NEAR-PATIENT HIV VIRAL LOAD MONITORING

ExaVir™ Load
NEAR-PATIENT TESTING WITHOUT COMPROMISING ACCURACY

Traditionally, gold-standard monitoring of HIV viral load has meant centralized testing dependent on costly equipment and advanced laboratory infrastructure. ExaVir™ Load allows healthcare providers to decentralize HIV viral load testing and bring gold-standard results to the near-patient environment.

Since its first release in 2002, ExaVir Load has been continually developed to make it more accurate, more reliable and more accessible to healthcare providers. From major urban research hospitals in London to small rural clinics in Botswana, ExaVir Load has established a new level of accuracy and reliability for HIV viral load testing. It provides clinicians with a clearer view of disease progression, therapeutic compliance, and the emergence of drug resistance. Just as important, ExaVir Load provides patients with greater access to proper HIV viral load monitoring because it is an affordable, near-patient solution that can be run in virtually any clinic.

Proven reliability
There is no shortage of ideas on how to measure HIV viral load. However, few succeed in making the transition from theory into practice. After a decade in the field, more than 40 peer-reviewed journal articles, and over 350,000 tests run, ExaVir Load’s reliability is well-proven. In fact, no other near-patient HIV viral load test is more well-documented or proven in the field.

Type and subtype independent
ExaVir Load is the only HIV viral load test able to detect all types and subtypes of HIV, including new strains, without any modification. That provides a more confident viral load assessment every run. Other HIV viral load tests are challenged in this regard because they are based on detection of viral RNA, which is prone to mutation. ExaVir Load’s RT platform measures the activity of the enzyme reverse transcriptase (RT), which is essential for HIV replication and is, therefore, maintained in all subtypes.

HIV viral load testing platform comparison

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Test name</th>
<th>Marker</th>
<th>Platform</th>
<th>Type and subtype independent</th>
<th>Near-patient testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavidi</td>
<td>ExaVir Load</td>
<td>RT</td>
<td>RT</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Abbot</td>
<td>Real Time</td>
<td>RNA</td>
<td>PCR</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>BioMerieux</td>
<td>Nuclisens</td>
<td>RNA</td>
<td>NASBA</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Roche</td>
<td>Amplicor</td>
<td>RNA</td>
<td>PCR</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Roche</td>
<td>Taqman</td>
<td>RNA</td>
<td>PCR</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Siemens</td>
<td>Versant</td>
<td>RNA</td>
<td>bDNA</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>
Suitable for any lab conditions

ExaVir Load is an ELISA-based test. That means it can be run in virtually any clinic. There is no need for specialized sample preparation and amplification rooms, or for costly capital investment. Running ExaVir Load requires only standard ELISA equipment and the inexpensive start-up equipment pictured below. That is why ExaVir Load has been used to decentralize HIV viral load testing in so many countries around the world. Making HIV viral load testing more accessible increases the quality of care provided and relieves pressure on central testing labs.

The gold standard

ExaVir Load offers gold-standard performance in the near-patient environment. Currently, RNA-based PCR tests are the gold standard used to reference HIV viral load tests. However, the cost and infrastructure requirements of these tests make them impractical for near-patient use. Several studies have compared ExaVir Load to the gold standard PCR test and each has found excellent correlation and comparable sensitivity and specificity.

ExaVir Load specifications

<table>
<thead>
<tr>
<th>ExaVir Load</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turnaround time</td>
<td>48 hours for up to 60 tests</td>
</tr>
<tr>
<td>Throughput</td>
<td>180 tests per week</td>
</tr>
<tr>
<td>Hands-on time</td>
<td>5 hours</td>
</tr>
<tr>
<td>Measuring range</td>
<td>200 to 600,000 copies equivalents/ml*</td>
</tr>
<tr>
<td>Reproducibility</td>
<td>Between-assay variation: 2-3%</td>
</tr>
<tr>
<td></td>
<td>Within-assay variation CV1: 4-8%</td>
</tr>
<tr>
<td>Analytical specificity</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>~200 copies equivalents/ml*</td>
</tr>
<tr>
<td>Number of samples analyzed in one kit</td>
<td>30</td>
</tr>
<tr>
<td>Type of sample</td>
<td>1 ml plasma</td>
</tr>
<tr>
<td>Kit storage</td>
<td>-14 to -25°C</td>
</tr>
</tbody>
</table>

* ExaVir Load measures RT activity and the results are obtained as fg RT/ml. The ExaVir Software converts the fg RT/ml values to RNA copy equivalents/ml automatically and presents both these two units in the generated report.
How ExaVir Load works

The ExaVir Load procedure has two parts: the separation and the RT assay. First, the virus particles are separated from other plasma components. The virions are then lysed and the resulting lysates are added to an RT assay solution containing an RNA template, a primer, and an RT substrate. If the lysate contains any RT then the enzyme will synthesize a DNA strand, which is detected by an enzyme-linked monoclonal antibody in the presence of a colorimetric substrate.

Intended used

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.

About Cavidi

For over two decades Cavidi has been dedicated to increasing access to HIV viral load monitoring for all HIV-positive patients. Our ExaVir Load test accomplishes this by bringing national reference lab quality to the near-patient environment. Independent studies confirm that ExaVir Load is as accurate as gold standard RNA-based tests yet is capable of running in virtually any lab. In fact, ExaVir Load is proven to perform at the District Hospital level where the need is greatest.

To date, over 350,000 ExaVir Load tests have been run backed by governments and major global NGOs in more than 25 countries. But there is still much work to be done. Cavidi is committed to continued innovation in this area in support of our conviction that the time for HIV viral load testing is now.

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

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The company is ISO 9001 and ISO 13485 certified. The ExaVir range of products are CE marked.

References

Please visit the download section on our website for training materials and relevant references.

What you will need in your lab (not included)

- One in-house positive control
- One in-house negative control
- Purified water
- General disinfectant
- ELISA-plate reader with $A_{405}$ 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® and Adobe® Reader®