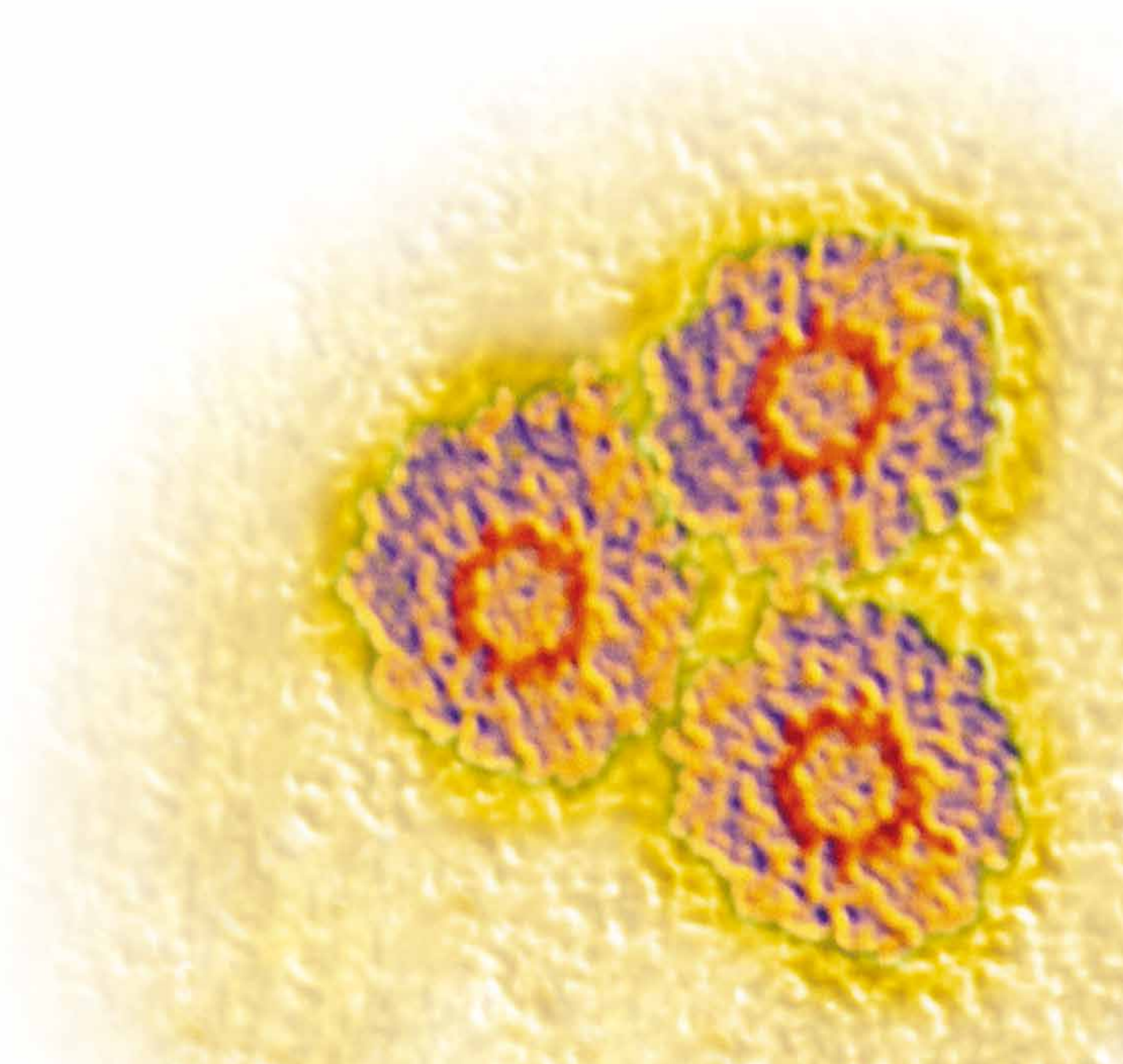


Hepatitis and Retrovirus

Hepatitis A and B **LIAISON**[®]

From challenges to solutions



DiaSorin

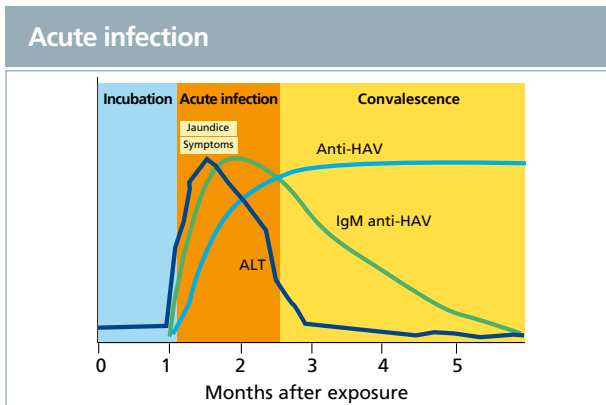
The Diagnostic Specialist

FOR OUTSIDE THE US AND CANADA ONLY

Early diagnosis? Acute or chronic infection? LIAISON® XL Hepatitis A and B is the Solution

Outbreaks of epidemic jaundice were known in both Greek and Roman times, but today viral hepatitis continues to be a disease of major significance in terms of morbidity and mortality. The symptoms of hepatitis vary considerably from one individual to another, even when the same causative agent is involved. Because the symptoms are not specific to the causative agent, it is impossible to distinguish among the various causative agents of hepatitis based on clinical symptoms alone. Serological testing is then required. A definitive diagnosis of viral hepatitis is only achievable by the use of viral-specific hepatitis tests. Viral hepatitis assays detect the presence of specific viral antigens and /or antibodies in serum or plasma and the physician uses these results to diagnose, screen and monitor a hepatitis infection.

