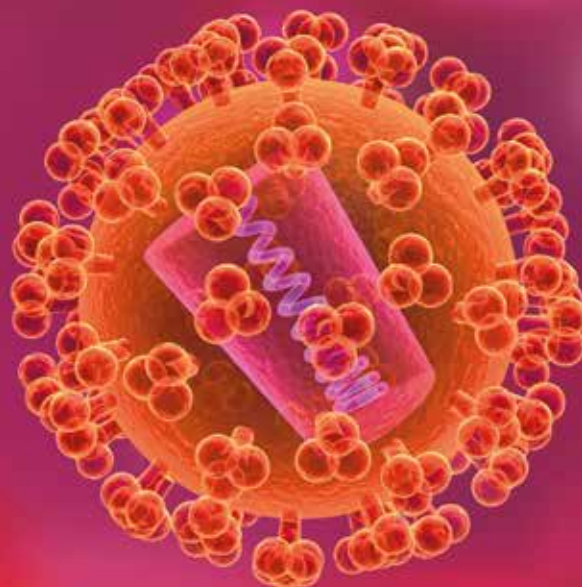


# Hepatitis and Retrovirus

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## LIAISON<sup>®</sup> XL **murex** HIV Ab/Ag

Accurate detection of HIV infection



DiaSorin

The Diagnostic Specialist

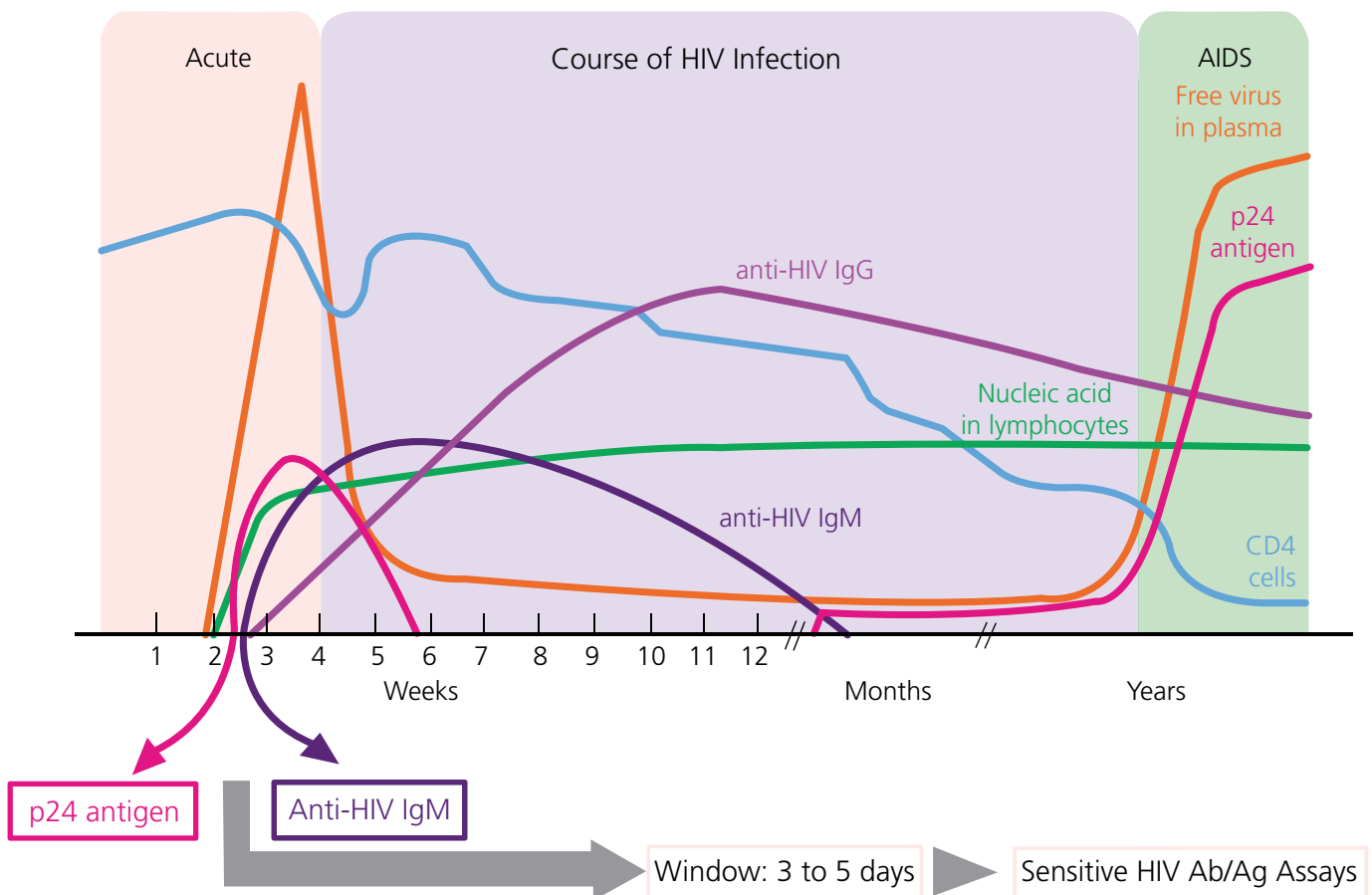
FOR OUTSIDE THE US AND CANADA ONLY

# How to prevent HIV spread? Earlier detection, variants recognition and late-stage determination of the disease...

## HIV/AIDS

Data from the AIDS epidemic update show that at 33.4 million [31.1 million–35.8 million] there are more people living with HIV than ever before as people are living longer due to the beneficial effects of antiretroviral therapy and population growth. However the number of AIDS-related deaths has declined by over 10% over the past five years as more people gained access to the life-saving treatment. New HIV infections are estimated around 2.7 million (2.4-3.0 million) and 430,000 children