Dependable CMV monitoring
Aid in disease management and patient care with the standardized Roche real-time PCR test

The COBAS® AmpliPrep/COBAS® TaqMan® CMV Test reliably monitors Cytomegalovirus (CMV) activity in patients receiving antiviral therapy. CMV is the most common and single most important viral infection in transplant recipients. It is also a significant source of morbidity in newborns born to mothers who develop primary infection during pregnancy and to people living with HIV/AIDS. Severe CMV infection in high risk patients usually develops during the first few months after transplantation. CMV disease is defined by evidence of CMV infection with a sequelae of CMV-specific symptoms. These symptoms are collectively referred to as CMV viral syndrome leading to tissue invasive disease. The COBAS® AmpliPrep/COBAS® TaqMan® CMV Test is a fully automated, standardized test that monitors CMV infections using a fully automated, easy-to-operate system capable of delivering reliable results to clinicians so that they can make critical treatment decisions.

Assay Performance and Specifications

**Limit of Detection (LOD)**
- 100 copies/mL, 91 IU/mL (based on an observed positivity rate of ≥99%)
- 61 copies/mL, 56 IU/mL (based on PROBIT analysis)

**Target Region**
PCR Targets the UL54 gene (Virus Coded DNA Polymerase)

**Sample Type**
EDTA Plasma

**Sample Processing and Input Volume**
- 500 μL sample input volume,
- 350 μL processing volume (150 μL "dead" volume)

**Quantitative Range**
- 150 copies/mL to 1 X 10^7 copies/mL
- 137 IU/mL to 1 x 9.1 X 10^6 IU/mL
Based on CLSI guideline EP6-A, for a < 0.3 log deviation

**Specificity**
> 98.5% using sero-negative samples

**Standardization**
Traceable to WHO Standard
1 copy/mL = 0.91 IU/mL; 1 IU/mL = 1.1 copies/mL

**Analytical Specificity**
No organisms (viruses, bacteria, fungus) showed cross reactivity when tested at 1.0E+06 particles/mL

**Assay time**
4.5 hours (includes instrument set up) for 1st 24 samples,
1 hour for each rack of 24 samples that succeed

Assay Advantages

**Standardization** The COBAS® AmpliPrep/COBAS® TaqMan® CMV Test is traceable to the first WHO International Standard for Human Cytomegalovirus for Nucleic Acid Amplification Techniques (NIBSC 09/162).

**Trustworthy**
- Ready-to-use, easy to load bar-coded reagent cassettes
- Bar-coded tracking capability, from primary tube (using p630 instrument) to patient sample result
- Simplify your work load by reducing hands-on time while minimizing manual preparation and errors for increased overall efficiency.

**Assurance** Multiple layers of contamination control including closed-tube processing and Roche AmpErase enzyme to ensure integrity of the patients results without compromising laboratory efficiency.
Maximize your throughput and minimize your hands-on-time with the CE In-Vitro Diagnostic approved COBAS® AmpliPrep/COBAS® TaqMan® CMV Test to monitor patients known to be infected with CMV and undergoing antiviral treatment.

Limit of Detection of the COBAS® AmpliPrep/COBAS® TaqMan® CMV Test using a Clinical Specimen and the Roche Molecular (RMS) CMV Secondary Standard

<table>
<thead>
<tr>
<th>Nominal CMV DNA Input</th>
<th>RMS CMV Secondary Std.</th>
<th>Clinical Specimen</th>
<th>No. of Replicates</th>
<th>No. of Positives</th>
<th>Positivity Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>IU/mL</td>
<td>copies/mL</td>
<td>IU/mL</td>
<td>copies/mL</td>
<td>208</td>
<td>208</td>
</tr>
<tr>
<td>364 IU/mL</td>
<td>400 copies/mL</td>
<td>339 IU/mL</td>
<td>373 copies/mL</td>
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<td>210</td>
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<tr>
<td>273 IU/mL</td>
<td>300 copies/mL</td>
<td>255 IU/mL</td>
<td>280 copies/mL</td>
<td>209</td>
<td>209</td>
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<tr>
<td>182 IU/mL</td>
<td>200 copies/mL</td>
<td>169 IU/mL</td>
<td>186 copies/mL</td>
<td>210</td>
<td>210</td>
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<tr>
<td>137 IU/mL</td>
<td>150 copies/mL</td>
<td>127 IU/mL</td>
<td>140 copies/mL</td>
<td>210</td>
<td>209</td>
</tr>
<tr>
<td>91 IU/mL</td>
<td>100 copies/mL</td>
<td>85 IU/mL</td>
<td>93 copies/mL</td>
<td>210</td>
<td>188</td>
</tr>
<tr>
<td>46 IU/mL</td>
<td>50 copies/mL</td>
<td>43 IU/mL</td>
<td>47 copies/mL</td>
<td>210</td>
<td>0</td>
</tr>
</tbody>
</table>
| 0 IU/mL | 0 copies/mL | 0 IU/mL | 0 copies/mL | 56 IU/mL (95% confidence interval: 50 - 66 IU/mL) | 61 copies/mL (95% confidence interval: 55 - 72 copies/mL)

Standardized For Improved Results

The COBAS® AmpliPrep/COBAS® TaqMan® CMV Viral Load Monitor Test is standardized to an international higher order standard and provides accurate, reproducible, sensitive and reliable results, particularly at clinically relevant titers. The tight precision of the assay minimizes variability in results. Correlation to other methods (e.g. COBAS® AMPLICOR CMV MONITOR Test) demonstrates similar quantitation throughout the linear dynamic range. The COBAS® AmpliPrep/COBAS® TaqMan® System has many other advantages, including automation and parallel processing with other viral load monitoring tests (HIV, HCV, and HBV). The COBAS® AmpliPrep/COBAS® TaqMan® System is designed to enable laboratorians to report accurate and reproducible results to their clinicians.

Intended Use: The COBAS® AmpliPrep/COBAS® TaqMan® CMV Test is an in vitro nucleic acid amplification test for the quantitation of cytomegalovirus DNA in EDTA human plasma using the COBAS® AmpliPrep Instrument for automated specimen processing and the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer for automated amplification and detection. The test can quantitate CMV DNA over the range of 150 - 10,000,000 copies/mL. One copy of CMV DNA (as defined by the COBAS® AmpliPrep/COBAS® TaqMan® CMV Test) is equivalent to 0.91 International Unit (IU) [1.1 cp/IU] on the First WHO International Standard for Human Cytomegalovirus for Nucleic Acid Amplification Techniques (NIBSC 09/162).

Note: The COBAS® AmpliPrep/COBAS® TaqMan® CMV Test is not intended for use as a screening test for the presence of CMV in blood or blood products or as a diagnostic test to confirm the presence of CMV infection. The results from the COBAS® AmpliPrep/COBAS® TaqMan® CMV Test must be interpreted within the context of all relevant clinical and laboratory findings.

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* The COBAS® AmpliPrep/COBAS® TaqMan® CMV Test is not available in the United States.