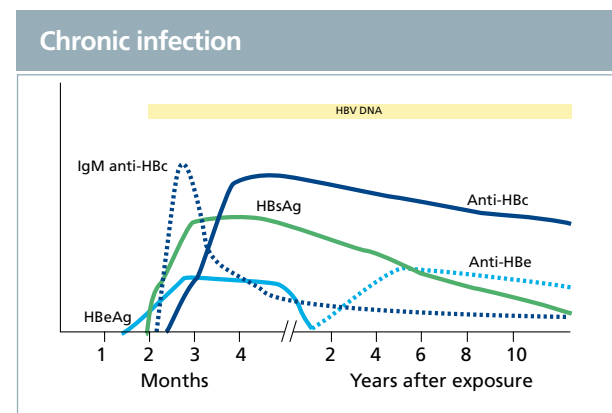
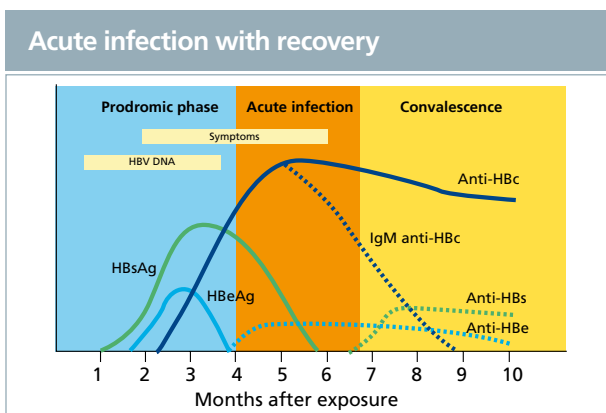
Hepatitis A



Most frequent patterns

	Total anti-HAV	IgM anti-HAV	AST/ALT
Subject susceptible to HAV	-	-	-
Recent HAV infection	-	+	+
Acute HAV infection	+	+	+
Past HAV infection, immunization, past vaccination	+	-	-
Non-HAV hepatitis	-	-	+

Hepatitis B



Most frequent patterns

	HBsAg	Anti-HBs	IgM anti-HBc	Total anti-HBc	HBeAg	Anti-HBe	HBV-DNA
Viral activity (mainly wild virus)	+	-	+	+	+	-	+
Viral activity (mainly pre-core minus variant)	+	-	+	+	-	+/-	+
Resolving acute HBV hepatitis	+	-	+	+	-	+/-	-
Healthy carrier	+	-	-	+	-	+/-	-
"Core window"	-	-	+	+	-	-	-
Post-natural infection immunization	-	+	-	+	-	+/-	-
Post-vaccination immunization	-	+	-	-	-	-	-
Never infected/Susceptible	-	-	-	-	-	-	-

<http://www.cdc.gov/hepatitis/index.htm>



The Diagnostic Specialist

Confidence in Your Results

DiaSorin LIAISON® XL HEPATITIS A and B LINE to achieve high safety for diagnosis and monitoring with

- Excellent seroconversion sensitivity
- High sensitivity in the recognition of viral variants and mutants
- LIAISON® XL Hepatitis A and B Specificity.
- High precision and wide measuring range
- Fast response

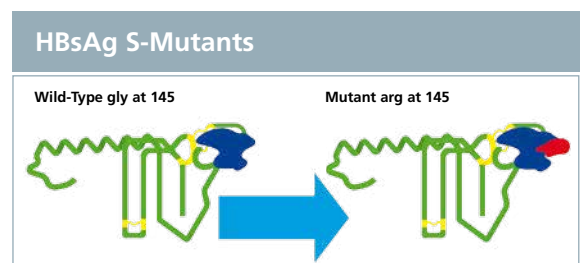
LIAISON® XL HEPATITIS A and B Specificity and Sensitivity Performance

