet , Alcohol Pad and Plaster.**

2°C 30°C	Store between 2-30°C		Consult instructions for use		Do not reuse		Manufacturer	MD	Medical device
REF	Catalogue number		Use-by date	LOT	Batch code	STERILE R	Sterilized using irradiation	CE	CE Mark
IVD	*In vitro* diagnostic medical device	Σ	Contains sufficient for <n> tests		Attention	EC REP	Authorized representative in the European Community / EU		

TECHNICAL SUPPORT

Europe & Middle East	Tel. +44 161 483 9032	Email: EME.techsupport@abbott.com
Africa	Tel. +27 10 500 9700	Email: ARCIS.techsupport@abbott.com
Asia Pacific	Tel. +61 7 3363 7100	Email: AP.techsupport@abbott.com
Taiwan	Tel. 00801 128036	Email: TW.techsupport@abbott.com
Russia & CIS	Tel. +7 499 403 9512	Email: ARCIS.techsupport@abbott.com
Latin America	Tel. +57 1 482 4033	Email: LA.techsupport@abbott.com
Brazil	Tel. 0800 111 3363	Email: LA.techsupport@abbott.com

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www.abbott.com/poct

CE 0123

C M Y K

Attention/注意:

1. The enclosed design will be applied to manufacture directly. Once approving the enclosed design, customer will accept all responsibility for the accuracy of the design. If an error is detected following the printing or manufacturing of a material, customer will be responsible for the cost of any inventory which is deemed unsuitable for sale. 所附的设计稿会直接应用于生产。客户批准所附的设计稿即代表客户已接受承担设计正确性的所有责任。如物料在随后的印刷和生产过程中发现有任何不适合销售的错误，客户将负责承担任何库存的费用。
2. Regulatory owner must ensure the compliance with all applicable regulations in the distribution territory. The applicable regulation means all federal, state and local laws, ordinances, rules, regulations, and mandatory ISO standards applicable to the design, development, manufacturer, control and marketing of the Product in the Territory. 法规所有人必须确保其销售区域适用法规的符合性。适用法规指的是所有联邦/州/地方性法律、法令、条例、规章以及强制的ISO标准，以用于产品在某区域的设计、开发、生产、控制和上市。

Regulatory owner's RA/RR: Regulatory owner's RA/Authorized Regulatory Representative

☐ US ■ OUS ☐ China

Description 描述	ABT CheckNOW CE IHI-402H EN PI	***Part Number*** PN 号码	1156183602	***Size*** 尺寸	420X297mm
Printing Contents 印刷内容	/	***L Number*** L 号码	/	***Size*** 尺寸	/
Designer 设计者	Sara	***Design Date/Version*** 设计日期/版本	June 17, 2021/C	***Mold Num.*** 模具号	/
Artwork Checked By 设计审核		***Material/ Checked By*** 材质/审核	70g双胶纸， 波浪四折+波浪三折(折法34)		
Approved by Regulatory owner's RA/RR / Date 法规所有人RA/RR 确认/日期		***Approved by US Customer*** US 客户确认/日期			
Approved by Affiliates QA / Date 关联公司QA确认/日期		***Approved by Marketing / Date*** 市场部确认/日期			
Approved by ABON RA / Date ABON 注册部 确认/日期		***Approved by PMT / Date*** 产品管理确认/日期			
Approved By ABON QA/Date ABON QA确认/日期					