were newly infected with HIV, the vast majority of them through mother-to-child transmission. Then diagnosis and monitoring are as essential to effective HIV/AIDS treatment as medicines. The earlier diagnosis is established, the better the outcome of treatment. (<http://www.who.int>)

## Serologic diagnosis of HIV infection

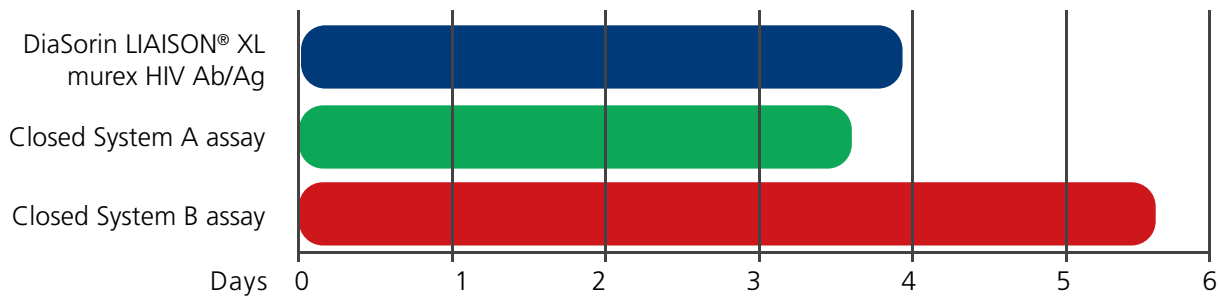


The variability between HIV-1 and HIV-2 requires the inclusion of antigens to both HIV-1 and HIV-2 for the screening of antibodies to HIV-1 and HIV-2. The presence of HIV-1 and/or HIV-2 antibodies and/or p24 antigen in the blood indicates potential infection with HIV-1 and/or HIV-2. Early after infection with HIV, but prior to seroconversion, HIV antigens may be detected in serum or plasma specimens. The HIV structural protein most often used as the marker of antigenaemia is the core protein p24, which becomes important to close the window to detect the infection earlier.

