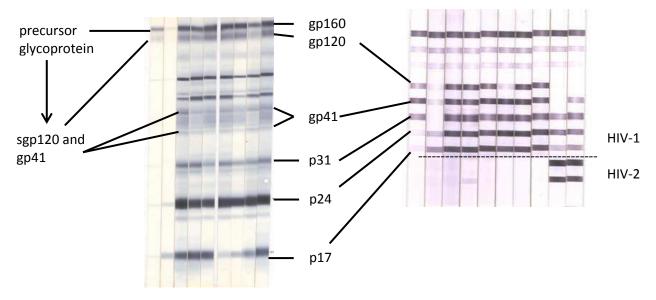


## • CAN INNO-LIA™ HIV I/II SCORE DISCRIMINATE BETWEEN HIV-1/HIV-2 INFECTION?

Yes, differentiation of HIV-1 (including HIV-1 group O) and HIV-2 is possible because LIA HIV uses antigens derived from each virus. Recombinant proteins are used for the confirmation of HIV antibodies and increase sensitivity, synthetic peptides are used for the confirmation and discrimination of antibodies on one strip. Because one line contains different epitopes, detection of ALL major subtypes (including HIV-1 group O) is possible. Worldwide, most HIV infections are HIV-1, whereas HIV-2 largely has been confined to persons in or from West Africa. HIV-1 and HIV-2 have the same routes of transmission, and both can cause AIDS; however, HIV-2 infections should be differentiated from HIV-1 infections because they are less likely to cause AIDS and their clinical management differs.

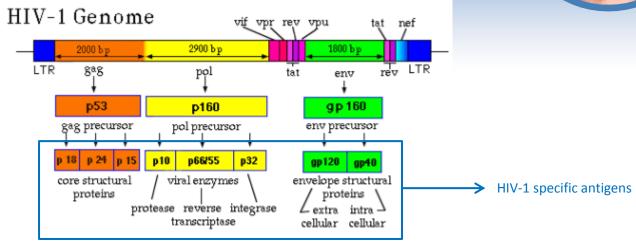
### IS INNO-LIA™ HIV I/II SCORE MISSING ANY ANTIGENS IN COMPARISON WITH WESTERN BLOT (WB)?

- WB shows "more" regions based on the fact that they start from lymphocyte-cultured viral lysates and therefore cannot make a more specific selection on antigen lines.
- For example, even precursor proteins such as gp160 are represented as a line on the WB strip. Figure 1 shows the difference between WB and LIA HIV strips and the transcription and translation of the HIV genome. For example, this illustration shows that the env gene (yellow) is transcribed and translated into ENV polyprotein (gp160) that is cleaved by proteases into the surface glycoprotein gp120 and transmembrane glycoprotein gp41.
- LIA works with the specific antigens only allowing to have complete information but at the same time avoiding aspecific reactions known to occur with WB.









- WHAT IS THE VALUE OF ANTIBODY (AB) CONFIRMATION IN A SETTING OF SCREENING + NAT TESTING?
  - In most countries NAT testing for blood screening is performed on pooled samples (pool size varies between 1 to 96 across countries).
    - Certain types of samples will be Ab-positive but negative for HIV RNA e.g. elite controllers

(HIV seropositive but no detectable HIV RNA (< 50 copies/ml) for > 2 years).

- Small percentage of Ab-positive donors have been tested negative by NAT tests.
- It is possible that an antibody positive and NAT negative donation might transmit infection to the recipient
- Therefore NAT Testing will not replace current serology tests in blood screening [1, 2].

Furthermore, a limitation of several of the commercial NAT systems is the inability to identify HIV-2.

[1]

http://www.bloodservices.ca/CentreApps/Internet/UW\_V502\_MainEngine.nsf/9749ca80b75a038585256aa 20060d703/708f54b29790a54585256abe0050069d?OpenDocument

[2]

http://72.14.203.104/search?q=cache:63M5sxAngMoJ:www.nzblood.co.nz/site\_resources/PDF\_Documents/dnr\_nat.pdf+will+NAT+replace+Antibody+screening&hl=en&gl=us&ct=clnk&cd=5



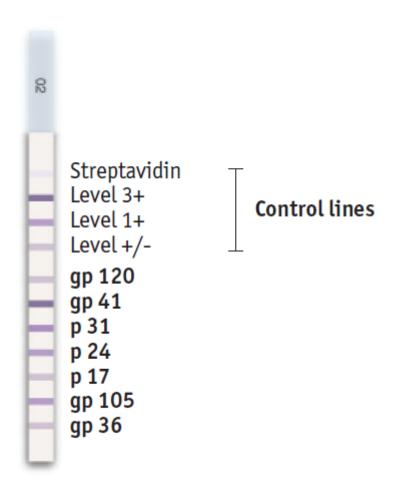
# FAQ INNO-LIATM HIV



#### WHAT DOES A 'NORMAL' STRIP LOOK LIKE?

A 'normal' strip shows reactivity on the three control lines: level 3+, 1+ and +/-.

The strip can be interpreted as positive for HIV-1 antibodies, positive for HIV-2 antibodies, positive for HIV-1 antibodies (untypable for HIV-1 or HIV-2), indeterminate or negative.



#### • WHERE IS THE PRODUCT USED?

The INNO-LIA™ HIV I/II Score is used in blood banks, clinical and hospital laboratories.

### CAN THE ASSAY BE AUTOMATED?

Yes, Fujirebio Europe N.V. has 2 automation options with different throughput.

- Auto-LIA™ 48 and Auto-LiPA™ 48 (48 samples)
- AutoBlot 3000 (H) (20 samples)



# FAQ INNO-LIATM HIV



The interpretation of the strips can be done by visual analysis (reading card included in the kit) or by the LiRAS™ for Infectious Diseases interpretation software. With the LiRAS™ for Infectious Diseases, the interpretation for all infectious diseases INNO-LIA™ Score products (HCV, HIV, Syphilis and HTLV) can be automated

• CAN I RUN DIFFERENT INNO-LIA™ SCORE PRODUCTS TOGETHER?

Yes, the INNO-LIA™ Score reagents are interchangeable except the sample diluent (assures high sensitivity/specificity) but reagents with different lot numbers should not be mixed.

