WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: ADVANCED QUALITY HIV Self-Test
WHO reference number: PQDx 0372-017-01

The ADVANCED QUALITY HIV Self-Test with product code ITPW02155-TC1**,** manufactured by InTec Products, Inc., Rest-of-World regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 4 August 2025.

Summary of WHO prequalification assessment for ADVANCED QUALITY HIV Self-Test[1]

	Date	Outcome
Prequalification listing	4 August 2025	Listed
Dossier assessment	Not Applicable (N/A)	MR
Site inspection(s) of the quality management system	11 to 13 October 2023	MR
Product performance evaluation	4th quarter of 2018	MR

MR: Meets Requirements

***Change notification**

In 2025, InTec Products, Inc., submitted a change notification for their prequalified product to introduce a new configuration with an intended use specific to HIV self-testing (ADVANCED QUALITY HIV Self-Test). The new format was adapted from the corresponding professional use product (ONE STEP Anti-HIV (1&2) Test), for which a WHO prequalification assessment has already taken place. InTec Products, Inc., generated additional data to meet 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 self-testing[2].

[1] The manufacturing site inspection and product performance evaluation for the ONE STEP Anti-HIV (1&2) Test were considered from for the assessment of the ADVANCED QUALITY HIV Self-Test. The ONE STEP Anti-HIV (1&2) was prequalified in 2019. Based on the manufacturing site inspection and product performance evaluation, the ADVANCED QUALITY HIV Self-Test meets WHO prequalification requirements. Please refer to the WHO Prequalification of Diagnostics Programme Public Report for the ONE STEP Anti-HIV (1&2). https://extranet.who.int/prequal/WHOPR/public-report-one-step-anti-hiv-12-test-pqdx-0372-017-00

[2] https://apps.who.int/iris/bitstream/handle/10665/251857/9789241511742-eng.pdf;jsessionid=153ABC9D88E7623A1AD1DF946A22B4C8?sequence=1

Intended use

According to the intended use claim from InTec Products, Inc., "*The Advanced Quality HIV Self-Test is a colloidal gold enhanced, rapid immunochromatographic assay for qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) in human fingerstick whole blood. The 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.*"

Assay description

According to the claim of assay description from InTec Products, Inc., "*The test band region on the nitrocellulose membrane is pre-coated with recombinant HIV antigen (containing predominant epitope of gp41, gp120 of HIV-1 and predominant epitope of gp36 of HIV-2), and the control band region on the nitrocellulose membrane is pre-coated with sheep anti-rabbit IgG. The fiberglass is pre-coated with recombinant HIV antigen (containing predominant epitope of gp41, gp120 of HIV-1 and predominant epitope of gp36 of HIV-2) conjugated with colloidal gold and rabbit IgG conjugated with colloidal gold. For positive specimens, HIV antigen conjugated with colloidal gold reacts with HIV antibody in whole blood, forming a colloidal gold conjugate/ HIV antibody complex. The complex migrates through the test strip and is captured by the recombinant HIV antigen immobilized in the test band region, forming a test band. A negative specimen will not produce a test band due to the absence of colloidal gold conjugate/HIV antibody complex. To ensure assay validity, a purplish red control band in the control region will appear regardless of test result. The assay is only valid when the control band appears.*"

Test kit contents

- 1 - Test card with desiccant and dropper
- 1 - Alcohol swab
- 1 - Sample diluent
- 1 - Instructions for use
- 1 - Sterile safety lancet

Materials required but not provided

- Timer
- Tissue
- Seal bag or biohazard trash bag
- Bandage.

Storage

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

Shelf-life upon manufacture

24 months (test kit and buffer).

Warnings/limitations

Please refer to the manufacturer's Instructions for Use (IFU) attached to this public assessment report.

Labelling

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

1. Labels

1.1 Labels

01.05.13.055-250704

Advanced Quality
HIV Self-Test

The 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.

