LIMITATIONS OF THE TEST

ImmunoFlow HIV1-HIV2 kit alone cannot be used to diagnose infection with HIV even if the sample is repeatedly reactive or has high intensity of bands. Clinical diagnosis can only be established by a physician. A negative result does not preclude the possibility of exposure to or infection with HIV. Since HIV 1 and HIV 2 viruses are similar in genomic structure and morphology and antibodies to them have (30-70 %) cross reactivity, reactive test bands for HIV1 and HIV 2 do not necessarily imply mixed infection with HIV 1 and HIV 2.

BIBLIOGRAPHY

1- 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.
2- Carlson, J. R.,et.al., AIDS serology testing in low and high risk groups. JAMA 1985;253:3405
3- Centers for Disease Control, Update on Acquired Immune Deficiency Syndrome (AIDS) MMWR 1982;31:507
4- 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.

SYMBOLS USED ON THE

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
I V D	In vitro diagnostic medical device
CARD	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Sample running buffer
	Manufactured By
	Date of Manufacture
	Contains sufficient <n> tests

Aspect Court, 4 Temple Row
Birmingham B2 5HG
UNITED KINGDOM

CE
0459

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ImmunoFlow HIV 1- HIV 2

Rapid test for the detection and differentiation of Antibodies to Human Immunodeficiency Virus (HIV 1 and HIV 2) in Serum.
Cat N° HIV-110022

INTRODUCTION

ImmunoFlow HIV1-HIV2 is intended to be used for simultaneous and differential detection of antibodies to HIV 1 and HIV 2 virus in human serum.

SUMMARY

ImmunoFlow HIV1-HIV2 is a third generation immunochromatographic method for simultaneous and differential detection of antibodies to HIV 1 and 2 virus in human serum . Highly purified antigens gp 41-120 and 'O' fusion polypeptide representing HIV- 1 and synthetic peptide gp 36 representing HIV-2 are stripped on the membrane as two separate test bands. An assay control forms the third band. The same antigens are also coated on colloidal gold.

PRINCIPLE

The membrane of ImmunoFlow HIV1-HIV2 is stripped separately with HIV 1 and 2 specific antigens and a reagent control. Specimen is added and allowed to move along the membrane. Any antibodies, if present, bind to their respective antigens coated on the colloidal gold forming an antibody-antigen-gold complex. This complex moves along the membrane and gets captured by the HIV specific antigens coated on the membrane forming a red/purple coloured band. The unbound material moves to the other end of the membrane where goat anti-rabbit IgG captures rabbit IgG gold forming the control band.

REAGENTS AND MATERIALS SUPPLIED

ImmunoFlow HIV1-HIV2 kit has the following components:

1. Device: Stripped with HIV 1 and 2 specific antigens and goat anti rabbit IgG along with HIV specific antigen and rabbit IgG gold conjugate. Individually pouched along with sample dropper and desiccant.
2. Sample running buffer: Tris buffer with 1.5 % Tween 20 and 0.1 % sodium azide.
3. Product insert.

STORAGE AND STABILITY

The sealed pouches in the test kit and the sample running buffer may be stored between 4°C to 30°C for the duration of the shelf life as indicated on the pouch and the vial.
After first opening of the sample running buffer vial, the buffer is stable untill the expiration date, if kept at 4°C to 30°C. Do not freeze the kit or components.

NOTES

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Sample running buffer contains sodium azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing.
7. If the colour of the desiccant has turned from blue to white at the time of opening the pouch, another test device must be run.

SPECIMEN COLLECTION AND PREPARATION

1. No prior preparation of the patient is required.
2. Collect blood specimen by venipuncture according to the standard procedure.
3. Specimen should be free of particulate matter and microbial contamination.
4. Preferably use fresh sample. However, specimen can be stored refrigerated for 24 hours. Maximun of two freeze/thaw cycles are allowed. For long storage, freeze at -20°C or below. Specimen should not be frozen and thawed repeatedly.
5. Do not heat inactivate before use.
6. Specimen containing precipitate or particulate matter should be clarified by centrifugation prior to use.
7. Do not use turbid,lipaemic, haemolysed,clotted or contaminated specimens

Precautions under the HIV regulations:

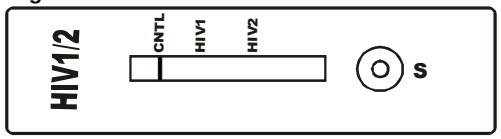
1. For professional use only, not to be used by the general public.
2. Negative result may not have detected recently acquired HIV infection.
3. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.
4. Bring all reagents and specimen to room temperature before use.
5. Do not pipette any material by mouth.
6. Do not eat, drink or smoke in the area where testing is done.
7. Use protective clothing and wear gloves when handling samples.
8. Use absorbent sheet to cover the working area.
9. Immediately clean up any spills with sodium hypochlorite.
10. Dispose off all the reagents and material used as if they contain infectious agent.
11. Neutralize acid containing waste before adding hypochlorite.
12. Do not use kit after the expiry date.
13. Do not mix components of one kit with another

