Detection of Cytomegalovirus DNA in EDTA Whole Blood Samples:
Evaluation of the Quantitative artus® CMV LC PCR Kit in
Conjunction with Automated Sample Preparation

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ABSTRACT

Whole blood has been found to be a reliable matrix for detection and quantitation of cytomegalovirus DNA. In this study, the performance of the artus® CMV LC PCR Kit in conjunction with automated sample preparation on the BioRobot EZ1 workstation was evaluated. Accuracy, linearity, analytical sensitivity, inter- and intra-assay variations were determined. A total of 102 clinical EDTA whole blood samples were investigated and results were compared with those obtained by the IVD (in vitro diagnostics)/CE-labeled CMV HHV6,7,8 R-gene Quantification kit. When accuracy of the new kit was tested, seven of eight results were found to be within ±0.5 log₁₀ unit of the expected panel results. Determination of linearity resulted in a quasilinear curve over more than 5 log units. The lower limit of detection of the assay was determined to be 139 copies/ml in EDTA whole blood. The interassay variation ranged from 15 to 58%, and the intra-assay variation ranged from 7 to 35%. When clinical samples were tested and compared with the routinely used IVD/CE-labeled assay, 53 samples tested positive and 13 samples negative with both of the assays. One sample was found to be positive with the artus® CMV LC PCR Kit only and 35 samples tested positive with the routinely used assay only. The majority of discrepant results were found with low-titer samples. In conclusion, the artus® CMV LC PCR Kit in conjunction with automated sample preparation on the BioRobot EZ1 workstation may be suitable for detection and quantitation of CMV DNA in EDTA whole blood in the routine low-throughput laboratory; however, low-positives may be missed by this assay.
INTRODUCTION

Human Cytomegalovirus (CMV) has the ability to establish lifelong persistent and latent infection following primary exposure. Under certain conditions, CMV can reactivate, resulting in asymptomatic viral shedding or development of disease (10). While in the immunocompetent individual the infection is held in check by the host’s immune response, CMV disease is generally restricted to the immunocompromised or immunologically immature host (15).

To avoid lethal outcome of CMV disease, the start of treatment at the earliest stage is of extreme significance (3, 8). The level of CMV DNA has been found to be an important prognostic marker for the ongoing disease (1, 2, 4). Today, laboratories use different sample materials for detection and quantitation of CMV DNA. Although whole blood has been found to be superior to blood cells or plasma, current guidelines do not recommend a specific kind of sample (5, 7, 8, 9, 11, 12, 16).

Recently, the artus® CMV LC PCR Kit (QIAGEN, Hilden, Germany) for quantitative detection of CMV DNA has been introduced. This molecular assay is designed and IVD (in vitro diagnostics)/CE-labeled for amplification and detection of CMV DNA after manual extraction of CMV DNA out of human plasma and serum samples.

The aim of this study was to evaluate the performance of the artus® CMV LC PCR Kit in conjunction with automated extraction of EDTA whole blood on the BioRobot EZ1 workstation. Accuracy was tested with a reference material. Linearity was analyzed by a dilution series of a high-titer sample and the lower limit of detection was determined by Probit analysis. Both interassay and intra-assay variations were tested. The clinical performance of the artus® CMV LC PCR Kit in the routine diagnostic laboratory was evaluated with routine clinical EDTA whole blood samples and the results were compared to those obtained by the IVD/CE-labeled CMV...
HHV6,7,8 R-gene Quantification kit (Argene SA, Varilhes, France).
MATERIALS AND METHODS

Sample preparation and molecular assays. Prior to amplification and detection with the artus® CMV LC PCR Kit, CMV DNA was extracted with the EZ1 Virus Mini Kit (QIAGEN) on the BioRobot EZ1 workstation (QIAGEN). When the CMV HHV6,7,8 R-gene Quantification kit was used, samples were prepared with the MagNa Pure Compact Nucleic Acid Isolation Kit 1 (Roche) on the MagNa Pure Compact instrument (Roche). For both assays, the LightCycler 2.0 instrument was employed for real-time PCR and detection. According to the manufacturers’ package inserts, the lower limit of detection is 78.9 copies/ml for the artus® CMV LC PCR Kit with plasma as sample matrix and 150 copies/ml for the CMV HHV6,7,8 R-gene Quantification kit with EDTA or citrate whole blood as sample matrix.

