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Performance Data

Determine® HIV-1/2 Ag/ Ab Combo



Excellent Sensitivity

Population	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- non B subtypes*	154	154	100.00%
HIV-2	133	133	100.00%
Total	1179	1179	100.00%

*subtypes: A, C, D, F, G, H, J, K and CRF, AE, AG, AD, BD, 06, 09 and 011

A total of 1179 confirmed HIV Ab positive specimens from patients at the chronic stage of the infection were tested. The diagnostic sensitivity of **Determine® HIV-1/2 Ag/Ab Combo** on this population of specimens is calculated to be 100%. These results were obtained in nine clinical trials conducted in Europe, Asia, Africa and Latin America.

Sensitivity on seroconversion panels

The capability of the **Determine® HIV-1/2 Ag/Ab Combo** to detect early infection was demonstrated on 33 commercial seroconversion panels. The results show that **Determine® HIV-1/2 Ag/Ab Combo** is able to identify infection on average 5 days earlier (range 2-20 days) than 3rd generation antibody tests.

Sensitivity on primary infection: pre and per seroconversion samples

Study by site	Total Number of Specimen Tested (pre & per)	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

- 117 samples (pre and per seroconversion) from primary HIV primary infected patients were tested
- Determine® HIV-1/2 Ag/Ab Combo identified 92.31% of samples when compared to commercial CE marked 4th generation EIA

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 the Ab line	Negative by Determine® HIV-1/2 Ag/Ab Combo Ag line	Specificity (%) of the Ag line
Seronegative Specimens	1783	1769	99.21%	1776	99.61%
Pregnant Women	200	200	100.00%	199	99.50%
Disease States Other than HIV and Potentially Interfering Substances*	360	356	98.89%	360	100.00%
Total	2343	2325	99.23%	2335	99.66%

A total of 2343 confirmed negative serum, plasma or whole blood specimens were tested including 1783 Seronegative specimens from 9 different clinical sites in Asia, Europe, Latin America and Africa, 200 from pregnant women and 360 from disease states other than HIV and potentially interfering substances.

*Please refer to the Pack Insert for further information.



Determine HIV-1/2 Ag/ Ab Combo is currently not available in the US