



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

NARI/SER/2009/232

To,
Santosh P.
Product Manager
Tulip Diagnostics (P)ltd.
Gitanjali, Dr. Antonic Do Rego Bagh,
Alto Santacruz
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 RETROQUIC HIV, batch no. 45203, expiry date 2010/03 . 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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(* 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

Retroquic HIV

Retroquic - HIV is a membrane based flow through immunoassay for the detection of antibodies to HIV-1 and HIV-2 in human serum and plasma

Lot No. 45203

Expiry:2010/03

Manufacturer :

Qualpro Diagnostics
88/89, Phase IIC,
Verna 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 :** membrane based flow through immunoassay
- **Source of antigen :** Highly purified synthetic peptides of gp120 and gp41 (HIV-1) and gp36 (HIV-2)
- **Type of solid phase :** Membrane of the test assembly coated with HIV-1 & HIV-2 recombinant proteins.

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- **Contents :**

The assay is available in kits of 50 tests. Each test kit contains :

- 1) Ready to use individually pouched , flow through test devices striped with HIV-1 specific purified synthetic peptides at test region “1” and HIV-2 specific purified synthetic peptides at test region “2” and a blue dyed protein A based control band at region “C” along with a specimen dropper and desiccant.
- 2) Dropper bottle with ready to use wash buffer solution
- 3) dropper bottle with ready to use protein A conjugated gold solution
- 4) package insert.

- **Controls :** - Inbuilt control

- **Conjugate and conjugate diluent:** Conjugate: protein A conjugated gold solution
Conjugate diluent: not applicable

- **Substrate and substrate diluent:** not applicable

- **Dimensions (cm) of kit (w-l-h):** 11- 31-7 cm (50 tests)

- **Labels:** clearly labeled.

- **Quantity of reagents:** sufficient quantity.

- **Manual of instructions for use of the assay kit:** The instructions are clear.

- **Storage conditions:** 2-8° C.

- **Shelf life:** approximately one year

B) Operational aspects

Stability after opening/preparation: stable until expiration date if stored at 2-8° C

Samples :

- Sample type: Human serum / plasma
- Sample size: one drop (25 ul)
- Number of samples per test run: Minimum : 1; Maximum : 49

- **Procedural details :**

Incubation temperature : Room temperature

Time required to perform the assay: 5 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 neither the test band nor the control band appears.

• **Interpretation :** Negative test result : Appearance of only one control band corresponding to control region "C".

Positive test result : In addition to control band C, appearance of reactive band at test region "1" indicates specimen is positive for antibodies to HIV-1.

In addition to control band C, appearance of reactive band at test region "2" indicates specimen is positive for antibodies to HIV-2.

In addition to control band C, appearance of reactive bands at test regions 1 and 2 indicate specimen is positive for antibodies to HIV-1 and HIV-2.

C) Results :

- **No. of kits used for evaluation** – Two (50 tests)
- **Lot. No : 45203 Expiry Date : 2010/03**
- **Sensitivity and specificity of the kit :**

Retroquic 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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