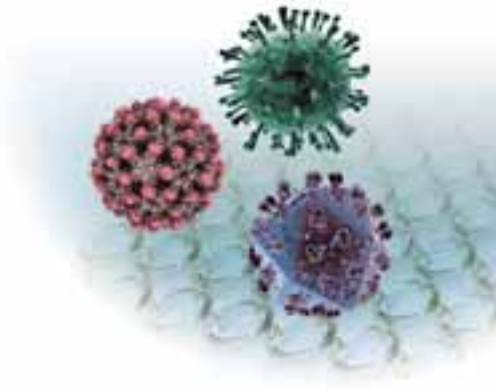


Murex HBsAg Confirmatory Version 3

ELISA Infectious disease

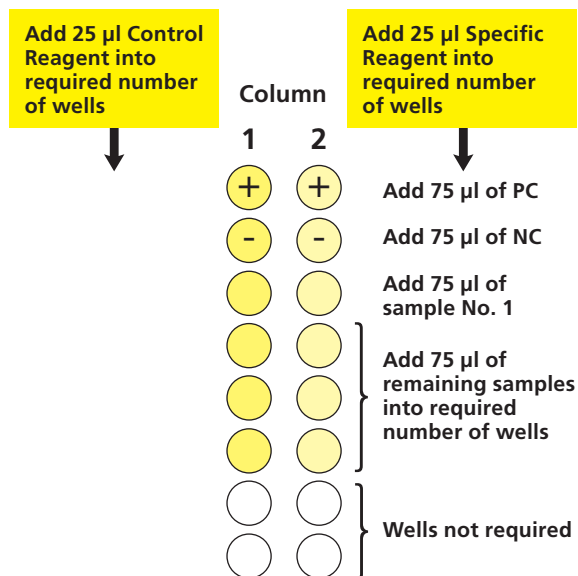


■ Technical Assay Details

Article Number:	2G27-01 (50 tests)
Kit Components:	Control Reagent (1.25 ml) and Specific Reagent (1.25ml) used in combination with Murex HBsAg Version 3 (9F80) kit.
Explanation of Test:	Murex HBsAg Confirmatory functions by means of specific antibody neutralization of HBsAg in samples that are repeatedly reactive in the Murex HBsAg version 3 (9F80) assay.
Pre-shaking time:	10 seconds
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 control and specific reagent/ 75µl sample / 50µl conjugate 100µl substrate (TMB) / 50µl stop solution
Wash Steps:	One wash step with 5x washes. Each wash using 500µl of wash buffer

■ Test principle and pipetting schedule:

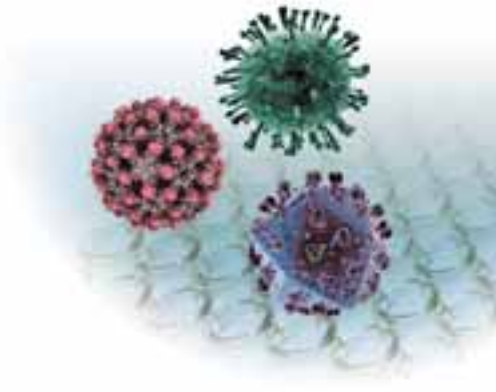
Figure 1
Configuration of Test



- Step 1** Prepare substrate solution and wash fluid. See Murex HBsAg Version 3 (9F80) Instructions for Use
- Step 2** Add 25 µl of control reagent into appropriate wells (see Figure 1).
- Step 3** Add 25 µl of specific reagent into appropriate wells (see Figure 1).
- Step 4** Add 75 µl of Murex HBsAg Version 3 (9F80) controls and 75 µl Test Samples to the wells (see Figure 1).
- Step 5** Shake the plate using a plate shaker for 10 seconds. Alternatively the plate may be manually agitated by gently tapping the side for 10 seconds.
- Step 6** Proceed from and including Step 5 of the Murex HBsAg Version 3 (9F80) test procedure as described in the Instructions for Use.

Murex HBsAg Confirmatory Version 3

ELISA Infectious disease



■ Quality Control Criteria and Cut Off

Controls (C):	2 controls included: 1 x NC, 1x PC (4 wells of C required per run) For each sample/C 2 wells are required.
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 >80% reduction in OD when incubated with specific reagent
Cut off Definition:	Mean value of NC + 0.05 OD
Result negative:	Samples giving less than 50% inhibition by the specific reagent are considered negative (see example of calculation in package insert)
Result positive:	Inhibition by the specific reagent must be equal to or greater than 50% (see example of calculation in package insert).

■ Assay Performance

A total of 169 samples, which were reactive with Murex HBsAg Version 3 (9F80) and at least one other immunoassay for the detection of hepatitis B surface antigen, have been tested with Murex HBsAg Confirmatory Version 3 (2G27). The samples included specimens from patients infected with known subtypes or mutant forms of hepatitis B. All of the samples were confirmed with and without further dilution in the Murex HBsAg Confirmatory Version 3 assay. A sensitivity of **100 %** was observed in this population of specimens.

■ Your Advantages

- **High security** for the operator. Each pipetting step is completely monitored by a colour change (full sample monitoring included).
- **Full reactivity** with HBsAg of all known HBV genotype A-H.
- **One of the most sensitive HBsAg assays** in combination with Murex HBsAg Version 3.
- **High reliability** in the confirmation of positive HBsAg test by precise neutralization of the HBsAg antigen.

Product availability subject to required regulatory approval



The Diagnostic Specialist

FOR OUTSIDE THE US AND CANADA ONLY

DiaSorin S.p.A.
Via Crescentino
13040 Saluggia (VC) - Italy
Tel. +39.0161.487526
Fax: +39.0161.487670
www.diasorin.com
E-mail: info@diasorin.it