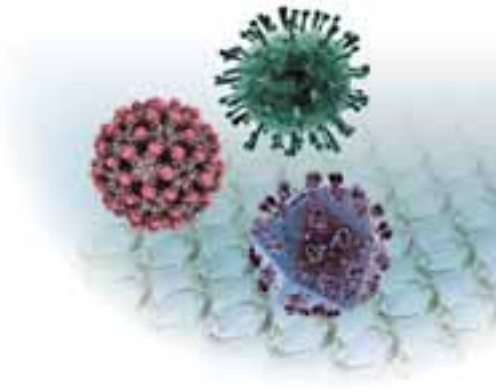


Murex HBsAg Version 3

ELISA Infectious disease



■ Technical Assay Details

Article Number:	9F80-01 (96 tests, 1 plate), 9F80-05 (480 tests, 5 plates)
Coating:	Mixture of Anti HBV surface antigen mouse monoclonal antibodies
Incubation Time:	60 min sample / 30min conjugate 30 min substrate (total 2.0 hours)
Incubation Temp.:	37°C / 37°C / 37°C
Assay Volumes:	25µl diluent / 75µl sample / 50µl conjugate 100µl substrate (TMB) / 50µl stop solution
Wash Steps:	One wash step with 5x washes each. Each wash using 500µl of wash buffer

■ Quality Control Criteria and Cut Off

Controls (C):	2 controls included: 2x NC, 1x PC (3 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 than mean value of NC
Cut off Definition:	Mean value of NC + 0.05 OD
Result negative:	OD value of the sample < cut off
Result positive:	OD value of the sample ≥ cut off

■ Assay Performance

Specificity:

The Murex HBsAg assay was used in a study where a total of 12330 routine donor samples were screened. In this study 0.03% (4/12330) were repeatedly reactive. None of the repeatedly reactive samples with Murex HBsAg version 3 and the alternative assays were confirmed as positive for the presence of hepatitis B surface antigen. The specificity is estimated to be **99.97%** (12326/12330).

Sensitivity:

A total of 630 samples from patients suffering from acute and chronic hepatitis B infection were tested with Murex HBsAg version 3. All 630 samples were confirmed with an alternative immunoassay for HBsAg and found to be positive in both assays. The sensitivity observed for this population of specimens was **100%**. A further six samples from patients infected with mutant forms of hepatitis B infection, confirmed by DNA sequencing, were also tested with Murex HBsAg version 3 and were all detected successfully (for more details see package insert).

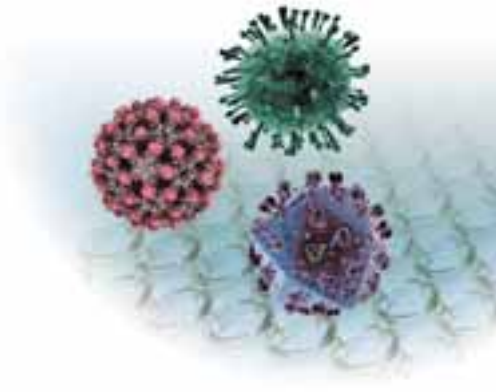


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murex
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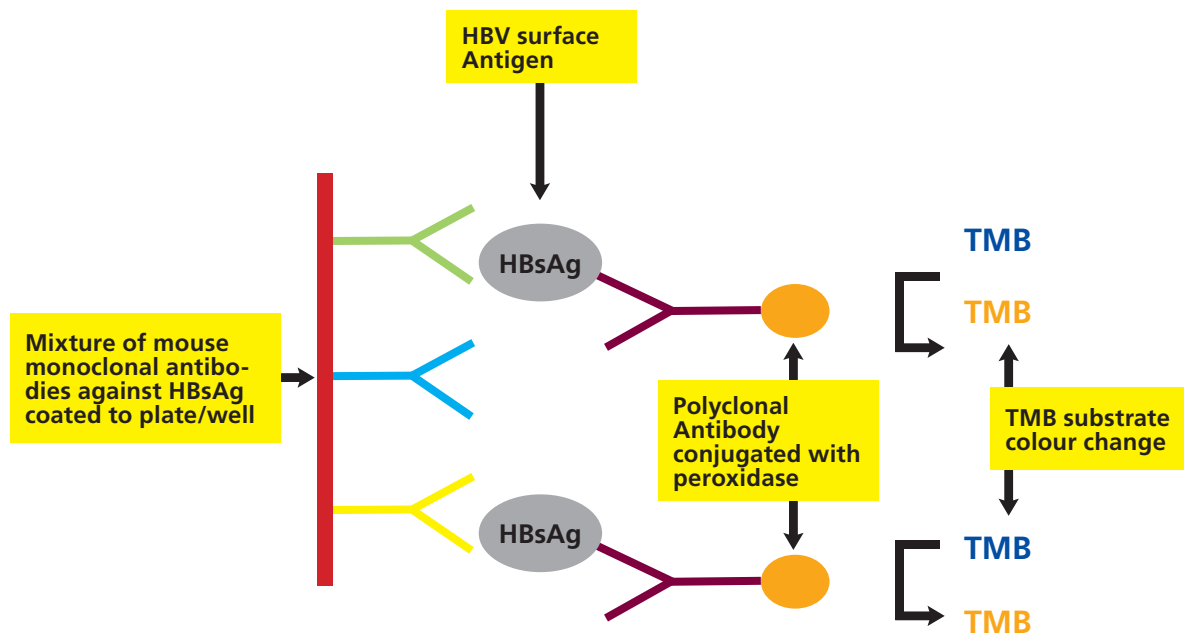
Murex HBsAg Version 3

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■ Assay Principle

Antigen Capture ELISA



■ 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 HBsAg assay in manual, semi-automated or fully automated way.
- **Full reactivity** with HBsAg of all known HBV genotypes A-H.
- **One of the most sensitive HBsAg assays** to be used as a first line screening test for blood donations
- **Less extra work**, because of a high specificity giving low numbers of false positive results.
- **Fewer blood donation discard** because of less false positive reactions.
- **High reliability** by precise detection of HBsAg in patient monitoring.

Product availability subject to required regulatory approval



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FOR OUTSIDE THE US AND CANADA ONLY

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