Size : 137 x 218 mm

QUALPRO HIV ™

Rapid Immunochromatography test for HIV - 1 and HIV - 2

DEVICE

INTENDED USE

QUALPRO HIV™, is a rapid, 3rd generation, qualitative, sandwich immunoassay for simultaneous and differential detection of total antibodies i.e. IgG, IgM, IgA etc. to HIV-1 and HIV-2 virus in human serum / plasma. For professional use.

SUMMARY

Acquired immuno deficiency syndrome (AIDS) is caused by at least two retroviruses, the HIV 1 and the HIV 2, collectively referred to as HIV 1 / 2. Antibodies to HIV 1 core protein p24, transmembrane protein (gp 41) and/or antibodies to HIV 2 transmembrane protein (gp 36) are prevalent in the sera of individuals with AIDS, ARC or at high risk of contracting AIDS. Detection of these antibodies indicates exposure to the HIV 1/2 virus.

PRINCIPLE

QUALPRO HIV™ utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. Highly purified antigens - gp41, gp120 and p24-O fusion polypeptide, representing HIV-1 and HIV-1 group "O" and synthetic peptide gp36 representing HIV-2 are stripped on the membrane as two separate test bands. An assay control forms the third band. Similar antigens are also coated on colloidal gold. A unique combination of synthetic peptides and recombinant antigens reduces cross-reactivity and enable better discrimination between HIV-1 & HIV-2 samples. As the test specimen flows through the membrane test assembly, the highly specific HIV-1/2 antigens-colloidal gold conjugate complexes with the HIV-1/2 specific antibodies in the specimen and travels on the membrane due to capillary action along with the rabbit globulin-colloidal gold conjugate. This complex moves further on the membrane to the test region where it is immobilized by the HIV-1/2 antigens coated on the membrane at two separate test regions for HIV-1 & HIV-2. This leads to the formation of colored band(s). The presence of colored band(s) in the test regions indicates the presence of antibodies to HIV-1/2 in the specimen. The unreacted conjugate and unbound complex, if any, along with rabbit globulin - gold conjugate move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region (C), forming a colored band. This control band acts as a procedural control and serves to validate the results.

REAGENTS AND MATERIALS SUPPLIED

QUALPRO HIV™ kit has the following components.

A. Individual pouched devices each comprising of:
   1. DEVICE Membrane test assembly: Stripped with HIV-1 and HIV-2 specific antigens and Agglutinating sera for rabbit globulin along with HIV specific antigen and rabbit globulin - gold conjugate.
   2. PIPETTE Disposable Plastic Sample Applicator.
   3. Desiccant Pouch

B. BUF Sample Running Buffer: Buffer containing surfactant and preservatives.

C. Package insert.

REF	402100050
Σ	50 Tests

STORAGE AND STABILITY

QUALPRO HIV™ is stable up to the expiry date mentioned on the label when stored at 4 - 30^{0}C. Once the pouch is opened, the membrane test assembly must be used immediately.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Disinfectant
2. Disposable gloves
3. Biohazard waste container

SAMPLE COLLECTION

1. **QUALPRO HIV**™ uses human serum / plasma as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. Preferably use fresh sample. However, specimen may be stored refrigerated (2–8^{0}C) for short duration. For long storage, freeze at –20 ^{0}C or below.
4. If serum is to be used as specimen, allow blood to clot completely. Centrifuge to obtain clear serum.
5. Repeated freezing and thawing of the specimen should be avoided.

6. Do not heat inactivate before use.
7. Do not use turbid, lipaemic and haemolysed serum/plasma.
8. Do not use haemolysed, clotted or contaminated specimens.
9. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
10. Refrigerated specimens must be brought to room temperature prior to testing.

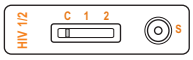
PRECAUTIONS

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Bring all reagents and specimen to room temperature before use.
3. Do not use beyond expiry date.
4. Read the instructions carefully before performing the test.
5. Handle all specimens as if potentially infectious.
6. Do not pipette any material by mouth.
7. Do not eat, drink or smoke in the area where testing is done.
8. Use protective clothing and wear gloves when handling samples.
9. Use absorbent sheet to cover the working area.
10. Immediately clean up any spills with sodium hypochlorite.
11. Dispose off all the reagents and material used as if they contain infectious agent.
12. Do not mix components of one lot with another.
13. If desiccant colour at the point of opening the pouch has turned from blue to white, another test assembly must be run.
14. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

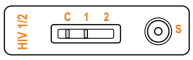
TEST PROCEDURE

1. Bring the sealed aluminium foil pouch of **QUALPRO HIV**™ membrane test assembly to room temperature.
2. Open a foil pouch by tearing along the "notch".
3. Remove the membrane test assembly and the sample applicator. Once opened, the membrane test assembly must be used immediately.
4. Label the membrane test assembly with specimen identity.
5. Place the membrane test assembly on a flat horizontal surface.
6. Carefully dispense **one drop (25µl)** of serum / plasma into the specimen well 'S' using the sample applicator provided.
7. Add **three drops** of sample running buffer into the same well 'S'.
8. Observe the development of visible coloured band at Test regions ('1' for HIV-1 and/or '2' for HIV-2).
9. Positive results may be observed within 20 minutes.
10. The test should be considered invalid if the control band 'C' does not appear. The test is also invalid if neither the control nor the test bands appear. Repeat the test with a new **QUALPRO HIV**™ membrane test assembly.

