Murex anti-HBc (total)
ELISA Infectious disease

■ Technical Assay Details

Article Number: 8G21-01 (96 tests, 1 plate), 8G21-02 (480 tests, 5 plates)
Coating: Recombinant HBV core 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): 2 controls included: 2x NC and 2x PC (4 wells of C required per test run)
QC Neg. Cont. (NC): Mean Value of NC – Mean value PC = 0.5 – 2.2 OD (optical density)
QC Pos. Cont. (PC): Mean Value of PC < 0.24
Cut off Definition: (Mean value of NC + Mean value of PC) / 2
Result negative: OD value of the sample > cut off
Result positive: OD value of the sample ≤ cut off

■ Assay Performance

Specificity:
A total of 360 specimens from patients with conditions unrelated to HBV infection and confirmed as negative for antibody to hepatitis B core antigen were also tested with Murex anti-HBc (total). These included haemolysed specimens, specimens from pregnant women, patients suffering with autoimmune disease and patients with other acute viral infections. The diagnostic specificity of Murex anti-HBc (total) on this population of clinical specimens is estimated to be 100 % (360/360). A total of 5344 routine donor specimens from two European and two South American blood transfusion centres were screened with Murex anti-HBc (total). The screening specificity of Murex anti-HBc (total) on this population of negative routine donor specimens is estimated to be 99.74% (5298/5312).

Sensitivity:
A total of 447 specimens from patients known to contain antibody to hepatitis B core antigen were tested and found to be reactive with Murex anti-HBc (total). The specimens were taken from patients at various stages of HBV infection and included 139 specimens with IgM antibody to hepatitis B core antigen. The diagnostic sensitivity of Murex anti-HBc (total) on this population of specimens is therefore estimated to be 100 % (447/447, for details see package insert).
Murex anti-HBc (total)

ELISA Infectious disease

Assay Principle

Competitive ELISA for human IgM and IgG detection

Competitive Assay

- **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 anti HBc (total) assay in manual, semi-automated or fully automated way.
- **Less extra work** because of a high specificity mediated by purified and standardized recombinant antigen coated to the micro titer plate.
- **Fewer blood donation discards** because of low false positive rate of the test.
- **Excellent sensitivity** can be expected by screening blood donations for anti-HBc antibodies.
- **High reliability** the anti HBc detection of HBsAg negative HBV infected donors or patients.