Both the BioRobot EZ1 and the MagNA Pure Compact instruments use magnetic particle technology to capture nucleic acids. For extraction with the BioRobot EZ1, a mixture of 75 µl Protease, of 2.5 µl carrier RNA, and of 7.5 µl internal control (IC) was manually prepared for each sample and loaded on the instrument together with the reagent cartridges and the EDTA whole blood samples. The sample input volume was 200 µl and the elution volume 75 µl. For extraction with the MagNA Pure Compact, the ready-to-use reagents were placed on the instrument. The sample input volume was 200 µl and a total of 5 µl of IC was automatically added to each sample. The elution volume was 50 µl.

For real-time PCR with the artus® CMV LC PCR Kit and the CMV HHV6,7,8 R-gene Quantification kit, 15 µl of master mix and 10 µl of the extracted sample were pipetted into LightCycler capillaries and loaded on the LightCycler instrument. Both of the kits allow quantitation of target nucleic acids based on a standard curve prepared with known concentrations of the same target (homologous external standards). The four standard samples included in each of the kits are amplified in separated capillaries but within the same run. The LightCycler software calculates the validity of the standard curve by taking several variables including the slope and the correlation coefficient into consideration. When using the same lot of the kit, the standard curve which was generated in a previous run and stored may be used; however, at least one quantitation standard must be included in each run as a calibrator for the imported standard curve. In this study, the LightCycler software version 4.05.415 was used to analyze fluorescence curves with channel 530 for the target fluorescence signal of both assays, channel 705/Back 530 for the IC fluorescence signal of the artus® CMV LC PCR Kit, and channel 560/Back 530 for the IC fluorescence signal of the CMV HHV6,7,8 R-gene Quantification kit.

Study design. Determination of accuracy, linearity, inter-and intra-assay variation and testing of
routine samples were done in an International Standard Organization (ISO9001, 2000)-certified
laboratory, the Molecular Diagnostics Laboratory, Institute of Hygiene.

Accuracy of the artus® CMV LC PCR Kit was determined with the Quality Control for Molecular
Diagnostics (QCMD) 2006 Human CMV proficiency panel (www.qcmd.org). The panel consisted of
eight plasma samples. CMV DNA was extracted employing the identical extraction protocol as that
used for EDTA whole blood throughout this study. The panel contained various concentrations of CMV
DNA (ranging from 2.0 X 10^2 up to 2.5 X 10^4 copies/ml) and two samples negative for CMV DNA.

Linearity of the artus® CMV LC PCR Kit was tested with a high-titer routine clinical EDTA whole
blood sample. A dilution series (0.5-log steps, i.e., 1:3.16 dilutions) was prepared using CMV-negative
EDTA whole blood. Each dilution was analyzed three times and the mean CMV DNA titer of each
sample was determined.

The lower limit of detection for EDTA whole blood samples with the artus® CMV LC PCR Kit in
conjunction with the LightCycler 2.0 instrument after sample preparation using the BioRobot EZ1
workstation in conjunction with the EZ1 Virus Mini Kit was determined by use of serial dilutions of pre-
quantified CMV (CMV Toledo strain) from cell culture supernatant (0.5 log steps in Buffer AE;
QIAGEN) spiked into human EDTA whole blood samples to create CMV concentrations ranging from
316 to 0.316 copies/ml. Analyses were performed on three days with six replicates per dilution per
day. Results were subjected to Probit analysis.

