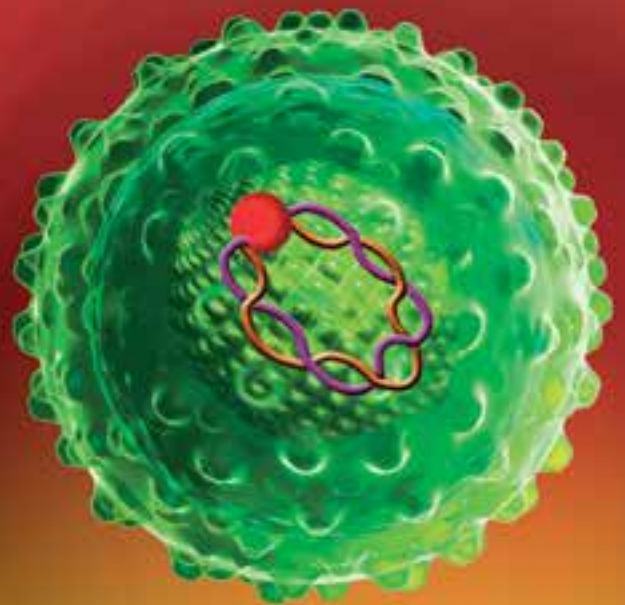


Hepatitis and Retrovirus

LIAISON[®] XL **murex** HBsAg Quant

Reliable detection of HBsAg mutants and genotypes for accurate differential diagnosis of the stage of infection



DiaSorin

The Diagnostic Specialist

FOR OUTSIDE THE US AND CANADA ONLY

LIAISON® XL murex HBsAg Quant...

Reliable detection of HBsAg mutants

HBsAg mutant susceptibility was obtained by testing ten common mutants, including the most prevalent Gly-Arg 145 mutant (G145R).

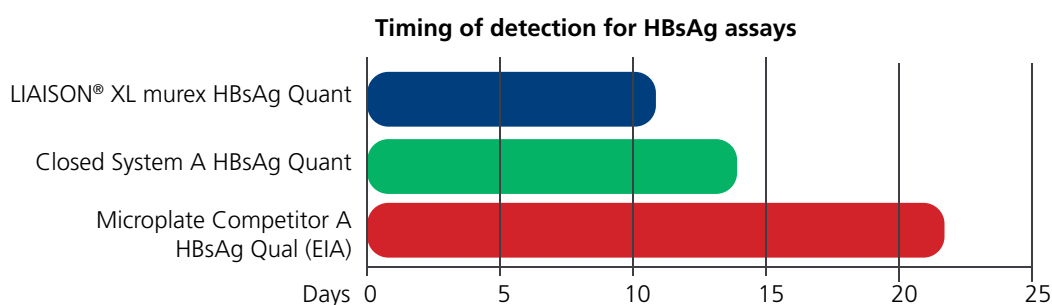
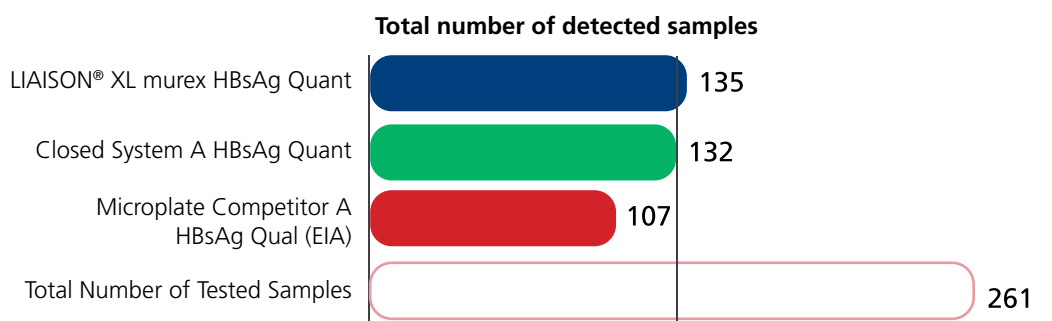
Panel ID	Mutation	LIAISON® XL murex HBsAg Quant IU/mL	Closed System B HBsAg Qual	Closed System A HBsAg Quant	Closed System C HBsAg Qual	Microplate Competitor A
1	T123N	0.92 (+)	reactive	reactive	reactive	reactive
2	T123N-T124S	0.24 (+)	reactive	non-reactive	reactive	non-reactive
3	P124L-F/Y143H D144E-G145R	0.31 (+)	non-reactive	non-reactive	non-reactive	non-reactive
4	I110R-S117I G119R-T123N	0.81 (+)	reactive	reactive	reactive	reactive
5	122+DT	1.0 (+)	reactive	reactive	reactive	reactive
6	122+DT-G145R	1.6 (+)	non-reactive	reactive	reactive	reactive
7	G145R	0.36 (+)	reactive	reactive	reactive	reactive
8	D144A	0.53 (+)	reactive	reactive	reactive	reactive
9	P142L-G145R	0.50 (+)	reactive	reactive	reactive	reactive
10	P142S-G145R	0.45 (+)	reactive	reactive	reactive	reactive

Superior analytical and diagnostic sensitivity for early diagnosis

Analytical sensitivity: 0.050 IU/mL, Second International Standard for HBsAg, subtype *adw2*, genotype A, NIBSC code: 00/588.

