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 / 30 min 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).
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- **Assay Principle**
  
  Combined Ag Capture + double Ag ELISA (bridge test)

  ![Diagram](image)

- **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

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