SIEMENS

Hepatitis B Testing

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VERSANT HBV DNA 1.0 Assay (kPCR)

VERSANT kPCR Molecular System

Assay Description

The VERSANT® HBV DNA 1.0 Assay (kPCR) is an in vitro nucleic acid amplification test for quantitative measurement of hepatitis B virus DNA in human plasma or serum samples from HBV–infected individuals. The assay is based on real-time polymerase chain reaction (PCR) technology, utilizing PCR for the amplification of specific target sequences and target-specific probes for the detection of amplified DNA. This assay is performed on the VERSANT kPCR Molecular System. Combined with Siemens Healthcare Diagnostics nucleic acid extraction technology, this assay provides a reliable and sensitive method for the quantitation of HBV in infected individuals.

Clinical Relevance

Viral load testing, using a real-time PCR-based method, is an established marker for the monitoring of HBV patients. Highly sensitive assays are needed in order to assess viral suppression. The latest clinical guidelines* recommend routine assessment of HBV viral load in conjunction with current HBV antiviral therapies.

HBV Assay Design

- Quality extraction of nucleic acids ensures accuracy.
- Highly sensitive and specific assay performance provides confidence.
- Outstanding precision across a wide dynamic quantitation range produces reliable results.
- Optimized TaqMan probes with Black Hole Quenchers.
- Referenced to the WHO 2nd Hepatitis B Virus (HBV) DNA International Standard (NIBSC 97/750) for IU/mL.

VERSANT kPCR Molecular System with VERSANT MiPLX Software Solution

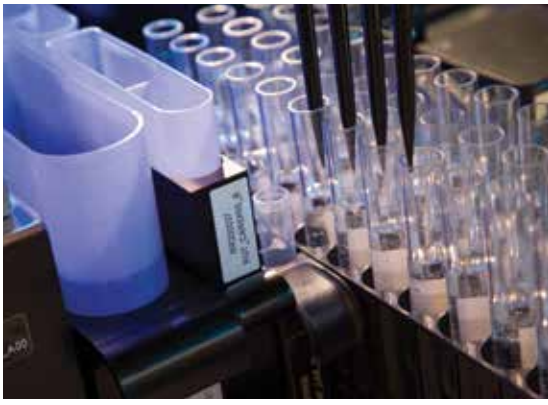
Advancing flexibility, workflow, customization, and consolidation in the molecular laboratory.

- Comprehensive and flexible solution for molecular diagnostics.
- Open-channel capabilities enables customization of laboratory-developed and third-party assays.†
- Multiplexing of up to six assays from one sample in one run.†
- Standardized extraction method for isolation of quality nucleic acids from a wide variety of specimen types.
- Consolidation of quality assays for infectious-disease testing on a single, automated platform.

*EASL clinical practice guidelines: Recommendations on the treatment of hepatitis, 2017.

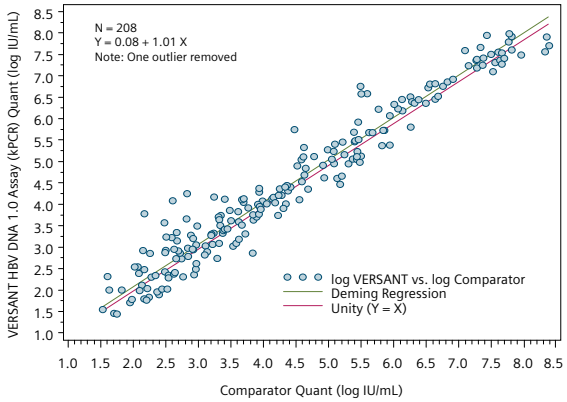
†Laboratory is responsible for validating their assay.

One Solution—More Choice.

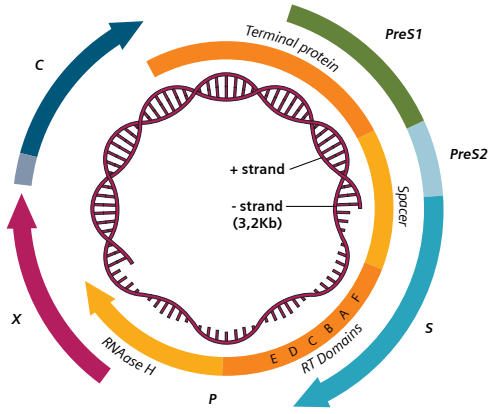


VERSANT HBV DNA 1.0 Assay (kPCR)

VERSANT HBV DNA 1.0 Assay (kPCR) vs. Roche COBAS® AmpliPrep/COBAS® TaqMan® HBV Test Version 2.0.



VERSANT HBV DNA 1.0 Assay (kPCR) Primers and Probe Information



- Targets overlapping region within the surface antigen (S) and RT region of the pol (P) gene
- Utilizes conserved consensus sequence across genotypes A-H with an amplicon size of 176 base pairs

Performance Characteristics

Description	Value
Dynamic Range	• 13 to 700,000,000 IU/mL • LoD = 13 IU/mL (for serum) • LoD = 9.5 IU/mL (for plasma)
Subtype Detection and Recovery	• Detects all HBV genotypes A-H.

Product Features

Description	Value
Contamination Control	UNG and physical barriers
Calibrators and Controls	Two calibrators made from rDNA Three controls (high positive, low positive, negative)
Validated Specimen Types	Serum and Plasma
Turnaround Time	4 hours and 30 minutes‡

‡Data on file at Siemens Healthcare Diagnostics, Nexus Global Solutions, Inc.

Product Specifications

Description	Value
Reagent Storage Conditions	HBV Assay (Box 1): –30°C to –10°C HBV Assay (Box 2): –90°C to –60°C Sample Preparation Reagents (Box 1): 15–30°C Sample Preparation Reagents (Box 2): 4°C
Sample Input Volume	500 µL§

§Total sample Input volume requirement depends on tube type and size.

Ordering Information

Catalog	Description	Quantity
10282480	VERSANT HBV DNA 1.0 Assay (kPCR), Box 1	48 tests
10282481	VERSANT HBV DNA 1.0 Assay (kPCR), Box 2	48 tests
10286026	VERSANT Sample Preparation 1.0 Reagents (Box 1)	96 tests
10286027	VERSANT Sample Preparation 1.0 Reagents (Box 2)	96 tests

CE-marked for IVD use.

Please contact your local sales representative to learn more about the full line of Siemens Healthcare Diagnostics molecular assays for infectious diseases or visit **siemens.com/molecular.**

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