Diagnostic sensitivity: 100% (95% confidence interval: 99.1-100.0%) testing 424 specimens from preselected HBsAg-positive patients (encompassing different HBsAg subtypes - *ad* and *ay* - and genotypes).

Earliest detection of seroconversion (N = 32 commercial panels)

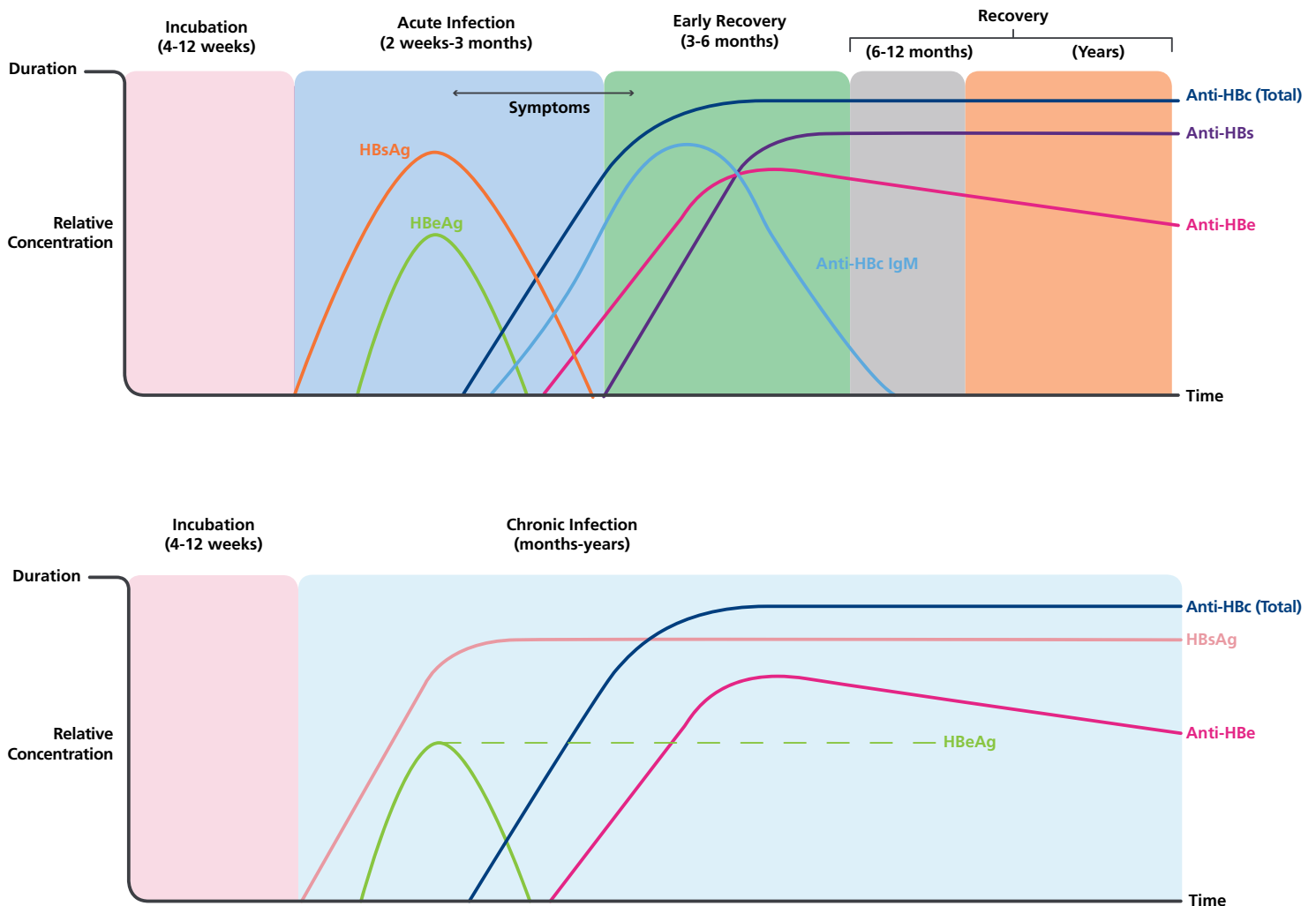


Early detection? Acute infection? Treatment monitoring?