Contents:

1 Test card
1 Desiccant
1 Dropper
1 Sample diluent
1 Sterile safety lancet
1 Alcohol swab
1 Instructions for use

REF LOT

For symbol glossary, refer to instructions for use

InTec PRODUCTS, INC.
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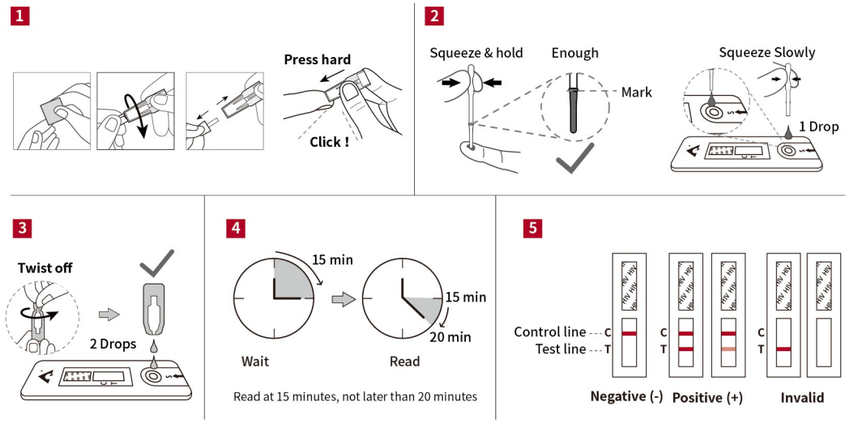
Website: www.intecasi.com
Email: intecproducts@asintec.com

HOW TO USE
Please refer to IFU

VIEW INSTRUCTIONS

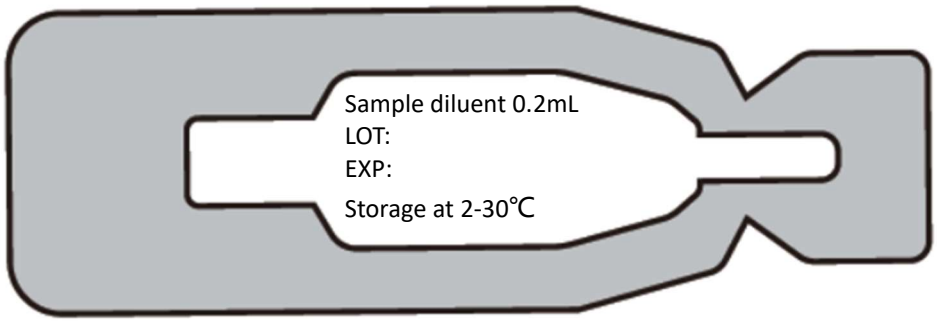


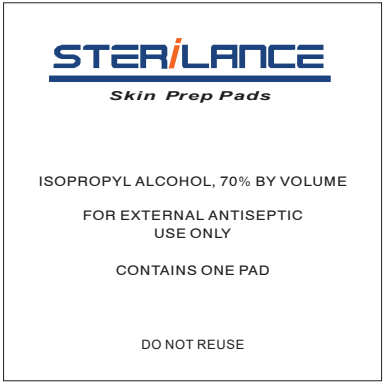
Advanced Quality HIV Self-Test
(Whole blood)

REF ITPW02155-TC1

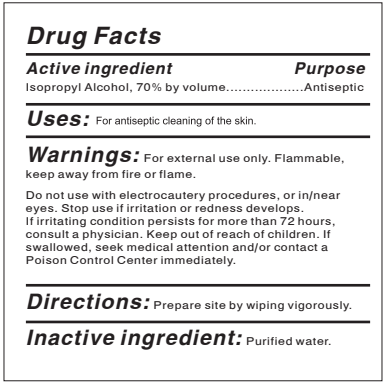
LOT

Contents
1 Test card
1 Desiccant
1 Plastic dropper


Sample diluent 0.2mL
LOT:
EXP:
Storage at 2-30℃


STERILANCE
Skin Prep Pads
ISOPROPYL ALCOHOL, 70% BY VOLUME
FOR EXTERNAL ANTISEPTIC
USE ONLY
CONTAINS ONE PAD
DO NOT REUSE

Front


Drug Facts
Active ingredient
Purpose
Isopropyl Alcohol, 70% by volume.....Antiseptic
Uses: For antiseptic cleaning of the skin.
Warnings: For external use only. Flammable, keep away from fire or flame.
Do not use with electrocautery procedures, or in/near eyes. Stop use if irritation or redness develops.
If irritating condition persists for more than 72 hours, consult a physician. Keep out of reach of children. If swallowed, seek medical attention and/or contact a Poison Control Center immediately.
Directions: Prepare site by wiping vigorously.
Inactive ingredient: Purified water.

Back

2.0 Instructions for use[3]

[3] 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.

Advanced Quality
HIV Self-Test

01.05.14.149-250701

ENGLISH

Please read all the steps before testing. The instructions should be followed carefully to ensure an accurate result.