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1.Bring all reagents and specimen to room temperature before use.
2.Take out required number of devices and label them.
3.Add one drop (25 µl) of serum in the sample well marked 'S'
4.Add two drops sample running buffer in the same well marked 'S'
5.Read results after 15 minutes.
6.The time may be extended to 30 minutes in case background is not cleared at 15 minutes to read the results correctly.
7.Do not read results after 30 minutes.

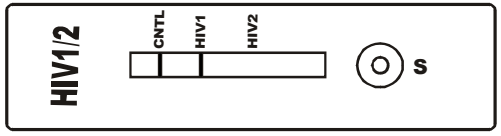
Interpretation of Results:

Negative

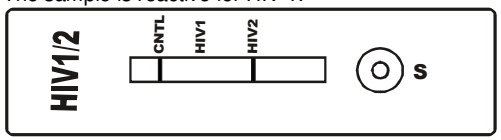


A coloured band appears only in the control area marked "CNTL".

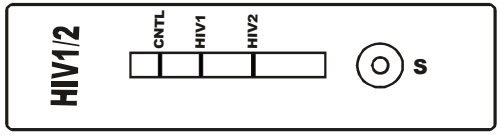
Positive



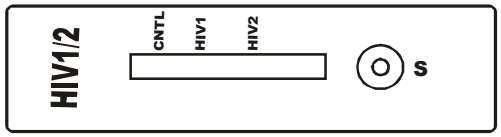
Positive HIV-1: A coloured band appears in control area as well as in the area marked "HIV1". The sample is reactive for HIV 1.



Positive HIV-2: A coloured band appears in control area as well as in the area marked "HIV2". The sample is reactive for HIV 2.



Positive HIV-1/2: A coloured band appears in control area as well as in the area marked "HIV1" and "HIV2". The sample is reactive for HIV 1 and HIV 2.



Invalid
No band appears in the control area. The test should be repeated with fresh device.

1. Although, depending on the concentration of antibodies to HIV in the specimen, positive results may start appearing as early as 2 minutes, negative results must be confirmed only at the end of fifteen minutes.
2. Some sample may take a longer time to clear. In such cases the result may be confirmed at 30 minutes. Do not read results after 30 minutes.

REMARK:

To control the proper test performance, it is recommended to include internal control samples.

TEST PERFORMANCE

1. **Diagnostic specificity:**

A total of 1000 samples were tested with the ImmunoFlow HIV1-HIV2 at an European blood Transfusion Centre. No false positive was recorded. The diagnostic specificity is determined as 100%.

Centre	Number of samples tested	ImmunoFlow HIV1-HIV2	
		Negative	Positive
A	1000	1000	0
Total	1000	1000 (100%)	0

2. **Diagnostic sensitivity:**

501 HIV positive samples were tested with the ImmunoFlow HIV1-HIV2, all of them were found positive. The diagnostic sensitivity is determined as 100%.

HIV Type	Number of samples tested	ImmunoFlow HIV1-HIV2	
		negative	positive
HIV-1	360	0	360
HIV-2	101	0	101
HIV-1 subtype non-B	40	0	40

Possible Interferences:

The table below shows the results of the ImmunoFlow HIV1-HIV2 tested on a variety of samples containing possibly interfering substances:

Sample type	Number of samples tested	ImmunoFlow HIV1-HIV2	
		negative	positive
clinical specimens	200	200	0
pregnant women	200	200	0
related infections (*)	100	100	0

(*) The results were negative for samples containing HBsAg (20), anti-HCV (20), anti-HTLV (15), Anti-HAV IgM (3), Anti-parvovirus B19 (15), Anti-Rubella (10), Anti-HBsAg (17).

To test interference by blood components on the performance of ImmunoFlow HIV1-HIV2 Precipath U was used as negative sample as well as diluent for positive samples.
Precipath U, is a lyophilized control based on human serum. The adjusted concentrations and activities of the components are in pathological range.
The results show that blood components present in the pathological range do not affect performance of ImmunoFlow HIV1-HIV2.

3. **Seroconverslon panels**

The sensitivity, evaluated on 30 commercially available seroconversion panels (Boston Biomedica Inc.), complying with European Directives for evaluation of in vitro diagnostic rapid assay- Data available upon request.

4. **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.