Interassay variation of the artus® CMV LC PCR Kit was determined by using eight routine clinical
samples within the linear range of the assay. Samples contained different concentrations of CMV DNA
ranging from 7.5 X 10^2 to 4.9 X 10^7 copies/ml and were tested five times on five different days. Intra-
assay variation of the new assay was tested by using four clinical routine samples. Samples contained
different concentrations of CMV DNA ranging from 9.9 X 10^2 to 5.7 X 10^6 copies/ml. Aliquots were
analyzed five times each in a single run.

Performance of the artus® CMV LC PCR Kit in the routine diagnostic laboratory was evaluated by
testing 102 clinical EDTA whole blood samples and comparing results with those obtained by the
IVD/CE-labeled CMV HHV6,7,8 R-gene Quantification kit as reference assay.
RESULTS

When 10 samples of the QCMD 2006 Human CMV proficiency panel containing various concentrations of CMV DNA were tested with the artus® CMV LC PCR Kit, 7 of 8 positives were found within ±0.5 log_{10} unit of the expected panel results (Table 1). One sample with an expected CMV DNA concentration of 2.0 \times 10^2 copies/ml tested negative. Both of the samples without CMV DNA were found to be negative.

Linearity was tested with a dilution series of a high-titer routine clinical sample. A quasilinear curve was observed up to the original concentration of 5.3 \times 10^6 copies/ml (Fig. 1). CMV DNA was inconsistently detected in dilutions containing less than 2.2 \times 10^2 copies/ml.

The lower limit of detection of the artus® CMV LC PCR Kit in combination with the LightCycler® 2.0 instrument for the amplification and detection of CMV DNA in human EDTA whole blood samples after sample preparation using the BioRobot® EZ1 workstation was determined to be 139 copies/ml (P ≤ 0.05) with a confidence interval of 74 to 406 copies/ml (Figure 2).

For determination of interassay variation, eight clinical EDTA whole blood samples were analyzed five times on different days. Coefficients of variation were found to be between 15 and 58% (Table 2). The intra-assay variation was determined by analyzing four routine clinical samples five times each in a single run. Coefficients of variation were found between 7 and 36% (Table 3).

Of 102 clinical EDTA whole blood samples, 53 tested positive with both of the assays and 13 were found to be negative with both of the assays (Table 4). One sample was found to be positive with the artus® CMV LC PCR Kit only. The viral load of this sample was found to be less than 139 copies/ml. A total of 35 samples were found to be positive with the CMV HHV6,7,8 R-gene Quantification kit only. Viral
loads of those samples ranged from less than 150 copies/ml (under lower limit of
detection) to 2.3 X 10^3 copies /ml with 24 of 35 samples (69%) below 150 copies/ml.
In order to clarify whether those negatives were caused by either the automated
sample preparation protocol or the artus\textsuperscript{®} CMV LC PCR Kit, 20 of them were
retested with both of the assays but the alternative sample preparation instrument.
There was no sample material available for the remaining 15 samples. When
samples were prepared on the BioRobot EZ1 workstation and amplified and detected
with the CMV HHV6,7,8 R-gene Quantification kit, 5 of 20 samples gave positive
results with viral loads ranging from 2.6 X 10^2 to 3.2 X 10^3 copies/ml (Table 5).
Additionally, the weak-positive sample of the QCMD proficiency panel which had
given a negative result with the artus\textsuperscript{®} CMV LC PCR Kit tested positive (6.8 X 10^2
copies/ml) with the CMV HHV6,7,8 R-gene Quantification kit. When samples were
prepared on the MagNa Pure Compact instrument and amplified and detected with
the artus\textsuperscript{®} CMV LC PCR Kit, 4 of 20 samples gave positive results with viral loads
ranging from less than 139 copies/ml up to 330 copies/ml (Table 5).
When results obtained by 37 samples with viral loads above the lower limit of
detection with both of the assays were compared, a correlation of $R^2=0.8593$ was
observed (Fig. 3a). Of those results, 28 were found to be within ±0.5 log\textsubscript{10} unit and 7
were found to be within ±0.5 and ±1.0 log\textsubscript{10} unit. The viral loads of the 2 remaining
samples showed a difference of more than ±1.0 log\textsubscript{10} unit (Fig. 4). Without both of
them, a correlation of $R^2=0.9099$ was found (Fig. 3b).
DISCUSSION

