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VERSANT HIV-1 RNA 1.5 Assay (kPCR)

VERSANT kPCR Molecular System

Assay Description

The VERSANT® HIV-1 RNA 1.5 Assay (kPCR) is an in vitro nucleic acid amplification test for quantitative measurement of human immunodeficiency virus (HIV-1) RNA in human plasma samples from HIV-1–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’s nucleic acid extraction technology, this assay provides a reliable and sensitive method for the quantitation of HIV-1 in infected individuals.

Clinical Relevance

Viral load testing, using a real-time PCR-based method, is an established marker for the monitoring of HIV-1 patients. Highly sensitive assays are needed in order to assess viral suppression. The latest clinical guidelines* recommend assessment of HIV-1 viral load every 3 to 6 months.

HIV-1 Assay Design

- Continuous surveillance program to address new HIV-1 variants.
- Highly conserved target region of integrase gene.
- Dual primers design to ensure mismatch tolerance.
- Optimized TaqMan probes with Black Hole Quencher.

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.

One Solution— More Choice.



*European AIDS Clinical Society (EACS). http://www.eacsociety.org/files/guidelines_english_71_141204.pdf.

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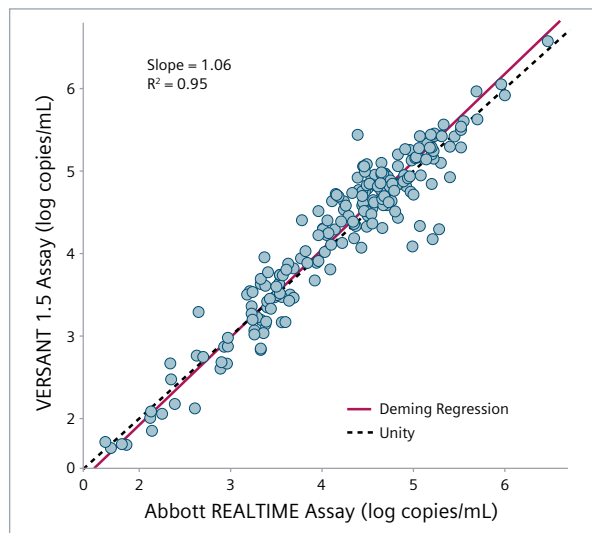
Performance Characteristics	
Description	Value
Dynamic Range	<ul style="list-style-type: none"> • 37 to 11,000,000 copies/mL • LoD = 37 copies (95% confidence interval)
Subtype Detection and Recovery	<ul style="list-style-type: none"> • A large number of patient samples covering HIV-1 group O and group M (subtypes A–H and recombinants including CRF02-AG) were tested and were within ± 0.2 log of the Abbott REALTIME HIV-1 assay.[†]

[†]Monga D, et al. Method Comparison between the Siemens VERSANT HIV-1 RNA 1.5 Assay (kPCR) and the Abbott REALTIME HIV-1 Assay. 2015.

Product Features	
Description	Value
Contamination Control	UNG and physical barriers
Calibrators and Controls	Two calibrators Three controls (high positive, low positive, negative)
Validated Specimen Types	Plasma (K ₂ EDTA, ACD-A, and PPT)
Turnaround Time	6 hrs 25 min for batch of 96 samples [‡]

[‡]Data on file at Siemens, Nexus Global Solutions, Inc.

Deming Scatter Plot



Product Specifications	
Description	Value
Reagent Storage Conditions	HIV-1 Assay (Box 1): -20°C HIV-1 Assay (Box 2): -80°C Sample Preparation Reagents (Box 1): 15–30°C Sample Preparation Reagents (Box 2): 4°C
Sample Input Volume	500 μ L [§]

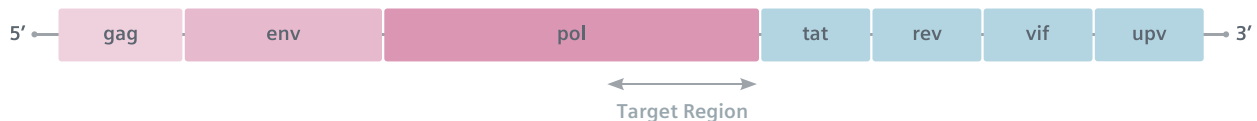
[§]Total sample input volume requirement depends on tube type and size.

Ordering Information		
Catalog	Description	Quantity
10729727	VERSANT HIV-1 RNA 1.5 Assay (kPCR), Box 1	96 tests
10729728	VERSANT HIV-1 RNA 1.5 Assay (kPCR), Box 2	96 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.

HIV-1 Probe Target: Integrase Region

Target: Highly conserved pol integrase region using mismatch-tolerant primers and TaqMan probes.



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

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Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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