LIAISON® XL HEPATITIS A						
Test	Diagnostic Specificity, %	95% CI, %	Diagnostic Sensitivity, %	95% CI, %	Analytical Sensitivity, %	Availability
Anti-HAV	99.79 (486/487)	98.86-100	99.00 (297/300)	97.10-99.80	18 mIU/mL (WHO 2 nd IS, 1998) (range: 15.5-21.5 mIU/mL)	LIAISON® Analyzer family
HAV IgM	100 (690/690)	99.47-100	97.92 (141/144)	94.03-99.57	-	LIAISON® Analyzer family
LIAISON® XL HEPATITIS B						
Test	Diagnostic Specificity, %	95% CI, %	Diagnostic Sensitivity, %	95% CI, %	Analytical Sensitivity, %	Availability
HBsAg Quant	BD 99.98 (5,200/5,201)	99.89-100	SS 100 (424/424)	99.10-100	0.050 IU/mL (NIBSC 00/588, 2003) LoD ≤ 0,030 IU/mL	LIAISON® XL Analyzer only
	HS 100 (386/386)	99.05-100				
Anti-HBs/ Anti-HBs Plus	SS 100 (214/214)	98.29-100	SS 100 (386/386)	99.05-100	3 mIU/mL (WHO 2 nd IS, NIBSC 07/164, 2008)	LIAISON® Analyzer family
	PS 99.55 (442/444)	98.38-99.95	PS 99.31 (286/288)	97.51-99.92		
Anti-HBc	BD LSN 99.70 (4,992/5,007)	99.51-99.83	SS 100 (618/618)	99.41-100	< 0.60 PEI U/mL (HBc Ref. M82 - IgG anti-HBc, Paul-Ehrlich-Institut)	LIAISON® Analyzer family
	BD XL 99.90 (5,002/5,007)	99.76-99.97				
HBc IgM	SS 99.87 (1,565/1,567)	99.54-99.99	SS 99.44 (359/361)	98.00-99.93	20.3 PEI U/mL (HBc Ref. S84 - IgM anti-HBc, Paul-Ehrlich-Institut) (range: 15.0-34.0 PEI U/mL)	LIAISON® Analyzer family
HBeAg Quant	SS 99.54 (1,720/1,728)	99.09-99.80	SS 99.49 (196/197)	99.10-100	0.1 PEI U/mL (HBe Ref. A82 - HBeAg, Paul-Ehrlich-Institut)	LIAISON® Analyzer family
Anti-HBe	SS 99.44 (1,242/1,249)	98.85-99.78	SS 99.25 (527/531)	98.08-99.80	0.076 PEI U/mL (HBe Ref. S82 - IgG anti-HBe, Paul-Ehrlich-Institut) (range: 0.050-0.120 PEI U/mL)	LIAISON® Analyzer family

BD = Blood Donors HS= Hospitalized Samples SS= Selected Samples PS= Prospective Samples LSN= LIAISON® XL= LIAISON® XL
(n. sample positive or negative/total n. of samples)

Excellent Mutant HBsAg Detection with LIAISON® XL Murex HBsAg Quant

The sensitivity performance for HBsAg mutant detection was assayed in different studies with large panels of HBsAg mutants, including a significant number of natural and recombinant mutants, with single - or multiple-point mutations. The studies showed that the assay is capable of detecting mutants, including the most frequent G145R mutant.



De Paschale M. et al. Journal of Medical Virology 2016 Jul 28
Fiedler M. et al. Journal of Clinical Virology 59 (2014) 44-49

Hepatitis and Retrovirus

DiaSorin LIAISON® XL HEPATITIS A and B LINE committed to better technology

■ MAIN FEATURES for reliable data

- Number of tests: 200 tests for HBsAg Quant, Anti-HBs, Anti-HBs Plus
100 tests for Anti-HBc, HBeAg Quant, Anti-HBe, Anti-HAV, HAV IgM
50 tests for HBc IgM
- Reagents: Unique selection of monoclonal antibodies and recombinant DNA technology
- Label: Isoluminol derivative
- Method: CLIA
- Assay Format: Qualitative for Anti-HBc, HBc IgM, Anti-HBe, Anti-HAV, HAV IgM
Quantitative for HBsAg (assay range 0.030 -150 IU/mL), Anti-HBs (assay range 3 -1,000 mIU/mL), Anti-HBs Plus (assay range 3 -90,000 mIU/mL), HBeAg (assay range 0.01 to 120 PEI U/mL)
- Sample Type: Serum and Plasma

■ FLEXIBILITY for safe, quick and accurate results

- Throughput: 90-171 tests/h
- Time to first results: 30-60 minutes
- Ready-to-use reagent cartridge
- Reagent stability on board: 4-12 weeks
- Calibration Stability: 4-8 weeks
- Sample volume: 20-150 µL

Values reported are different depending on the assay: for detailed information on each assay refer to the package insert.

Ordering information

LIAISON® XL murex HBsAg Quant (code 310250)
HBsAg Confirmatory Test (code 310110)
LIAISON® XL murex Anti-HBs (311220)
LIAISON® Anti-HBc (code 310130)
LIAISON® HBc IgM (code 310140)
LIAISON® XL murex Anti-HBs Plus (311230)

LIAISON® Anti-HBc (code 310130)
LIAISON® HBc IgM (310140)
LIAISON® HBeAg (code 310150)
LIAISON® Anti-HBe (code 310160)
LIAISON® Anti-HAV (code 310170)
LIAISON® HAV IgM (code 310180)

Product availability subject to required regulatory approval



The Diagnostic Specialist

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