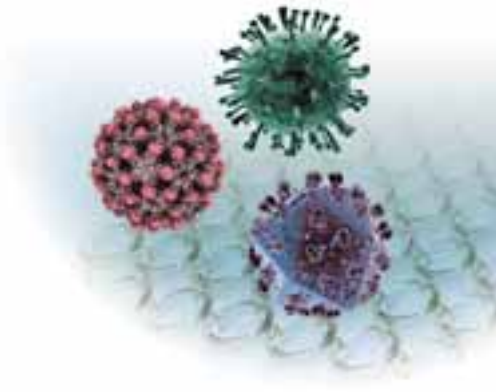


# Murex HTLV I + II

## ELISA Infectious disease



### ■ Technical Assay Details

Article Number:	8E22-02 (96 tests, 1 plate), 8E22-04 (480 tests, 5 plates)
Coating:	Synthetic peptides from ENV HTLV I and II immunodominant regions and a recombinant trans membrane protein from HTLV II.
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):	2 controls included: 3 x NC, 1x PC (4 wells of C required per run)
QC Neg. Cont. (NC):	Mean Value of NC < 0.2 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 11869 presumed negative donor samples were analyzed in seven European and one Australian blood transfusion center. In the whole study **99,94%** (11862/11869) were non-reactive (see package insert).

#### Sensitivity:

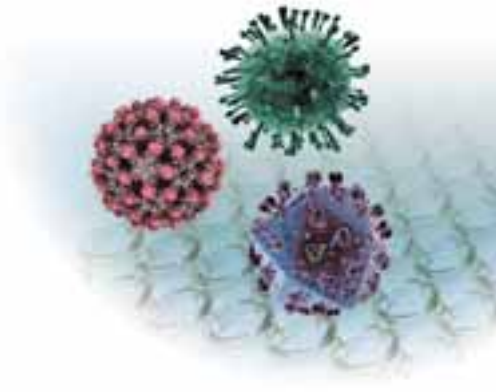
Vrieling et al. Vox Sanguinis, 1999,76, 187-191 compared four HTLV-I and -II ELISA by PROBIT analysis (serial dilution of positive samples). The authors conclude that all four assays are appropriate to be used in blood donation screening. The Murex assay mediated the highest analytical sensitivity relative to the other tests.

A total of 1291 specimens from patients in various clinical categories, including 505 samples from patients known to be infected with HTLV-I or HTLV-II were tested with Murex HTLV I+II. The results showed that Murex HTLV I+II detected antibody to HTLV in all samples (**100%** sensitivity) where antibody to HTLV was demonstrated to be present using an alternative enzyme immunoassay, Western blot and/or PCR.



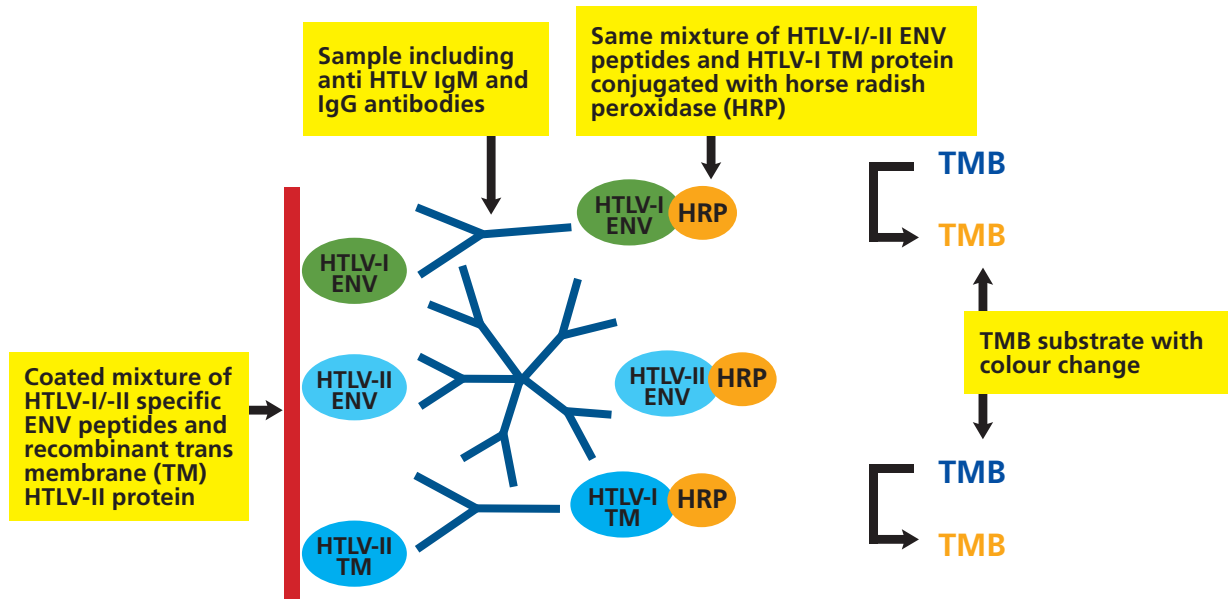
# Murex HTLV I + II

## 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 HTLV-I/-II assay in manual, semi-automated or fully automated way.
- **More blood safety** by significantly reducing the window period in using a total antibody test for the simultaneous detection of IgA, IgG and IgM.
- **High sensitivity in HTLV I + II detection** by using a third generation assay as a first line screening test.
- **Detects all subtypes** of HTLV I and II worldwide.
- **Excellent and better analytic sensitivity** compared to other tests.

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