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## The next level of proven HIV testing

Enzygnost HIV Integral 4 Assay

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# Early Identification of HIV is Crucial

The stunning success of antiretrovirals and improved education on HIV risk factors have led many to believe that HIV infection could be on the wane. However, recent data suggests increased HIV transmission in many countries, including regions in both Europe and the United States.<sup>1,2</sup>

Early identification of infected individuals is crucial to reduce new transmission and promote earlier intervention with antiretroviral therapies. Recognizing this, revised guidelines from both the European Union and the U.S. call for dramatically increased screening for HIV infection. Sensitive testing technologies are central to this move toward more widespread screening, providing tools for early detection that support both optimal patient management and infection control.

## Improved Antigen/Antibody Assays Allow Earlier Detection of HIV Infection

Use of a combination (i.e., HIV Combo) test that detects the HIV p24 antigen as well as antibodies to HIV provides an improvement in earlier detection compared to existing, sensitive, antibody-only immunoassays. The HIV Combo test is becoming the standard screening technique recommended by the European Union, and there is an increasing trend among blood banks to use HIV Combo assays.

A common concern among the HIV testing community is that HIV Combo assays provide decreased specificity compared to antibody-only assays. This perception has to some extent hindered adoption of HIV Combo assays. However, a new HIV Combo assay from Siemens provides specificity comparable to current, leading antibody-only assays as well as the benefits of superior sensitivity and earlier HIV detection.

## Enzygnost HIV Integral 4 Assay: The Next Level of Proven HIV Testing

The Enzygnost® HIV Integral 4 Assay is a combination assay that provides qualitative determination of HIV antibodies, including HIV-1, HIV-1 group O, and HIV-2, plus p24 antigen. As a member of the trusted Enzygnost family of assays, it employs proven ELISA technology and runs on microtiter plates. The test has been validated on the widely used and highly reliable BEP 2000 Advance®, BEP® III, and Quadriga BeFree® Systems.

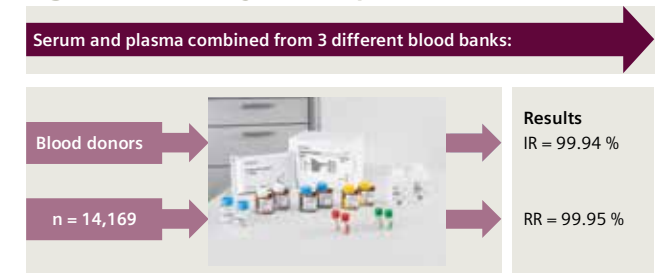
Siemens brings many years of experience, expertise, and leadership in HIV testing to the development of this new assay. The Enzygnost HIV Integral 4 Assay is the latest and most powerful product in a series of Siemens HIV tests that includes the Anti-HIV 1/2 Plus and HIV Integral II Assays.

The HIV Integral 4 Assay fully meets the specificity and sensitivity requirements of blood banks and other testing facilities. It quickly and reliably delivers the accurate results clinicians need to identify HIV infection and improve patient care.

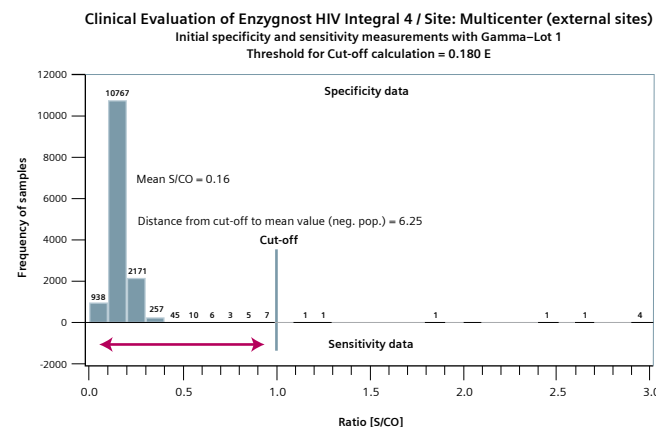
## Specificity fully meets blood bank requirements

As shown in the images below, in a study of 14,169 donor samples tested at three different blood banks, the HIV Integral 4 Assay demonstrated specificity of 99.94%.

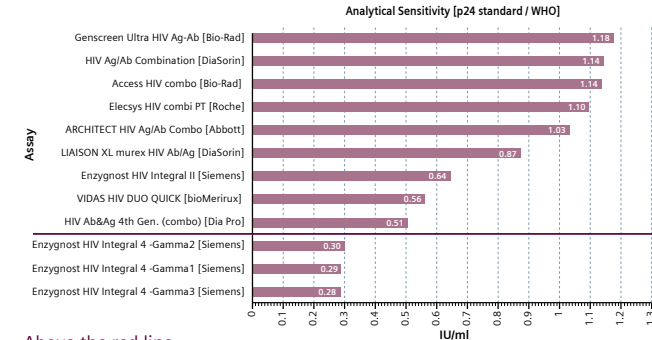
## Higher sensitivity and superior seroconversion



The HIV Integral 4 Assay has higher sensitivity and provides superior seroconversion performance compared to other currently available assays. Diagnostic sensitivity is 100%, and analytical sensitivity is 0.29 IU/mL (WHO standard). Seroconversion is at least one bleed better than any currently available alternative, based on 39 seroconversion panels tested.



