

# EXAVIR LOAD

The world's first reverse transcriptase viral load test

**ExaVir™** Load

*Version 3*



# SUBTYPE-INDEPENDENT HIV VIRAL LOAD TESTING FOR THE WORLD

ExaVir™ Load is used in clinics around the world to monitor HIV viral load through reverse transcriptase (RT) activity. Since the release of ExaVir Load Version 1 in 2002, we have continually developed our ExaVir products to make them even more accessible to physicians and patients from Nairobi to New York. It starts with our subtype-independent RT platform and continues with its robust design and minimal resource footprint. From major urban research hospitals to small rural clinics, ExaVir Load is establishing a new level of accessibility and reliability for viral load testing.

## The difference with RT

Today there are four primary platforms for HIV viral load monitoring. Each of these platforms has proven its ability to detect HIV activity under the right conditions. Three of these platforms are based on detecting and measuring RNA. The notable exception is the RT platform. It looks for a different HIV marker. Instead of detecting RNA, which changes with mutations, the RT platform measures the activity of the enzyme reverse transcriptase (RT), which is unaffected by mutations in the RNA. This enzyme is essential for the replication of the virus and is present in any HIV-1 subtype as well as HIV-2. With HIV subtype variation on the rise across the world, the advantages of a subtype-independent viral load test are relevant everywhere.

## New platform, new access

In developed nations, the value of HIV viral load testing is not disputed. In these countries, it is a routine part of HIV management. That's because viral load testing helps doctors use ARVs more effectively to extend a patient's length and quality of life, limit the development of viral resistance and minimize the waste of medication. However, for those living in resource-limited settings, which are more than 80% of the world's population, HIV viral load testing is all but non-existent. There are several reasons for this, but foremost are perceptions developed a decade ago that viral load testing cannot adequately address the clinical and financial realities of these settings. While this may have been true before, today's RT platform offers several distinct advantages that make viral load testing accessible to those who previously had to do without.

## HIV Viral Load Testing Platforms

Platform	Manufacturer	Measures	Test Name	Introduced
PCR	Hoffman-La Roche	RNA	Amplicor	1994
NASBA	bioMerieux	RNA	NucliSens	1994
bdNA	Siemens	RNA	Versant	1995
RT	Cavidi	Reverse Transcriptase	ExaVir Load	2002

## ExaVir Load Specification Overview

ExaVir Load	Specifications
Speed	48 hours for 30 or 60 tests
Throughput	Maximum 180 tests per week
Hands-on time	~5 hours
Measuring range	1–3,000 fg/ml (~200–600,000 copies equivalents/ml)
Precision	Within-assay variation: 4–8% Between-assay variation: 2–3%
Analytical specificity	>99%
Sensitivity	1 fg/ml (~200 copies equivalents/ml)

# SEPARATION EQUIPMENT WITH EXAVIR LOAD VERSION 3

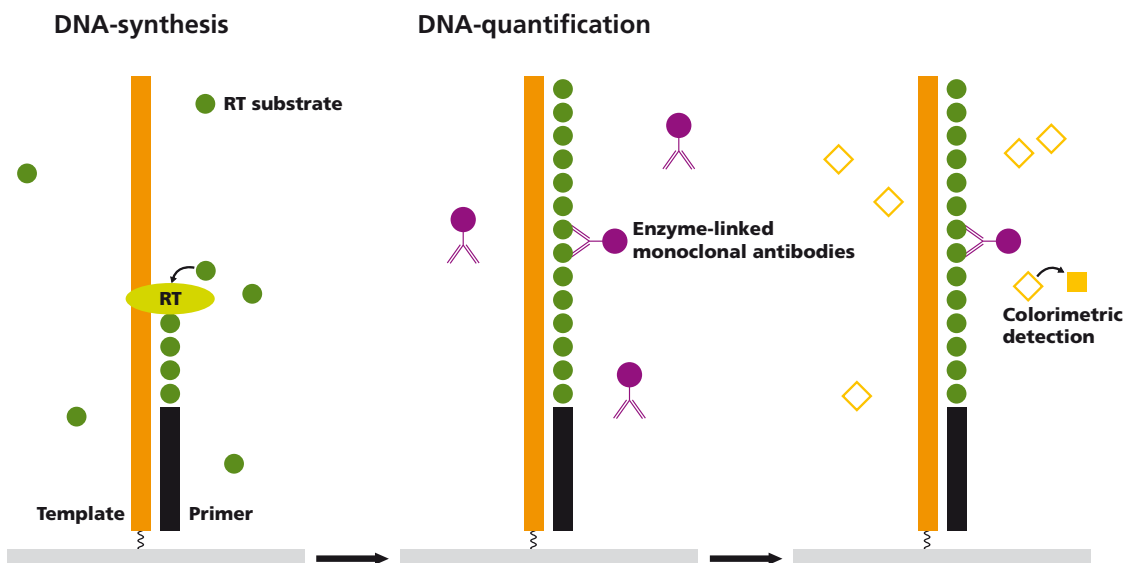
- 1 Column Holder
- 2 Waste Collector
- 3 Lysate Collector
- 4 Collector Tube Rack
- 5 Vacuum Pump
- 6 Waste Container
- 7 Buffer Dispenser
- 8 Vacuum Tubing