Hepatitis B

Approximately one third of the world population has serological evidence of past or present infection with HBV and 350 million people are chronically infected. The rate of progression from acute to chronic hepatitis B is affected by the age at infection. The rate is up to 90% for perinatally acquired infection, 20-50% for infections between the age of one and five years, and less than 5% for adult-acquired infection. Hepatitis B virus infection is prevalent in Asia, Africa, Southern Europe and South America, where the prevalence of HBsAg in the general population ranges from 2 to 20%.

HBV serological pattern: from acute to chronic HBV infection



Several important markers are used in the diagnosis and monitoring of hepatitis B infection. The presence of HBsAg is the main indicator that a patient is infected and it is therefore the most suitable marker to be detected in blood banks and in pregnancy screening. Latest pieces of evidence support the role of HBsAg (quantification of HBsAg) as a predictive marker for the anti-HBV treatment response. All the other markers provide significant clinical information.

Confidence in Your results

Excellent diagnostic specificity to reduce retesting

Population	Number of cases	Initially reactive samples, No.	Repeat reactive samples, No.	Confirmed positive samples, No.	Diagnostic specificity, %	Diagnostic specificity, 95% CI
Blood donors	5201	6	1	0	99.98 (5200/5201)	99.89 - 100.0
Hospitalised patients	390	5	4	4	100.0 (386/386)	99.05 - 100.0
Dialysis patients	278	3	3	2	99.64 (275/276)	98.00 - 100.0
Pregnant women	100	0	0	0	100.0 (100/100)	96.38 - 100.0
High-risk subject	143	7	5	4	99.28 (138/139)	96.05 - 99.98

LIAISON® XL murex HBsAg Quant assay is flexible, easy to use and precise

- Full automation makes your daily routine convenient and easy.
- Quick testing for better patient management.

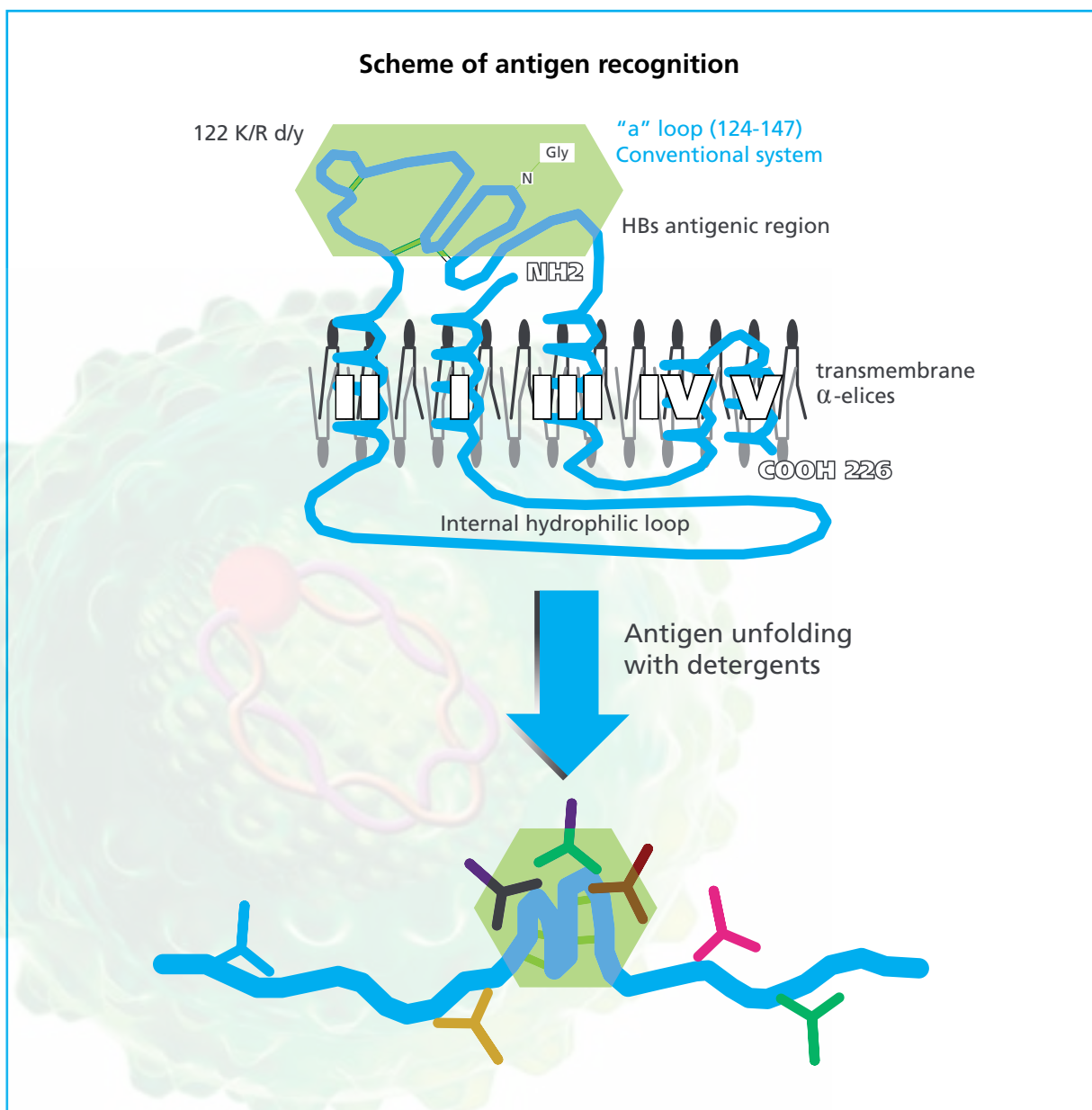
Standard Calibrators	2 Calibrators (referenced to NIBSC standard - WHO 2nd IS) included in the cartridge Assay Range 0.030 - 150 IU/mL HBsAg
Controls	Negative, Positive, ready to use (4 weeks stability)
Interpretation of Results	Specimens with concentration equal to or above 0.05 IU/mL should be graded Reactive
Minimum Sample Volume	Routine = 150 µL Specimen plus 150 µL dead volume
Sample Type	Human serum or plasma (including serum collected in serum separator tubes). Anticoagulants: sodium citrate, potassium EDTA, lithium and sodium heparin, potassium oxalate, ACD, CPDA
Reagent Stability	Assay reagent (open on board stable 4 weeks)
Sample Diluent	Specimens containing HBsAg concentrations above 150 IU/mL should be diluted (recommended dilution factor 1:400)
Precision (≥ 0.05 IU/mL)	Repeatability CV% < 12% - Interlot Reproducibility CV% < 14%

