



your HIV Diagnosis
is under control

determine[®]
HIV-1/2 Ag/Ab Combo
Detecting acute HIV infection

 inverness medical

detect...
diagnose...
determine...



NEW



Despite decades of aggressive prevention efforts and significant advances in effective treatment, HIV infection and AIDS remain a worldwide pandemic, with serious socio-economic consequences^(1, 2).

Global disease burden¹

- 33.2 million (30.6 – 36.1 million) people estimated to be living with HIV in 2007
- 2.5 million (1.8 – 4.1 million) people became newly infected in 2007
- 2.1 million (1.9 – 2.4 million) people died of AIDS in 2007
- An estimated 68% of the people living with HIV are in sub-Saharan Africa
- Eight countries in sub-Saharan Africa account for almost one-third of all new HIV infections and AIDS deaths globally

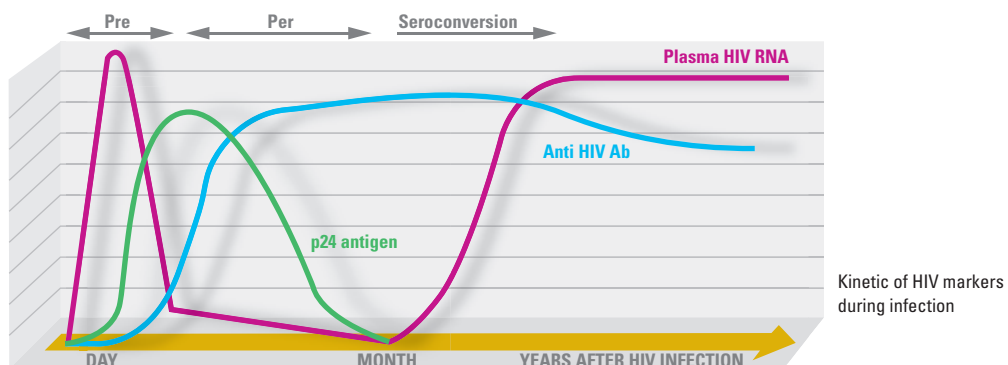
Early diagnosis of primary HIV infection is a matter of global public health importance

Many individuals infected with HIV are unaware of their HIV-positive status:

- USA: in 2006 approximately 25% of the 1 million individuals infected with HIV were unaware of their status³
- France: 40,000 people estimated to be ignoring they are HIV infected⁴
- UK: 30% of people in the UK living with HIV do not know that they have become infected⁵
- According to CDC reports 25% of individuals who are unaware of their infection are responsible for 54%-70% of new HIV infections³

Diagnosis of acute HIV infection:

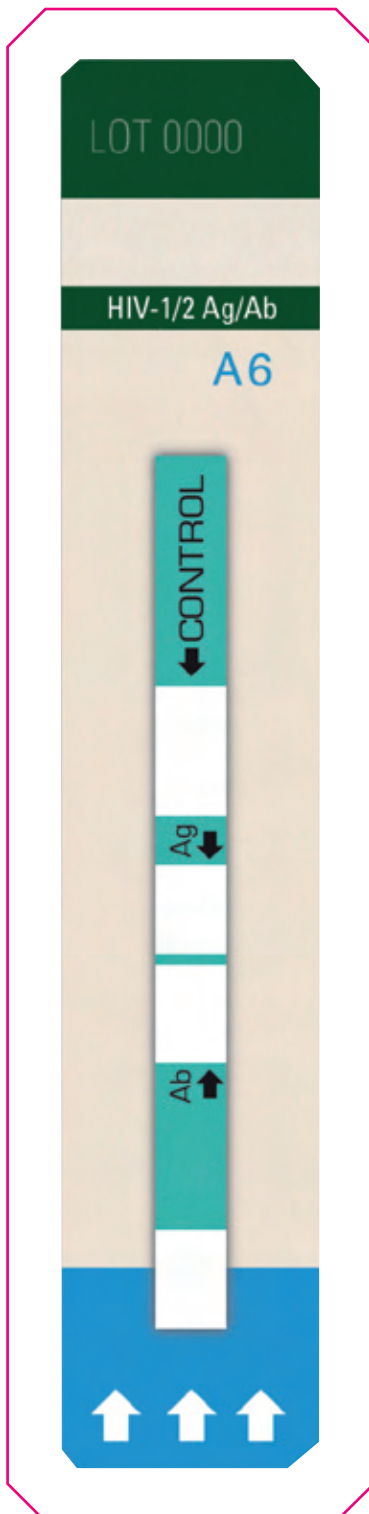
- The earliest phase of HIV infection is the pre seroconversion where only viral components can be detected.