VIEW INSTRUCTIONS

Do not self test:
- if you have a bleeding disorder or you are on antiretroviral therapy(ART)
- if the test kit pouch is damaged or any components are damaged
- if the test kit or its components have been used
- if it has passed the expiry date on the packaging

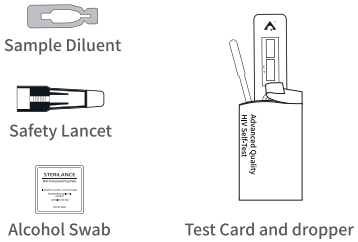
Caution:
For children under the age of 12 or elderly people, the testing procedure must be performed by the guardian or with guardian's consent.

Step 1 : Preparation

1. Prepare a timer and tissue, bandage and biohazard trash bag.

2. Open the pouch and place all materials on a flat, clean table with bright light.

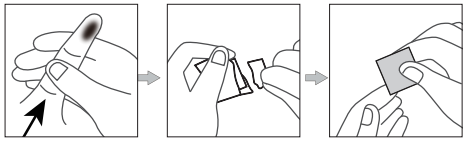
Note: The pictures shown below are for reference only.



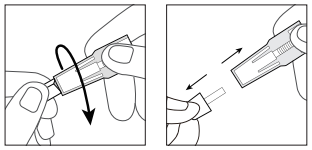
3. Wash hands and dry them before testing.

Step 2 : Collect blood

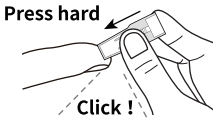
4. Rub finger until warm to increase circulation. Open the alcohol swab and clean the finger with swab.



5. Twist the lancet cap until it is removed.

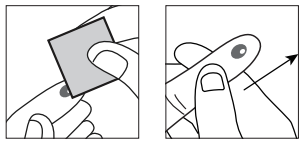


6. Place the lancet on the finger, and press hard to trigger it. Do not remove the device until an audible click is heard.

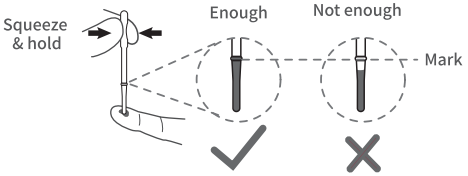


The lancet only pricks once!

7. Wipe away the first drop of blood. Massage finger to create **a whole drop of blood.**



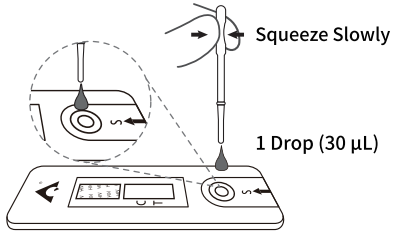
8. Squeeze dropper bulb and hold while dipping into blood, and then release to collect blood to fill the dropper up to the marked line.



Avoid forming bubbles when collecting blood

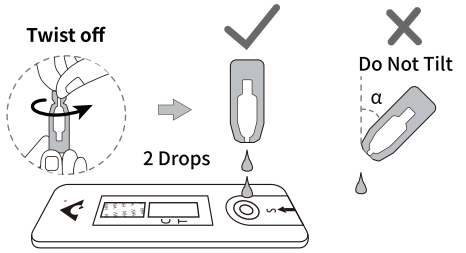
Step 3 : Test

9. Add 1 drop (30 µL) of blood into the **"S"** well, by gently squeezing dropper bulb.

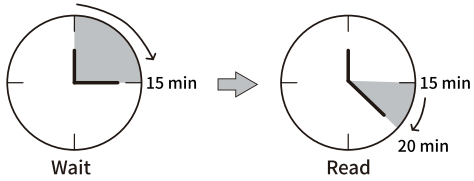


If your finger is still bleeding use a tissue or bandage.

10. Twist off the tip of sample diluent immediately after adding blood. Hold vertically to add 2 drops into the **"S"** well.

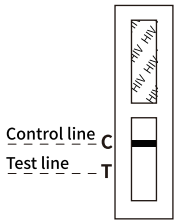


11. Read the results after **15 minutes**, but no more than **20 minutes.**



Step 4 : Read result

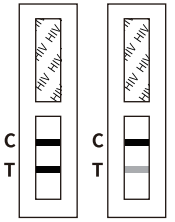
Negative (-)



One line appears in the "C" area and no line in "T" area.

Test again in 3 months from latest risk of HIV exposure.
Negative results cannot rule out the possibility of early HIV infection.

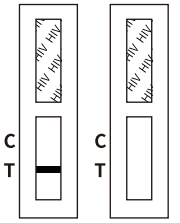
Positive (+)



One line appears in the "C" area, and one line in "T" area, no matter how faint the "T" line.