LIAISON® XL **murex** HBsAg Quant is Your solution

The LIAISON® XL murex HBsAg Quant direct two-step sandwich chemiluminescence assay format ensures reliable data.

- Based on novel murine monoclonal antibodies (Mabs).
- Unique capability in detecting HBsAg mutants.
- Superior sensitivity for early diagnosis.
- Excellent specificity to meet laboratory needs.
- High reproducibility for confidence in results.

The unique capability in detecting both the described HBsAg mutants and the HBsAg genotypes is linked to a **patented technology** which brought to the isolation of a panel of murine monoclonal antibodies (Mabs). Such antibodies are capable of binding the unfolded antigen in the presence of a high concentration of detergents and are directed towards the “classical a” loop region as well as to highly conserved domains derived from both the internal hydrophilic loop and the transmembrane regions.



LIAISON® XL murex HBsAg Quant

Improving performance and ease of use, targeting the best quality and safety in result reporting with LIAISON® XL system



- Quality in results reporting
- Consistent throughput up to 180 tests/h
- High reagent capacity & complete traceability
- High walk away time
- Service remote access

Ordering Information

Product Name	Description	Code
LIAISON® XL murex HBsAg Quant	200 tests	310250
LIAISON® XL murex Control HBsAg Quant (neg & pos)	2 x 4.0 mL each	310251
LIAISON® XL murex HBsAg Quant Specimen Diluent	50 mL	310252
HBsAg Confirmatory Test	20 specimens	310110
LIAISON® XL	Platform	I0050
LIAISON® XL Cuvettes	7200/box	X0016
LIAISON® XL Disposable Tips	6912/box	X0015
LIAISON® XL Starter Kit	3000 test	319200
LIAISON® XL Wash/System Liquid	6 vials/box	319100
LIAISON® XL Waste Bags	50 bags/box	X0025

References:

1. **EASL** Clinical Practice Guidelines: Management of chronic hepatitis B European Association for study of the liver. Journal of Hepatology 57: 167–185 (2012).
2. **T.D. Ly** Detection HBsAg Mutants by Immunoassays. Journal of Medical Virology 79:S37–S41 (2007).
3. **A Consensus Report of an Expert Meeting** Diagnostic Problems Caused by HBsAg Mutants - Intervirology 47: 310 313 (2004).
4. **M.R. Brunetto** A new role for an old marker, HBsAg. Journal of Hepatology 52: 475-477 (2010).

Product availability subject to required regulatory approval

DiaSorin

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