- HIV Antibody assays, including most sensitive third-generation tests do not target viral components and so far are limited in their ability to detect infection during the pre-seroconversion phase or can only partially identify per-seroconversion cases.
- Fourth generation screening assays were developed shortening the duration on the “diagnostic window” by detecting HIV antibodies and HIV-1 p24 antigen simultaneously⁶.

determine[®]

HIV-1/2 Ag/Ab Combo



A breakthrough, fourth generation, rapid *in vitro* immunoassay for the qualitative detection of HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2 in serum, plasma and whole blood.

RAPID

- Clear, reliable results in 20 minutes

EARLIER DETECTION

- Can identify HIV infection through detection of the HIV-1 p24 antigen before the presentation of antibody response
- HIV infection detected an average of 5 days (range: 2-20 days) earlier than the Determine[®] HIV-1/2 (3rd generation) antibody test
- Simultaneous and differentiated detection of HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2 reduces the "window period" by several days when compared to third generation test

FLEXIBLE

- Can use whole blood or serum/plasma
- Specimen collection can be by fingerstick or venipuncture

FOIL STRIP PACKAGING

- Limited storage space required and reduced waste of materials

STORAGE 2-30°C

- Ready to use – room temperature
- Easy to transport and store
- No device refrigeration required

SIMPLE PROCEDURE

- Requires minimal training and no laboratory equipment

INBUILT PROCEDURAL CONTROL

- Confirmation that test has been performed correctly

your HIV Diagnosis *is under control*

Performance Characteristics

The performance of the Determine® HIV-1/2 Ag/Ab Combo was evaluated in-house and at nine (9) clinical sites in Africa, Asia, Europe and Latin America.

Excellent sensitivity

Sensitivity by HIV type (confirmed HIV antibody samples)

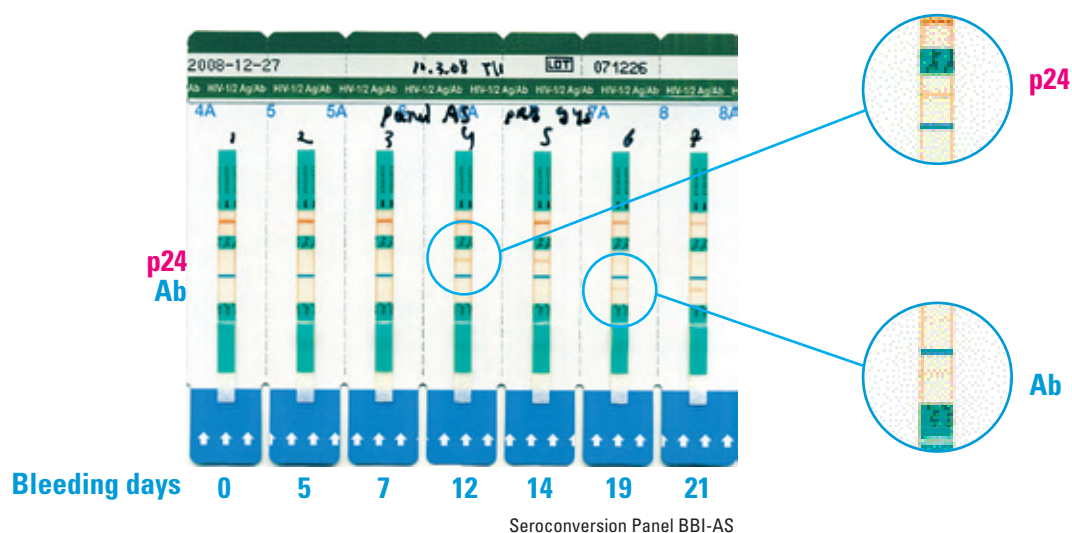
	Number of Specimens Tested	Positive by Determine® HIV-1/2 Ag/Ab Combo	Sensitivity (%)
HIV-1	885	885	100.00%
HIV-1 group O	7	7	100.00%
HIV-1 non B subtypes*	154	154	100.00%
HIV-2	133	133	100.00%
Total	1179	1179	100.00%