# LIAISON® XL murex HIV Ab/Ag...

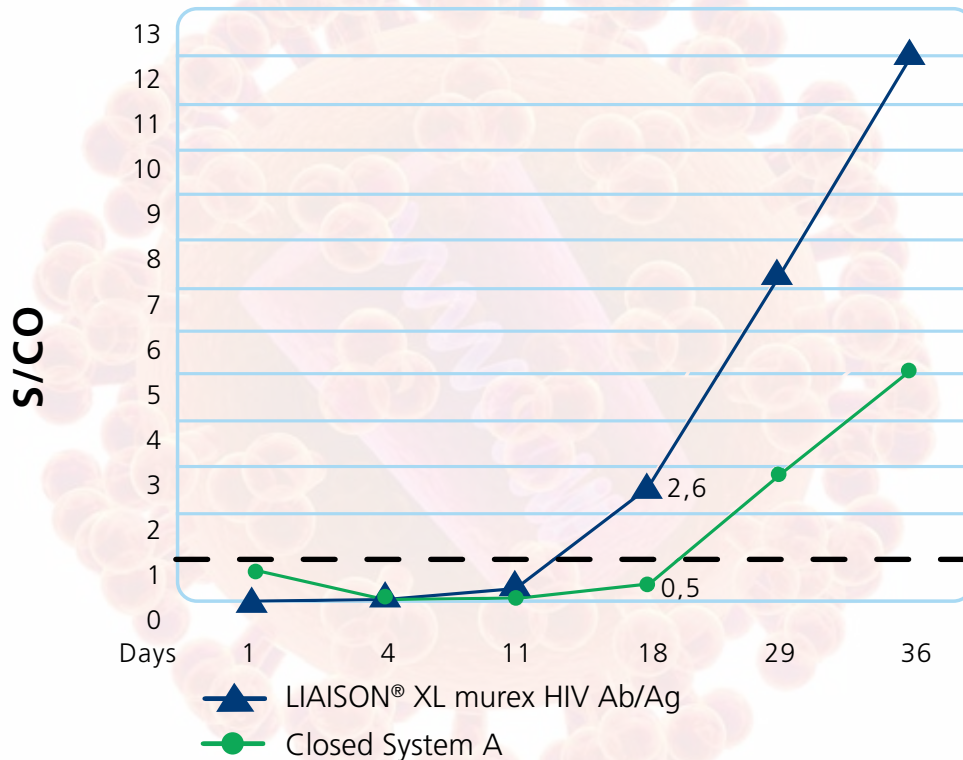
Excellent diagnostic sensitivity in the detection of HIV from the early phase of infection, closing the window period up to 5 days earlier with proven greater sensitivity in seroconversions with undetectable or low level of HIV antigen

## Seroconversions (n = 19): timing of detection for HIV Ab/Ag assays



Proven greater sensitivity in seroconversions with undetectable or low level of HIV antigen

## Zeptomatrix HIV9017: days of detection



The LIAISON® XL murex HIV Ab/Ag immunoassay is a true combined Ab-Ag assay for the combined screening of HIV Ag and HIV Ab with HIV p24 Ag sensitivity of 1.26 IU/mL WHO First International Reference Reagent (NIBSC code 90/636) and cut-off value for HIV p24 antigen that equates to 27.4 pg/mL by testing the HIV-1 Panel of the French Agency for Health Safety (Agence Française de Sécurité Sanitaire des Produits de Santé, Afssaps)

# Confidence in Your results

## Excellent detection of all major HIV variants and subtypes

Population	Number of cases	Reactive samples No.	Diagnostic sensitivity, %	Diagnostic sensitivity, 95% CI
Anti-HIV-1-positive patients	552	552	100.0 (552/552)	99.33-100.0
Anti-HIV-O-positive patients	10	10	100.0 (10/10)	69.17-100.0
Anti-HIV-2-positive patients	100	100	100.0 (100/100)	96.38-100.0
Total	662	662	100.0 (662/662)	99.44-100.0
HIV p24-positive patients	52	52	100.0 (52/52)	93.15-100.0

## High specificity to minimize delay in result reporting and costly confirmatory testing

Population	Number of cases	Initially reactive samples, No.	Repeat reactive samples, No.	Diagnostic specificity, %	Diagnostic specificity, 95% CI
Blood donors	5117	17	16	99.69 (5101/5117)	99.49-99.82
Hospitalised patients	394	4	4	98.98 (390/394)	97.42-99.72
Dialysis patients	196	0	0	100.0 (196/196)	98.14-100.0
Pregnant women	98	0	0	100.0 (98/98)	96.30-100.0
High-risk subjects	131	0	0	100.0 (131/131)	97.23-100.0

## The LIAISON® XL murex HIV Ab/Ag assay is flexible and easy to use

- Full automation makes your daily routine convenient and easy.
- Quick testing for better patient management.

