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 / 30 min 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:
a) 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-1 infection and 201 samples from patients infected with HIV-2.
b) 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).
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■ 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.O assay in manual, semi-automated or fully automated way.

■ High sensitivity because the Murex HIV-1.2.O 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