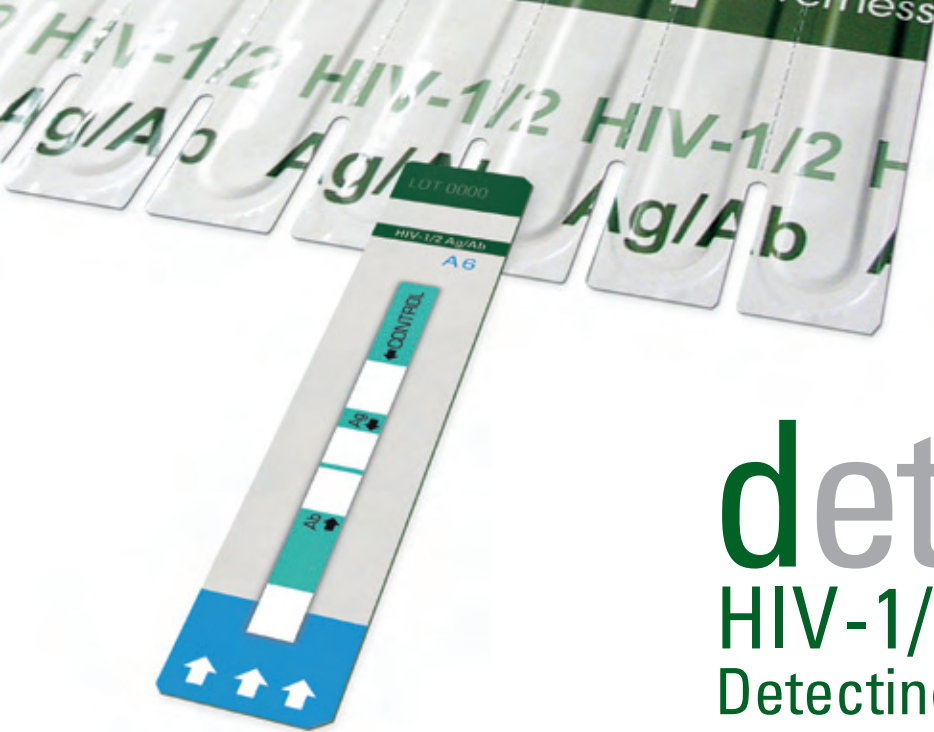
* Subtype A, C, D, F, G, H, J, K, and CRF01_AE, CRF02_AG, CRF06_cpx, CRF09_cpx, CRF11_cpx, CRF35_AD, and BD

Seroconversion Panel Specimens

A total of 33 seroconversion panels were studied and the Determine® HIV-1/2 Ag/Ab Combo results were compared to the results of Determine® HIV-1/2 (3rd generation) antibody test. Determine® HIV-1/2 Ag/Ab Combo detected HIV infection an average of 5 days (range: 2-20 days) earlier, depending on the panel tested.

For example, when panel BBI-AS was tested p24 antigen was detected 7 days earlier than the appearance of HIV antibodies.





determine[®]

HIV-1/2 Ag/Ab Combo

Detecting acute HIV infection

Sensitivity of Determine[®] HIV-1/2 Ag/Ab Combo on Primary HIV Infection: Pre and per seroconversion samples

	Number of Specimens Tested	Positive by Determine [®] HIV-1/2 Ag/Ab Combo	Sensitivity (%)
Belgium	10	8	80.00%
UK	18	16	88.89%
Thailand	7	2	28.57%
France	81	81	100.00%
Colombia	1	1	100.00%
Total	117	108	92.31%

Excellent specificity

Specificity of Determine[®] HIV-1/2 Ag/Ab Combo

Population	Number of Specimens Tested	Negative by Determine [®] HIV 1/2 Ag/Ab Combo Ab line	Specificity (%) of Ab line	Negative by Determine [®] HIV 1/2 Ag/Ab Combo Ag line	Specificity (%) of Ag line
Seronegative plasma or serum*	1783	1769	99.21%	1776	99.61%
Pregnant women	200	200	100.00%	199	99.50%
Disease States Other than HIV**	210	206	98.09%	210	100.00%
Potentially Interfering Substances***	150	150	100.00%	150	100.00%
Total	2343	2325	99.23%	2335	99.66%

* Conducted in 9 clinical trial sites: Belgium, Uganda, Senegal, UK, Thailand, France, Ethiopia, South Africa, Colombia.

