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 / 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):** 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).
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■ Assay Principle

Competitive ELISA for human IgM and IgG detection

Competitive Assay

■ 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 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.

Product availability subject to required regulatory approval

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