## HOW THE RT-ASSAY WORKS

The ExaVir Load procedure is divided into two main parts: the Separation and the RT-assay. In the separation part, virus particles are separated from the plasma and any disturbing factors, such as antibodies or antiretroviral drugs, are washed away. To obtain the RT, the virion is then lysed.

During the RT-assay phase, these lysates are mixed with an RNA template, a primer and an RT substrate. If the lysates contain any RT, the enzyme will synthesize a DNA strand, which is detected by monoclonal antibodies conjugated to alkaline phosphatase (AP). The product can then be quantified by the addition of a colorimetric AP substrate.



The figure illustrates the basic principle of the RT-assay. It depicts one well in the 96-well RT Reaction Plate, where the RT enzyme from the HIV particle is analyzed in an ELISA set-up.

## intended use

The ExaVir™ Load kit is intended for determination of the activity of the enzyme RT as a marker of retroviral replication. The ExaVir Load kit is not intended to be used as a screening test for HIV, nor is it to be used as a diagnostic test to confirm the presence of HIV infection.

## Compatibility

ExaVir Load is currently in its third version. Version 3 kits cannot be run with Version 2 separation equipment. Conversely, Version 2 kits cannot be run with Version 3 separation equipment. To run the ExaVir Load kit, you must use the new Version 3 separation equipment.

## Key technical specifications

- *Number of samples analyzed in one kit:* 30
- *Type of sample:* 1 ml plasma
- *Measuring range:*  
1–3,000 fg/ml (~200–600,000 copies equivalents/ml)
- *Analytical specificity:* >99%
- *Sensitivity:* 1 fg/ml (~200 copies equivalents/ml)
- *Precision:* Within-assay variation: 4–8%,  
between-assay variation: 2–3%
- *Kit storage:* -14 to -25°C
- *Stability:* >12 months at -20°C

## What you will need in your lab (not included)

- 1 In-house positive control
- 1 In-house negative control
- Purified water
- Vircon or other relevant disinfectant
- ELISA-plate reader with A<sub>405</sub> filter
- Incubator set at 33°C
- Freezer set at -14 to -25°C
- End-over-end mixing table
- Vortex
- Single-channel pipettes 100–1000 µl
- Multi-channel pipettes 30–200 µl
- Reservoirs for multi-channel pipettes
- Pipette filter tips (1000 µl)
- Pipette tips (200 µl)
- 25 ml bottle/tube
- Absorbing paper
- Plastic Pasteur pipettes
- Computer with Microsoft Excel® version 97 or later and Adobe® Reader®

If you would like more information about Cavid AB or our products, please contact us directly.

### Cavid AB

Uppsala Science Park  
SE-751 83 Uppsala, Sweden  
Tel: + 46 18 55 20 40  
Fax: + 46 18 55 20 41  
E-mail: [info@cavidi.se](mailto:info@cavidi.se)  
[www.cavidi.com](http://www.cavidi.com)

Cavid AB is a Swedish biotech company specialized in developing highly accessible medical diagnostic tests. The company is ISO 9001 and 13485 certified. The ExaVir range of products are CE marked.