GO TO CLINIC for confirmatory testing as soon as possible.

Invalid

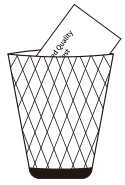


No line appears in the "C" area, even if a line appears in the "T" area.

Test again with a new kit or go to clinic for confirmatory testing.

Step 5 : Disposal

Put all items back into the biohazard trash bag or seal bag or pouch.



Dispose of the used pouch in the waste bin.

Blood can transmit infectious, so be cautious and clean up any spills. Discard with normal household waste or in accordance with local regulations.

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Questions and answers

About HIV

1. What is HIV and AIDS?

The HIV (human immunodeficiency virus) is the virus that causes AIDS (Acquired Immunodeficiency Syndrome) if infected person is not received treatment. Once a person gets HIV infected, the virus starts to attack his/her immune system, resulting in the human body gradually losing ability to defense against illness. There is no cure for the AIDS. However with proper medical care, AIDS can be controlled. People with HIV who has effective HIV treatment can live long, healthy live and protect their partners.

2. How is person infected by HIV?

HIV spreads through contact with body fluids of HIV infected persons, including blood, semen, vaginal fluids, rectal fluids and breast milk. Transmission can occur through unsafe sex. It can be result by receiving contaminated blood transfusions through sharing of syringes or needles. And from mother-to-infant during pregnancy, childbirth and breast feeding. HIV cannot be transmitted by casual contacts (e.g. sharing of food, clothing), saliva, casual kissing or insect bites etc.

About Test Result

1. What is the "Window Period"?

The window period for an HIV test refers to the time between HIV exposure and when a test can detect HIV in your body. The window period depends on the type of HIV test used[1]. There is No HIV test can detect HIV infection immediately after exposure. There is typically a window period of 23 days to 90 days[1] after exposure before HIV antibodies can be detected. Many HIV antibody rapid tests may give false-negative self-test results within the Window Period. According to the WHO guidelines, individuals with known or possible HIV exposure in the 6 to 12 weeks prior to testing should retest or seek facility-based testing at an appropriate interval based on the person's risk and type of test used[2].

2. What should I do if my test results is Negative?

It is critical to consider the window period (refer above Question 4). If the window period has passed, you are likely to be HIV negative. If within the window period since your latest HIV risk activity, you would need to retest in 3 months. If you are unsure, get advice from your doctor.

3. What should I do if my test results is Positive?

Go to a clinic as soon as possible. You should get laboratory testing to confirm positive result. HIV is preventable and you must avoid high risk sexual behaviors to prevent passing HIV to your partner.

4. I am worried I have been exposed to HIV in last few days, what should I do?

You should go to local clinic or emergency department as soon as possible, ideally within 72 hours, as you may be able to get a course of medication called "PEP" (Post-Exposure Prophylaxis) to prevent HIV infection after exposure.

Product Information

Intended use

The Advanced Quality HIV Self-Test is a colloidal gold enhanced, rapid immunochromatographic assay for qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) in human fingerstick whole blood. The 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.

Summary

Human immunodeficiency virus (HIV) is the pathogen of Acquired Immunodeficiency Syndrome (AIDS)3-4. The Advanced Quality HIV Self-Test is an easy, visual qualitative test that detects antibodies to HIV-1/2 in human fingerstick whole blood, and presents the result at 15 minutes, but not after 20 minutes.

The test band region on the nitrocellulose membrane is pre-coated with recombinant HIV antigen (containing predominant epitope of gp41, gp120 of HIV-1 and predominant epitope of gp36 of HIV-2), and the control band region on the nitrocellulose membrane is pre-coated with sheep anti-rabbit IgG. The fiberglass is pre-coated with recombinant HIV antigen (containing predominant epitope of gp41, gp120 of HIV-1 and predominant epitope of gp36 of HIV-2) conjugated with colloidal gold and rabbit IgG conjugated with colloidal gold. For positive specimens, HIV antigen conjugated with colloidal gold reacts with HIV antibody in whole blood, forming a colloidal gold conjugate/ HIV antibody complex. The complex migrates through the test strip and is captured by the recombinant HIV antigen immobilized in the test band region, forming a test band. A negative specimen will not produce a test band due to the absence of colloidal gold conjugate/HIV antibody complex. To ensure assay validity, a purplish red control band in the control region will appear regardless of test result. The assay is only valid when the control band appears.

