



राष्ट्रीय एड्स अनुसंधान संस्थान  
**NATIONAL AIDS RESEARCH INSTITUTE**  
भारतीय आयुर्विज्ञान अनुसंधान परिषद  
(INDIAN COUNCIL OF MEDICAL RESEARCH)

NARI/SER/2009/231

To,  
Santosh P.  
Product Manager  
Tulip Diagnostics (P)ltd.  
Gitanjali, Dr. Antonic Do Rego Bagh,  
Alto Santa Cruz  
Bambolim Complex Post Office  
Goa 403202

Date:25/05/09

Dear Sir

This is in reference to your letter dated 15/05/09 regarding the evaluation of RETROSCREEN HIV, batch no. 48071, expiry date 2011/02. The report on the evaluation of the same is enclosed herewith.

With Regards.

Yours sincerely,

Dr. A. R. Risbud  
Scientist F

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एम. आई. डि. सी., भोसरी,  
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(\* National AIDS Research Institute (NARI) is a WHO Collaborated center for HIV diagnostics and monitoring of antiretroviral therapy.)

## Evaluation Report of the kit detecting HIV 1&2 antibodies

**Name of the assay kit and product code**

**RETRO SCREEN HIV**

Retroscreen HIV is a rapid ,third generation, qualitative, sandwich immunoassay for the simultaneous and differential detection of total antibodies i. e. IgG, IgM, IgA etc. to the HIV1 and HIV2 virus in serum or plasma .

**Lot No. 48071**

**Expiry:2011/02**

**Manufacturer**

Qulapro Diagnostics  
88/89, Phase II C ,  
Verma Industrial Estate,  
Verna, Goa 403 722

**Name of the organization performing evaluation :**

National AIDS Research Institute  
G-73, MIDC, Bhosari, Pune – 411026.

**Scope / Purpose/ Objective of evaluation :**

To evaluate its performance on serum

**Description of kit :**

**(A) General information about the assay kit**

- **Type of assay:** - Rapid immunochromatographic test
- **Source of antigen:** Highly purified antigens gp41, gp120 and p24-0 fusion polypeptide, representing HIV-1 and HIV-1 group "O" and synthetic peptide gp36 representing HIV-2.
- **Type of solid phase:** Membrane of the test assembly coated with HIV-1 & HIV-2 recombinant proteins.

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Website : www.nari-icmr.res.in

- **Contents** : The assay is available in kits of 50 tests. It consists of :
  - 1) Retroscreen HIV membrane test assembly comprises of HIV specific recombinant antigen-colloidal gold conjugate co-dispensed with rabbit IgG colloidal gold conjugate; predispensed with HIV specific recombinant antigen at region and goat anti-rabbit antiserum predispensed at the region C .
  - 2) Sample Running Buffer
- Controls : Inbuilt control
- Conjugate and conjugate diluent : Conjugate: colloidal gold conjugate  
Conjugate diluent: not applicable
- Dimensions (cm) of kit (w-l-h): 11-21-14.2 cm
- Labels: Clearly labeled.
- Quantity of reagents: sufficient quantity.
- Manual of instructions for use of the assay kit: The instructions are clear.
- Storage conditions: At 4-30° C.
- Shelf life: Approximately one year

**B) Operational aspects:**

Stability after opening/preparation: stable until expiration date if stored at 4-30° C

● **Samples:**

Sample type : Human serum or plasma  
 Sample size : One drop of serum or plasma (25µl)  
 Number of samples per test run : Minimum : 1; Maximum : 49

● **Procedural details :**

Incubation temperature : Room temperature  
 Time required to perform the assay: 20 minutes.  
 Equipments not supplied in the kit : Timer.

- **Details of the panel :**

Panel of sera tested : A total of 90 sera including 45 confirmed anti-HIV positive sera and 45 confirmed anti-HIV negative sera.

To determine the HIV serological status, each serum specimen included in the evaluation panel was first screened with commercially available three ELISA and three rapid tests. Specimens found negative in all ELISA and rapid tests were considered to be anti-HIV negative. The samples positive in all these tests were confirmed by Western Blot assay. All reference assays were interpreted according to the instructions given by the manufacturer.

- **Validity criteria :**

The test should be considered invalid if the control band “C” does not appear. The test is also invalid if only the test band & no control band appear.

- **Interpretation :**

1) **Negative test result :** A colored band appears only in the control area marked “C”

2) **Positive test result :** a) Colored band appears in the control area as well as in the area marked “1”. The sample is reactive for HIV-1.

b) Colored band appears in the control area as well as in the area marked “2”. The sample is reactive for HIV-2.

c) Colored band appears in the control area as well as in the areas marked “1” & “2”. This indicates a mixed infection.

**C ) Results :**

- **No. of kits used for evaluation - Two ( 50 tests)**

- **Lot. No : 48071** ● **Expiry Date : 2011/02**

- **Sensitivity and specificity of the kit :**

Retroscreen HIV	Standard Test		
	Pos	Neg	Total
Pos.	45	_____	45
Neg	_____	45	45
Total	45	45	90

Sensitivity : 100 %

Specificity : 100 %

• **Kit Appraisal by the technician :**

	Rating	Poor	Satisfactory	Good	Excellent
Kit instructions	clarity				X
	presentation				X
	content				X
	safety instructions				X
Reagent & packing					X
Labeling					X
Ease of performance					X
Interpretation clarity				X	



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