CE 0483

Automated Strip Interpretation

*recom*Line HIV-1 & HIV-2 IgG

Strip-Immunoassay with antigens produced by recombinant techniques for the detection of IgG antibodies against HIV-1 and HIV-2

Acquired Immunodeficiency Syndrome (AIDS) was described as separate disease pattern in 1981 and the Human immunodeficiency Virus (HIV) was identified as the causative pathogen in 1983. The virus is mainly transmitted through blood or sexual contact.

The greatest challenges in HIV serology are early detection of the infection and reliable detection of all HIV variants. Solving these two problems

- Increases the safety of blood donations and blood products
- Helps to prevent the further spread of HIV infections
- Shortens response times of individual HIV tests after contact (e.g. needle stick injuries)

Because of the serious consequences of a positive result, positive screening tests must be verified using a confirmatory test. The *recom*Line HIV-1 & HIV-2 IgG test solely uses recombinant antigens based on the ENV, POL and GAG gene segments and allows simple and safe confirmation of HIV screening results.

React. Control
Conjugate Contr. IgG

Cut-off Contr.

gp120
gp41

p51
p31

p24

p17

gp105

gp36
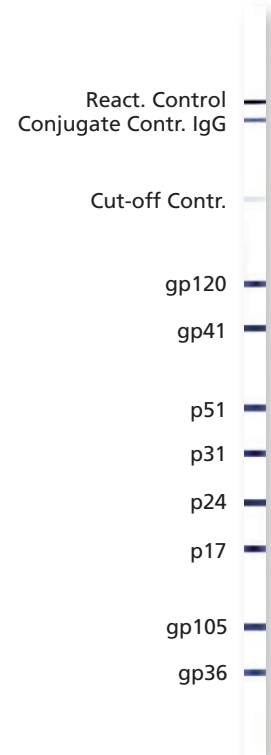
Product advantages

- Recombinant antigens
  - ➢ Use of 8 serologically relevant HIV antigens
  - ➢ Easy and clear interpretation due to easy readable bands
  - ➢ Determination of the HIV type on a single strip
- Highest specificity - unmatched in comparison with corresponding HIV confirmatory tests
- 100% sensitivity
- Very high seroconversion sensitivity for an early stage diagnosis
- Control band on every strip
- Antibody detection of different subtypes of HIV-1 like group M and group O
- Easy test procedure; automation possible
- Easy and objective evaluation and documentation by *recom*Scan software
- CE label: The *recom*Line HIV-1 & HIV-2 IgG meets the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

Recombinant HIV antigens

Antigen	Gene region	Function/localisation
gp120	ENV HIV-1	Glycoprotein, component of outer membrane of HIV-1
gp41	ENV HIV-1	Component of outer membrane of HIV-1
p51	POL	Reverse transcriptase of HIV-1
p31	POL	Integrase of HIV-1
p24	GAG	Capsid protein of HIV-1
p17	GAG	Matrix protein of HIV-1
gp105	ENV HIV-2	Glycoprotein, component of outer membrane of HIV-2
gp36	ENV HIV-2	Transmembrane glycoprotein, component of outer membrane of HIV-2

Test Principle and Procedure
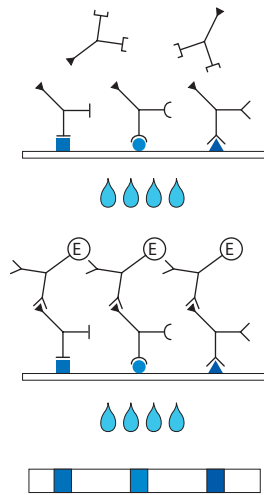
1st Incubation — A test strip loaded with HIV antigens is incubated with diluted serum or plasma in a dish for **3 hours**.

wash 3 times

2nd Inkubation — Peroxidase conjugated anti-human antibodies (IgG specific) are added. Incubate for **45 minutes**.

wash 3 times

Color reaction — **8 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

Evaluation

Sensitivity

recomLine HIV-1 & HIV-2	HIV-1* (n = 238)	HIV-2 (n = 104)
Negative	0	0
Borderline	0	1
Positive	238	103
Sensitivity	100 %	100 %

Differentiation between HIV 1 and HIV 2

recomLine HIV-1 & HIV-2	HIV-1* (n = 238)	HIV-2 (n = 103)
Positive for HIV-1	233	0
Positive for HIV-2	0	101
Differentiation not possible	5	2
Correct differentiation	98 %	98 %

* including samples of subtypes A, B, C, D, F, G, CRF01, CRF02 from group M and group O

Specificity

recomLine HIV-1 & HIV-2	Blood donors (n = 300)	Clinical samples (n = 340)	Potentially interfering samples (n = 56)
Negative	298	336	54
Borderline	2	4	2
Positive	0	0	0
Specificity	99,3 %	98,5 %	96,4 %

Article No.

6672	**recomLine HIV-1 & HIV-2 IgG** Reagents for 20 determinations
Included in the kit	**Positive control serum IgG**, 140 µl **Negative control serum IgG**, 140 µl

Storage

+2°C - +8°C