Reagent and materials provided

1 - Test card with desiccant and dropper
1 - Sample diluent
1 - Sterile safety lancet
1 - Alcohol swab
1 - Instructions for use

Limitations

- The kit is designed to detect antibodies to HIV-1 and/or HIV-2 in human fingerstick whole blood. Specimens other than those specified may not supply accurate results and the device will not notify the user of such misuse.
- The intensity of test line does not necessarily correlate to the titer of antibody in the specimen.
- As this product is intended to detect antibodies against HIV from individuals, clinical diagnosis of HIV infection or AIDS should not be made only based on the results of the product.
- A negative result should not exclude the possibility of HIV infection. A false-negative result can occur in the following situations:
  - Recently acquired HIV infection, i.e. within the window period.
  - Low antibody levels which are below the detection limit of the test.
  - Have been on antiretroviral therapy (ART).
  - HIV antibodies in the patient that do not react with specific antigens utilized in the assay configuration. In exceptional cases this may lead to an observation of negative results.
  - High concentrations of a particular analyte.
  - Recently discovered type or subtype of HIV.

  For reasons above, care should be taken in interpreting negative results. Other clinical data (e.g., symptoms or risk factors) should be used in conjunction with the test results.
- A false-positive result can occur if you participated in an HIV vaccine clinical study, but it may not mean that you are HIV infected.
- If the sample diluent is added to test kit without any blood, the test result is invalid even if the control line appears.
- Use of hemolytic specimens, rheumatoid factors-containing specimens, hyperlipemia specimens or icteric specimens may lead to impairment to the test result.
- Only specimens with good fluidity and without hemolysis can be used with this test.

Warnings and precautions

- For in vitro diagnostic use IVD
- This product is for in vitro diagnosis of the infection of HIV only, other diseases cannot be analyzed with any component of this kit.
- Do not use expired test kits.
- Do not use the test kit or accessories if the seal or package is damaged.
- Do not use if the cap of safety lancets has already pulled off before use.
- Do not reuse the accessories. All the accessories are for single use.
- Do not use the test if you are under 12 years old. For children under the age of 12 or elderly people, testing must be performed by the guardian or with guardian's consent.

Storage conditions and stability

Store test kit at 2-30°C. Do not use the test kit if the expiry date on the pouch has passed over. Test kit should be used immediately after the foil pouch is open. Use the test kit at room temperature (10-30°C).

Performance characteristics

The diagnostic performance demonstrated diagnostic specificity of 100% (2000/2000) from HIV-negative samples and diagnostic sensitivity of 100% (600/600) from HIV-positive samples by professional users in European laboratory settings.

There were 900 untrained users from South Africa and China who participated in the clinical study in self-test settings. Among these participants, 17 were HIV positive and 883 were HIV negative. The diagnostic sensitivity was 100% (17/17) and the diagnostic specificity was 100% (863/863). The overall failure rate was 2.2% (20/900).

To confirm that other medical conditions (potentially interfering substances or cross reactants) do not affect the performance of Advanced Quality HIV Self-Test, HIV negative blood samples with those substances were tested. These included total protein, elevated IgM, IgG, Pregnancy, Hospitalized patients, Hemoglobin, Anti-Escherichia coli, HAMA, Bilirubin, Rheumatoid factors, ANA, SLE, Triglyceride, Multiple blood transfusions , Pregnant (multifarious) women , CMV, HAV, anti-HBc, anti-HBs, anti-HCV, anti-HEV, anti-HTLV-1/2, VZV, EBV, Malaria positive, Influenza A, Influenza B, Influenza A & Influenza B, Chagas, Citrate, EDTA, Heparin. And study result showed that the mentioned substances were tested negative, indicating that the above substances would not affect the specificity of the product.

Symbols

	CAUTION		KEEP DRY		DO NOT REUSE		USE-BY DATE
	KEEP AWAY FROM SUNLIGHT		CONSULT INSTRUCTIONS FOR USE	LOT	BATCH CODE		CONTAINS SUFFICIENT FOR <N> TESTS
REF	CATALOGUE NUMBER	IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE		MANUFACTURER		DATE OF MANUFACTURE
	TEMPERATURE LIMITATION		DO NOT USE IF PACKAGE IS DAMAGED	STERILE R	STERILIZED USING IRRADIATION		

References

1. Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention. June 22, 2022
2. World Health Organization. (2016). Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services. World Health Organization.
3. Blattner, W., Gallo, R.C. and Temin. H.M. HIV causes AIDS. Science. 241:515, 1988.
4. Curran, J.W., Morgan. W.M., Hardy, A.M., et al. The epidemiology of AIDS: Current status and future prospects. Science 1985; 229: 1352-7.

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