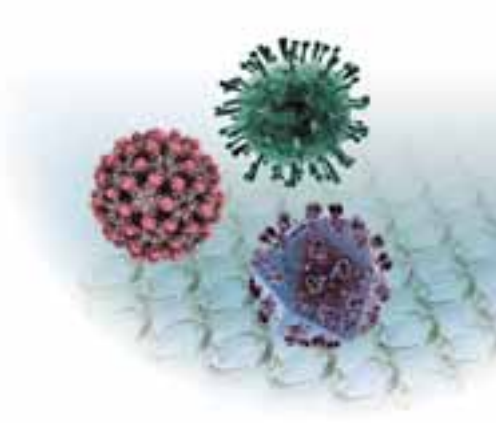


Murex anti-HBc (total)

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).

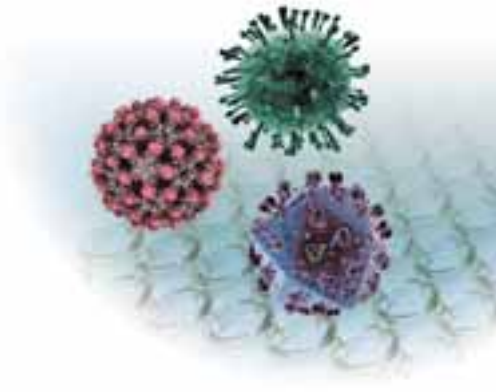


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murex
Murex® is a DiaSorin trademark

Murex anti-HBc (total)

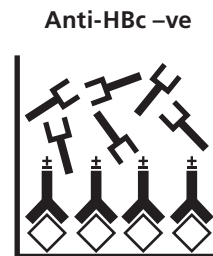
ELISA Infectious disease



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

FOR OUTSIDE THE US AND CANADA ONLY



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