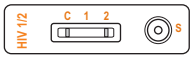
INTERPRETATION OF RESULTS



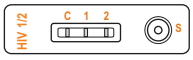
NEGATIVE
A coloured band appears only in the control area marked 'C'.



HIV-1 POSITIVE
A coloured band appears in the control area as well as in the area marked '1'. The sample is reactive for HIV-1.



HIV-2 POSITIVE
A coloured band appears in the control area as well as in the area marked '2'. The sample is reactive for HIV-2.



HIV-1 & HIV-2 DUAL POSITIVE
A coloured band appears in the control area as well as in the areas marked '1' & '2'. This indicates a mixed infection.

INVALID
The test should be considered invalid if the control band 'C' does not appear .The test is also invalid if only the test band and no control band appear. Repeat the test with a new **QUALPRO HIV**™ membrane test assembly.

PERFORMANCE CHARACTERISTICS

Internal Evaluation

Six hundred and twenty four samples-out of which, one hundred and fourteen HIV-1 Positive, HIV-2 positive and HIV1+2 dually positive specimen and five hundred and ten HIV negative samples were tested with **QUALPRO HIV**™ and compared with commercially available ELISA. The results are as shown below.

Specimen Data	Total	QUALPRO HIV™	Commercial ELISA
Total Number	624	624	624
HIV Positive	114	114	114
HIV Negative	510	509	510

Based on this evaluation:
Sensitivity of **QUALPRO HIV**™: 100%
Specificity of **QUALPRO HIV**™: 99.8%

External Evaluation – I (Diagnostic specificity):

A total of One thousand HIV-negative samples were tested with the **QUALPRO HIV**™ at a European blood Transfusion Centre. No false positive result was recorded. Therefore, the diagnostic specificity as per this evaluation is determined as **100 %**.

Number of samples tested	QUALPRO HIV™	
	Negative	Positive
1000	1000	0

External Evaluation – II (Diagnostic sensitivity):

Four Hundred and Sixty One HIV- positive samples were tested with the **QUALPRO HIV**™ in a reputed Laboratory in Europe. The samples included HIV-1, HIV-2 and HIV-1 non-B subtype (HIV-1 Subtype C prevalent in India) positive samples. All of them were found positive. Therefore, the diagnostic sensitivity as per this evaluation is determined as **100%**.

HIV Type	Number of samples tested	QUALPRO HIV™	
		Negative	Positive
HIV-1	320	0	320
HIV-2	101	0	101
HIV-1 subtype non-B	40	0	40

External Evaluation – III (Possible Interferences):

To check possible interferences with potentially cross-reactive sera, an independent evaluation was performed with five hundred samples in a reputed Laboratory in Europe. The sera sample includes clinical samples, pregnant women and related infections like HBV, HCV, HAV etc. The table below shows the results of **QUALPRO HIV**™ tested on a variety of samples containing possibly interfering substances:

Sample Type	Number of samples tested	QUALPRO HIV™	
		Negative	Positive
Clinical Specimens	200	200	0
Pregnant women	200	200	0
Related infections*	100	100	0

*Related infections: These are samples (total 100 Nos.) from other infectious disease that potentially interfere with anti-HIV immunoassays. The following table depicts the details:

Sample Type	No. of samples tested
HBsAg –positive	20
Anti-HCV positive	20
Anti-HTLV positive	15
Anti-HAV IgM positive	3
Anti-parvovirus B19 positive	15
Anti-Rubella positive	10
Anti-HBsAg	17
TOTAL	**100**

External Evaluation – IV (Seroconversion panel sera evaluations)
Thirty commercially available seroconversion panels from Boston Biomedica Inc., USA that contains a total of one hundred and seventy four samples was compared with commercially available ELISA's registered in Europe in reputed European laboratories. The results of **QUALPRO HIV**™ were found to be comparable with the said ELISA's.

Precision
Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive HIV samples. No variations were found in the outcome of the different tests.