** Other viral or bacterial infections (HBV, HCV, HTLV, CMV, Toxo IgG, Syphilis, HSV 1/2, EBV, Flu vaccinated patients and Chlamydia IgG/IgM). Cancer patients.

*** IV drug users, multiparous pregnancy, rheumatoid factor, alcoholic cirrhosis, autoimmune (ANA), high cholesterol, lipemic, high bilirubin, hemolyzed, anti mouse IgG.

Multiple (matched) specimens:

Seropositive and negative specimens (serum, plasma, whole blood and fingerstick) were tested in multiple matched combinations. The results obtained from all specimen matrices showed 100% correlation, demonstrating that Determine[®] HIV-1/2 Ag/Ab Combo gives identical results for these types of specimen matrices.

Test Procedure:

For Serum/Plasma



1
Remove tests



2
Remove cover



3
Add sample
Add sample (50ul) to sample pad

Wait 20 minutes - Read result



Note: Removal of the test units should start from the right side of the test card to preserve the lot number which appears on the left side of the card

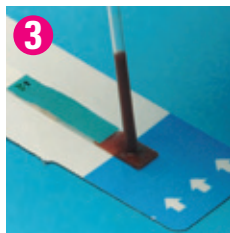
For Whole Blood



1
Remove tests



2
Remove cover



3
Add sample
Add sample (50ul) to sample pad (finger stick or venipuncture)

Wait 1 minute



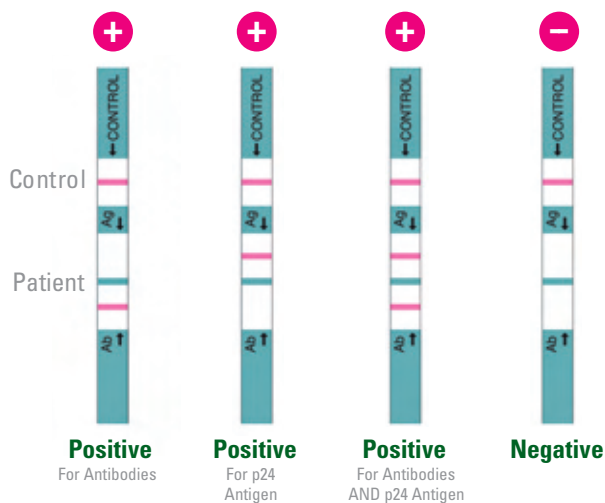
4
Add one drop of chase buffer

Wait 20 minutes



Read result

Reading the results



Product Specifications

Catalogue Number	Product	Non CE	CE Marked
	Whole Blood*, Serum and Plasma 20 test	N/A	7D2646
	Whole Blood*, Serum and Plasma 100 test	7D2643	7D2647
	Chase Buffer	7D2243	7D2247
	EDTA Capillaries	7D2222	7D2227
	Lancets	100 contents	7D2232
	Method	Lateral flow	
	Time to Result	20 minutes	
	Storage conditions	2-30°C	
	Shelf life	9 months	
	Sample Type	Serum/Plasma/Whole Blood	
	Kit Contents	20 or 100 test units	

* For Whole Blood please order Chase Buffer

References

1. AIDS Epidemic Update 2007, Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization, November 2007
2. Barré-Sinoussi F, Chermann JC, Rey F et al. (1983) Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immunodeficiency syndrome (AIDS). Science 220: 868-871
3. Clinical Laboratory News, HIV Screening, January 2009: volume 35, No 1
4. CNS/ANAES report November 16th 2006
5. HPA estimate 2006
6. Saville R, Constantine NT, Cleghorn FR, Jack N, Bartholomew C, Edwards J, Gomez P and Blattner WA (2001) Fourth-generation enzyme-linked immunosorbent assay for the simultaneous detection of human immunodeficiency virus antigen and antibody. Journal of Clinical Microbiology 39: 2518-2524

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