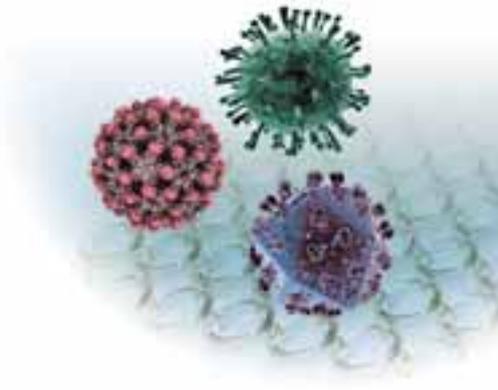


Murex HIV Ag/Ab Combination

ELISA Infectious disease



■ Technical Assay Details

Article Number:	7G79-09 (96 tests, 1 plate), 7G79-11 (480 tests, 5 plates)
Coating:	Anti p24 HIV mouse monoclonal antibodies and a mixture of recombinant proteins and synthetic peptides of HIV-1/-2 (including HIV-O)
Incubation Time:	60 min sample / 30min conjugate / 30 min substrate (total 2,0 hours)
Incubation Temp.:	37°C / 37°C / 37°C
Assay Volumes:	25µl diluent / 100µl sample / 100µl conjugate 100µl substrate (TMB) / 50µl stop solution
Wash Steps:	Two wash steps with 5x washes each. Each wash using 500µl of wash buffer

■ Quality Control Criteria and Cut Off

Controls (C):	4 controls included: 3x NC, 1x PC (p24), 1x HIV-1 and 1x HIV-2 (6 wells of C required per run)
QC Neg. Cont. (NC):	Mean Value of NC < 0.15 OD (optical density)
QC Pos. Cont. (PC):	Mean Value of PC > 0.8 OD above mean value of NC
Cut off Definition:	Mean value of NC + 0.15 OD
Result negative:	OD value of the sample < cut off
Result positive:	OD value of the sample ≥ cut off

■ Assay Performance

Specificity:

A total of 9290 samples from blood donors were analyzed in three blood donor centers. The specificity was **99,78 %** (see package insert).

Sensitivity:

A total of 497 specimens from patients with confirmed HIV-1 infection were tested and found to be reactive with Murex HIV Ag/Ab Combination. The specimens were taken from patients at various stages of HIV infection and included 24 specimens from patients with HIV-1 subtype O infection and a further 139 specimens from patients infected with HIV-1 subtypes other than subtype B. In addition a total of 100 specimens from patients with confirmed HIV-2 infection were also tested with Murex HIV Ag/Ab Combination and found to be reactive. The diagnostic sensitivity of Murex HIV Ag/Ab Combination on this population of specimens is therefore estimated to be **100 %** (597/597, for more details see package insert).



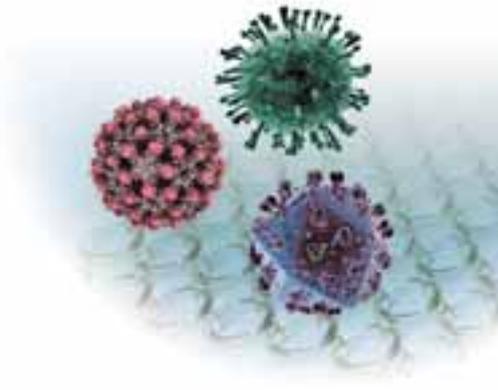
The Diagnostic Specialist



Murex® is a DiaSorin trademark

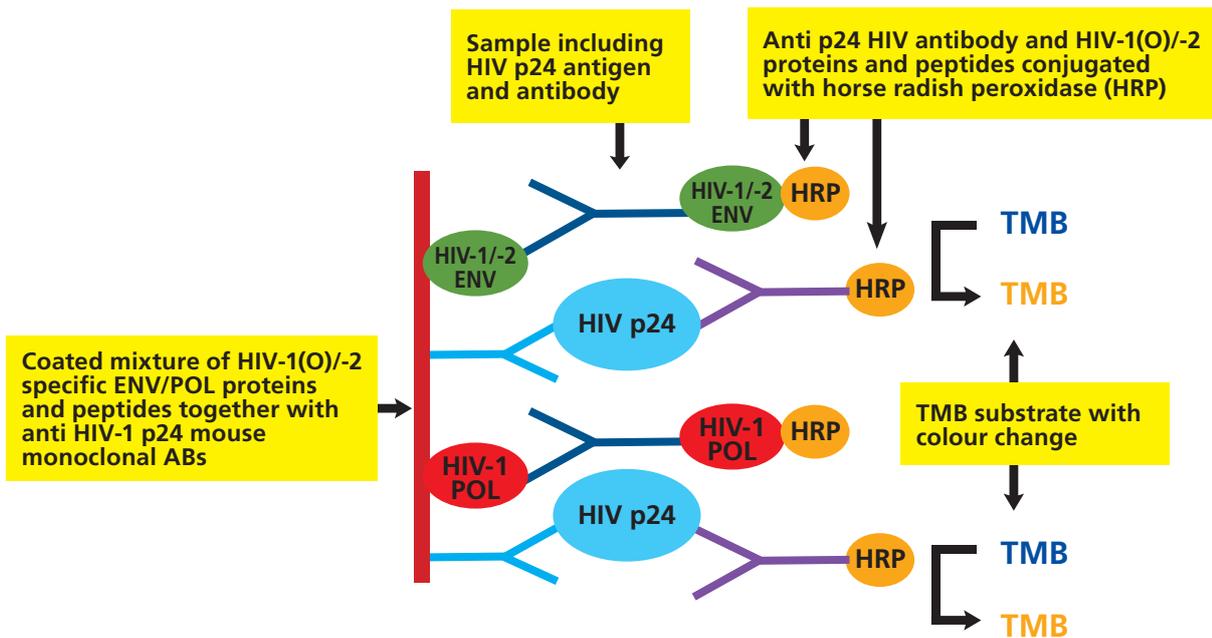
Murex HIV Ag/Ab Combination

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Assay Principle

Combined Ag Capture + double Ag ELISA (bridge test)



Your Advantages

- **Improved throughput** by detecting HIV antigen and antibody in a single assay run.
- **High security** for the operator. Each pipetting step is completely monitored by a colour change (full sample monitoring included).
- **Ease of use** by performing the Murex HIV Ag/Ab Combination assay in manual, semi-automated or fully automated way.
- **More blood safety** by earlier detection of viral infection when a combined antigen and antibody test principle is used (combination test).
- **The reduction of the window period** by using HIV combination assays was at least 3-5 days compared to HIV antibody only assays (S. Laperche, 2008 Transfusion 57, Vol. 48, p576-579).
- **Viable and economic alternative** to nucleic acid testing (NAT).
- **Capable of detecting p24 antigen** levels as low as 16 pg/ml (following Sanofi standard).

Product availability subject to required regulatory approval

FOR OUTSIDE THE US AND CANADA ONLY



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