<b>Standard Calibrators</b>	1 Calibrator included in each integral
<b>Controls</b>	Negative, Positive, ready to use (4 weeks stability)
<b>Interpretation of Results</b>	Specimens with signal-to-cut-off (S/CO) ratios above or equal to 1 are considered Reactive for HIV p24 antigen and HIV antibodies
<b>Minimum Sample Volume</b>	Routine = 200 µL Specimen plus 150 µL dead volume
<b>Sample Type</b>	Either human serum or plasma (including serum collected in serum separator tubes). Anticoagulants: sodium citrate, potassium EDTA, lithium and sodium heparin, potassium oxalate, ACD, CPDA
<b>Reagent Stability</b>	Assay reagent (open on board stable 4 weeks)
<b>Reagent Preparation</b>	None
<b>Precision (S/CO ≥ 1)</b>	Repeatability CV% < 10% - Interlot Reproducibility CV% < 13%

# LIAISON® XL murex HIV Ab/Ag is Your solution

## LIAISON® XL murex HIV Ab/Ag main features

The LIAISON® XL murex HIV Ab/Ag sandwich chemiluminescent assay format ensures reliable data.

- **Unique selection of raw materials for reliable results.**
- **Reliable interpretation of data is obtained by the automatic combination of results from anti-HIV antibody and HIV p24 antigen assays.**
- **Superior sensitivity for early diagnosis.**
- **Detection of all major HIV variants and subtypes.**
- **Excellent specificity to meet laboratory needs.**
- **High reproducibility for confidence in results.**

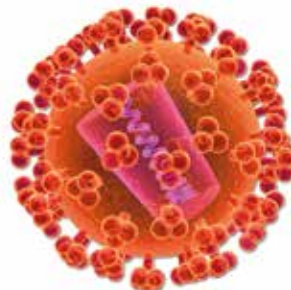
Two different reagent integrals, one for anti-HIV detection and one for HIV p24 antigen detection, but one automatic combination of results.

### FROM 2 JOINT DETECTIONS A SINGLE PATIENT DIAGNOSIS

ANTIBODY S/CO



ANTIGEN S/CO



1 PATIENT RESULT  
reactive/non-reactive

Solid phase and conjugates tailor made for reliable results by using unique selected monoclonal antibodies (Mabs) to HIV p24 antigen and soluble and properly folded recombinant antigens: HIV-1 gp41 (group M and group O) as well as HIV-2 gp35 (both obtained in E. coli)

# LIAISON® XL murex HIV Ab/Ag

Improving performance and ease of use, targeting the best quality and safety in result reporting with LIAISON® XL system



- Quality in results reporting
- Consistent throughput up to 180 tests/h
- High reagent capacity & complete traceability
- High walk away time
- Service remote access

## Ordering Information

Product Name	Description	Code
LIAISON® XL murex HIV Ab/Ag	200 tests	310260
LIAISON® XL murex Control HIV Ab/Ag (neg & pos)	2 x 2.5 mL for anti-HIV 2 x 2.5 mL for HIV Ag	310261
LIAISON® XL	Platform	I0050
LIAISON® XL Cuvettes	7200/box	X0016
LIAISON® XL Disposable Tips	6912/box	X0015
LIAISON® XL Starter Kit	3000 test	319200
LIAISON® XL Wash/System Liquid	6 vials/box	319100
LIAISON® XL Waste Bag	50 bags/box	X0025

Product availability subject to required regulatory approval

### References

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2. **Sickingen E et al** Multicenter evaluation of a new automated enzyme-linked immunoassay for detection of HIV-specific antibodies and antigens. J Clinical Microbiology, vol 42, n 1, 2004.
3. **Weber B et al** Evaluation of a new combined antigen and antibody HIV screening assay, Vidas Duo Ultra. J Clinical Microbiology, vol 40, n 4, 2002.
4. **Speers D et al** Combined assay detecting both HIV p24 antigen and anti-HIV antibodies open a second diagnostic window. J Clinical Microbiology, vol 43, n 10, 2005.
5. **Saville RD et al** Fourth generation enzyme-linked immunosorbent assay for the simultaneous detection of HIV antigen and antibody. J Clinical Microbiology, vol 39, n 7, 2001.

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