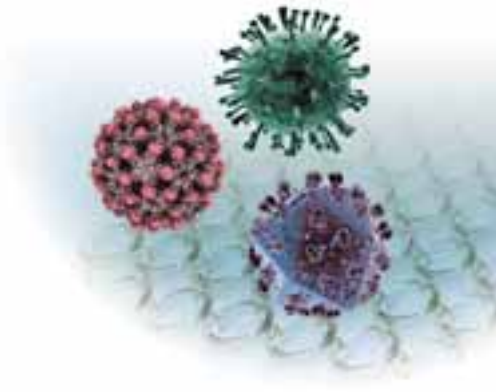


Murex HIV-1.2.O

ELISA Infectious disease



■ Technical Assay Details

Article Number:	9E25-01 (96 tests, 1 plate), 9E25-02 (480 tests, 5 plates)
Coating:	Synthetic peptide (HIV-O) and recombinant proteins of HIV-1 and -2 ENV and HIV-1 GAG antigen.
Incubation Time:	30 min sample / 30min conjugate 30 min substrate (total 1.5 hours)
Incubation Temp.:	37°C / 37°C / 37°C
Assay Volumes:	50µl diluent / 50µl sample / 50µl 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):	3 controls included: 3 x NC, 1 x PC (HIV-1), 1 x PC (HIV-2) - (5 wells of C required per run)
QC Neg. Cont. (NC):	Mean Value of NC < 0.3 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 + 0.2 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 8225 routine donor samples were screened with Murex HIV-1.2.O at four blood transfusion centers. In the study, **99.91%** (8218/8225) of samples were non-reactive and **0.09%** (7/8225) were repeatedly reactive. None of the repeatedly reactive samples were confirmed as positive for the presence of antibody to HIV-1 or HIV-2 (see further details in the package insert).

Sensitivity:

A total of 1895 specimens were tested with Murex HIV-1.2.O. The samples were collected at a number of European laboratories and included:

- 1455 samples where antibody was demonstrated by alternative format enzyme immunoassays and/or Western blot. The samples comprised 1254 samples (including HIV-O) from patients at various stages of HIV-1infection and 201 samples from patients infected with HIV-2.
- 440 samples from patients with other diseases unrelated to HIV were tested, too. In this study, Murex HIV-1.2.O detected antibody to HIV in all 1455 samples in group a) and none of the 440 samples in group b). The relative sensitivity of Murex HIV-1.2.O on these populations of samples was **100%** (1455/1455).

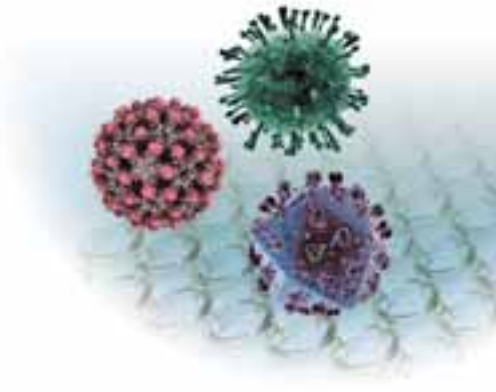


The Diagnostic Specialist



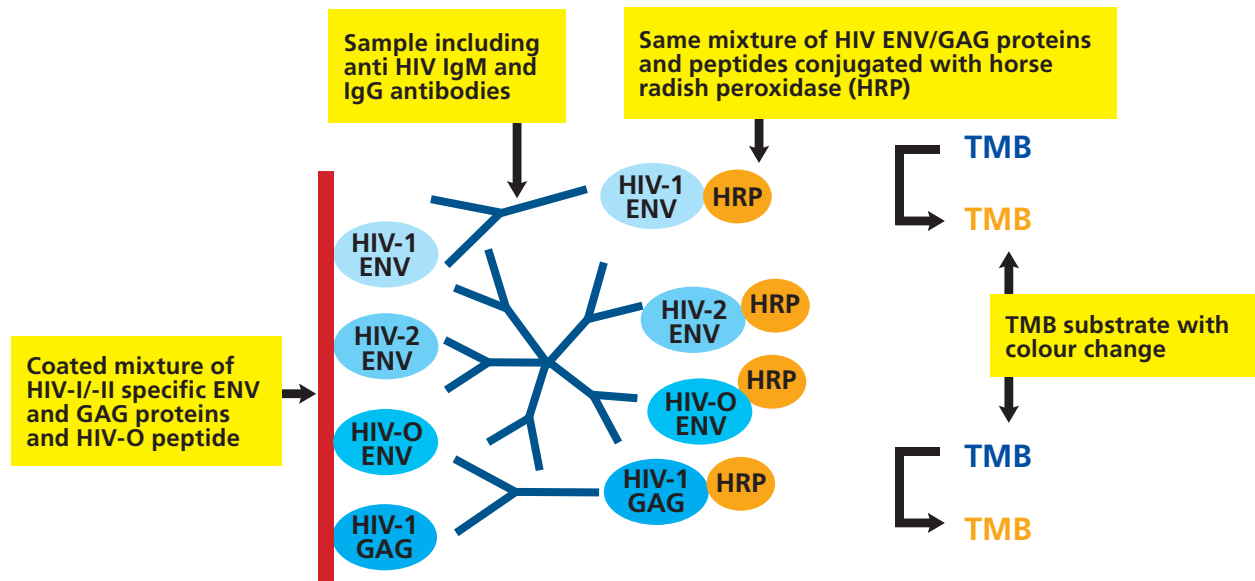
Murex HIV-1.2.0

ELISA Infectious disease



Assay Principle

Double Antigen ELISA for total Ab detection (bridge test)



Your Advantages

- **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-1.2.0 assay in manual, semi-automated or fully automated way.
- **High sensitivity** because the Murex HIV-1.2.0 test was proven to be one of the most sensitive anti-HIV assays of the 3rd generation.
- **Ideally used as an HIV confirmation assay** when it is done together with the Murex HIV Ag/Ab combination assay (Art. No. 7G79-09/11).
- **Reliability** in the detection of HIV-1, HIV-2 and HIV-O antibodies.

Product availability subject to required regulatory approval



The Diagnostic Specialist

FOR OUTSIDE THE US AND CANADA ONLY

DiaSorin S.p.A.
Via Crescentino
13040 Saluggia (VC) - Italy
Tel. +39.0161.487526
Fax: +39.0161.487670
www.diasorin.com
E-mail: info@diasorin.it