## Analytical Sensitivity: WHO-Standard



Above the red line: parts taken from Ly TD, Plantier JC, Leballais L, Gonzalo S, Lemée V, Laperche S. The variable sensitivity of HIV Ag/Ab combination assays in the detection of p24Ag according to genotype could compromise the diagnosis of early HIV infection. J Clin Virol. 2012;55(2):121-7.

Below the red line: HIV Integral 4 (in-house testing)

## Step Up to the Next Level of HIV Testing

The Enzygnost HIV Integral 4 Assay represents the next level of HIV testing performance. Its high specificity and sensitivity allow earlier identification of HIV infection so clinicians can begin treatment sooner and ultimately improve patient care.

Because HIV Integral 4 is a member of the trusted, proven Enzygnost family of assays, you can be confident in the accuracy and consistency of the results it delivers. And the reliability, fast turnaround, and high throughput provided by the BEP and Quadriga BeFree infectious-disease testing systems help keep your lab operating at full productivity and efficiency.

Move up to the next level of HIV testing performance—step up to the Enzygnost HIV Integral 4 Assay. Contact your Siemens representative for more information.

## Seroconversion Performance

Panel ID	Day	PCR	Enzygnost HIV Integral 4 Assay			Integral 4 Extern	Competitor 1 Ag/Ab assay 1	Competitor 2 Ag/Ab assay 2	Competitor 2 Ag/Ab assay 3	Competitor 3 Ag/Ab assay 4	Competitor 1 Antibody only assay 5	Competitor 3 Antibody only assay 6
			Validation Lot 1	Validation Lot 2	Validation Lot 3							
12008-08	23	POS	POS	POS	POS	POS	NEG	NEG	NEG	NEG	NEG	NEG
12008-09	28	POS	POS	POS	POS	POS	POS	POS	POS	POS	NEG	NEG
12008-10	33	POS	POS	POS	POS	POS	POS	POS	POS	POS	POS	POS
6243-07	25	POS	POS	POS	POS	POS	POS	NEG	POS	POS	NEG	NEG
6243-08	27	POS	POS	POS	POS	POS	POS	NEG	POS	POS	POS	NEG
6243-09	32	POS	POS	POS	POS	POS	POS	POS	POS	POS	POS	POS
6247-07	21	POS	POS	POS	POS	POS	NEG	NEG	NEG	NEG	NEG	NEG
6247-08	23	POS	POS	POS	POS	POS	POS	POS	POS	POS	NEG	NEG
6247-09	28	POS	POS	POS	POS	POS	POS	POS	POS	POS	NEG	NEG
6247-10	30	POS	POS	POS	POS	POS	POS	POS	POS	POS	NEG	POS
9012-5	14	POS	POS	POS	POS	POS	NEG	NEG	NEG	NEG	NEG	NEG
9012-6	16	POS	POS	POS	POS	POS	POS	POS	NEG	POS	NEG	NEG
9012-7	21	POS	POS	POS	POS	POS	POS	POS	POS	POS	NEG	NEG
9012-8	23	POS	POS	POS	POS	POS	POS	POS	POS	POS	POS	POS
9018-8	25	POS	POS	POS	POS	POS	NEG	NEG	NEG	NEG	NEG	NEG
9018-9	28	POS	POS	POS	POS	POS	POS	POS	POS	POS	NEG	NEG
9018-10	32	POS	POS	POS	POS	POS	POS	POS	POS	POS	POS	POS
9032-07	22	POS	POS	POS	POS	NEG	NEG	NEG	NEG	NEG	NEG	NEG
9032-08	24	POS	N/A	POS	POS	POS	NEG	POS	POS	NEG	POS	NEG
9032-09	29	POS	POS	POS	POS	POS	NEG	POS	POS	NEG	POS	POS
9032-10	36	POS	POS	POS	POS	POS	POS	POS	POS	POS	POS	POS

Ordering Information		
Product	Product Code	Siemens Code Number
HIV Integral 4 2x96	OPKR 035	10641823
HIV Integral 10x96	OPKR 055	10641824
HIV Integral 10x96Q	OPKR 075	10709364
Supplementary	OUPV 175	10446495
Supplementary Q	OUPV 275	10482444

## References

1. Joint WHO/Europe and European Centre for Disease Prevention and Control (ECDC) surveillance report on HIV/AIDS in the WHO European Region (53 Member States), 2008.
2. Campsmith ML, Rhodes P, Hall HI, Green T. HIV prevalence estimates – United States 2006. MMWR Morb Mortal Wkly Rep. 2008; 57(39):1073-6.