LIMITATIONS

(1) **QUALPRO HIV**™ alone cannot be used to diagnose HIV infection even if the sample is repeatedly reactive or has high intensity of bands. (2) A negative result with **QUALPRO HIV**™ does not preclude the possibility of exposure to or infection with HIV. (3) Presence of a band at the test region(s) even if low in intensity or formation is a positive result. (4) The deliberate slow reaction kinetics of **QUALPRO HIV**™ is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity. (5) Most positive results develop within 20 minutes. However, certain sera samples may take a longer time to flow. Therefore, negatives should be confirmed only at 30 minutes .Do not read results after 30 minutes. (6) Since HIV-1 and HIV-2 viruses are similar in genomic structure and morphology, antibodies to them may cross react. Reactive test bands for both HIV-1 and HIV-2 do not necessarily imply mixed infection. However, to reduce cross-reactivity & better discrimination, **QUALPRO HIV**™ uses a synthetic peptide gp36 with highly conserved epitopes for HIV-2 detection instead of recombinant gp36 antigen. Despite this some HIV-2 sera may show both the bands with **QUALPRO HIV**™. (7) As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated. (8) **QUALPRO HIV**™ should only be used as a screening test and its results should be confirmed by other supplemental methods before taking clinical decisions.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1) Centers for Disease Control, Update on Acquired Immune Deficiency Syndrome (AIDS) MMWR 1982; 31:507.(2) Popovic, M., et.al, Detection Isolation and continuous production of Cytopathic Retroviruses (HTLV-III) from patients with AIDS and pre –AIDS. Science 1984; 224:497. (3) Gallo, R. C., et. al. Frequent detection and isolation of Cytopathic Retroviruses (HTLV-III) from patients with AIDS and a risk for AIDS. Science 1984; 224:500. (4) Carlson, J. R.,et.al, AIDS serology testing in low and high risk groups. JAMA 1985;253:3405. (5) Hashida S et. al. Earlier Detection of Human Immunodeficiency Virus Type 1 p24 Antigen and Immunoglobulin G and M Antibodies to p17 Antigen in Seroconversion Serum Panels by Immune Complex Transfer Enzyme Immunoassays. Clinical and Diagnostic Laboratory Immunology, Nov. 2000, p. 872-881 Vol. 7, No. 6. (6) Dorn J et. al. Analysis of Genetic Variability within the Immunodominant Epitopes of Envelope gp41 from Human Immunodeficiency Virus Type 1 (HIV-1) Group M and Its Impact on HIV-1 Antibody Detection. Journal of Clinical Microbiology, Feb. 2000, p. 773-780 Vol. 38, No. 2. (7) Vanhems P et al. HIV seroconversion interval and demographic characteristics: no evidence of selection bias. Sex Transm Inf 2001;77:446-448. (8) Ngan CCL et. al. Alternative Strategies for Confirmation of Human Immunodeficiency Virus Infection Require Judicious Use. Journal of Clinical Microbiology. Jan. 2002, p. 314-315 Vol. 40, No. 1. (9) Persaud D et. al. Latency in Human Immunodeficiency Virus Type 1 Infection: No Easy Answers. Journal of Virology, Feb. 2003, p. 1659-1665 Vol. 77, No. 3. (10) Gupta V and Gupta S. Laboratory Markers Associated with Progression of HIV Infection. Indian Journal of Medical Microbiology, (2004) 22 (1):7-15. (11)Data on file: Qualpro Diagnostics.

SYMBOL KEYS

Temperature Limitation	Consult Instructions for use	Date of Manufacture	LOT Batch Number / Lot Number	Do not reuse
Manufacturer	IVD *In vitro* Diagnostic Medical Device	DEVICE Device	BUF Sample Running Buffer	This side up
Use by	REF Catalogue Number	PIPETTE Disposable Plastic Sample Applicator	Σ Contains sufficient for <n> tests	

Manufactured by:

Qualpro Diagnostics

A Division of Tulip Diagnostics (P) Ltd.

88/89, Phase II C, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.

Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

0821/VER-02

Size : 65 x 125 mm

QUALPRO HIV ™

DEVICE

Rapid Immunochromatographic Test for HIV 1 / 2 Antibodies

CONTAINS ONE MEMBRANE TEST ASSEMBLY WITH DESICCANT AND SAMPLE APPLICATOR

IVD IN VITRO DIAGNOSTIC MEDICAL DEVICE NOT FOR MEDICINAL USE

FOR SINGLE USE ONLY. DO NOT REUSE

4°C 30°C STORE BETWEEN 4°C TO 30°C

REFER PACKAGE INSERT FOR INSTRUCTIONS BEFORE USE

Σ 1

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Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

Size : 65 x 125 mm

M.L. No. : .

Lot No. : .

Mfg. Dt. : .

Exp. Dt. : .

LOT

0317/VER-01

Size : 125 x 90 mm

Contents:
- 50 x Test devices.
- 2 x Sample running buffer bottles.
- 50 x Disposable sample applicators.
- 1 x Package insert.

DEVICE	50
BUF	2
PIPETTE	50
	1

REF Cat No.: 402100050

8 906010 980580

4°C – 30°C Store at 4°C to 30°C
Do Not Freeze

M. L. No.: 963

(DO NOT ACCEPT IF THE SEAL IS BROKEN)

50 TESTS

Σ 50

QUALPRO HIV™

DEVICE

Rapid Immunochromatography Test for HIV 1 & HIV 2
(Serum / Plasma)

0317/VER-01

70 x 18 mm

IVD For in vitro diagnostic use only
Not for medicinal use
Read package insert for instructions before use

Manufactured by:
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QUALPRO HIV™
SAMPLE RUNNING BUFFER
BUF

4°C – 30°C Store at 4°C to 30°C
Do Not Freeze

M.L. No.: 963
Lot No. :
Mfg. Dt. :
Exp.Dt. :
Vol. :

VER-01