For both prophylactic and pre-emptive therapy of CMV disease, quantitation of CMV DNA in whole blood has been reported to be an important marker (6, 7, 11, 13, 16). In this study, the quantitative artus® CMV LC PCR Kit in conjunction with automated sample preparation on the BioRobot EZ1 workstation was evaluated. Quantitative results of 102 EDTA whole blood samples obtained by the new molecular assay were compared to those obtained by the CMV HHV6,7,8 R-gene Quantification kit.

When samples of the QCMD 2006 Human CMV proficiency panel were tested, 9 of 10 samples gave correct results. One sample with an expected viral load of 200 copies/ml tested negative. The lower limit of detection for EDTA whole blood samples was analyzed by Probit analysis and found to be 139 copies/ml ($P \leq 0.05$) for the artus® CMV LC PCR Kit in conjunction with automated sample preparation. This is slightly higher than the detection limit for plasma (78.9 copies/ml) as stated in the package insert.

The linear range of the artus® CMV LC PCR Kit was determined by analysis of dilutions of an EDTA whole blood sample with a high titer of CMV DNA. The new assay revealed sufficient linearity up to $5.3 \times 10^5$ copies/ml. Dilutions containing less than $2.2 \times 10^2$ copies/ml were inconsistently detected. The interassay variation ranged from 15 to 58% and the intra-assay variation ranged from 7 to 35% with a trend showing higher deviations for samples with lower viral loads. These results are in concordance with those reported for other molecular assays based on automated sample preparation and real-time PCR (14).

When clinical samples were tested with the new assay, discrepant results were found particularly in samples with lower viral loads. The reason for these
discrepancies remains unclear but incompatibility of the buffer systems cannot be excluded. The highest number of positives was obtained when samples were extracted on the MagNa Pure Compact instrument followed by amplification and detection with the CMV HHV6,7,8 R-gene. However, CMV DNA concentrations of the majority of those samples were found to be weak-positive or within half a log above the lower limit of detection. At routine diagnostic laboratories, CMV levels this low are usually not considered significant.

In conclusion, the artus® CMV LC PCR Kit in conjunction with automated sample preparation on the BioRobot EZ1 workstation may be suitable for detection and quantitation of CMV DNA in EDTA whole blood in the routine low-throughput laboratory. Detection of low-positives may be improved by use of an alternative test system.
ACKNOWLEDGEMENTS

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REFERENCES


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TABLE 1. Results obtained by the new molecular assay in comparison with those obtained by reference laboratories with samples from the Quality Control for Molecular Diagnostics 2006 Human CMV Proficiency Program panel.

<table>
<thead>
<tr>
<th>Sample number</th>
<th>Results obtained by the artus® CMV LC PCR Kit (copies of CMV DNA/ml)</th>
<th>Results obtained by reference laboratories (copies of CMV DNA/ml)</th>
<th>Log₁₀ unit difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6.8 X 10^4</td>
<td>2.5 X 10^4</td>
<td>0.44</td>
</tr>
<tr>
<td>2</td>
<td>5.9 X 10^3</td>
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<tr>
<td>3</td>
<td>8.3 X 10^2</td>
<td>1.0 X 10^3</td>
<td>0.08</td>
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<td>4</td>
<td>4.5 X 10^2</td>
<td>2.0 X 10^2</td>
<td>0.36</td>
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<td>7</td>
<td>7.0 X 10^2</td>
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</tr>
<tr>
<td>8</td>
<td>tnd^b</td>
<td>2.0 X 10^2</td>
<td>-</td>
</tr>
</tbody>
</table>

^a One replicate of each sample was tested.

^b tnd, target not detected.
TABLE 2. Results of interassay testing

<table>
<thead>
<tr>
<th>Sample no.</th>
<th>Copies of CMV DNA/ml detected a</th>
<th>Coefficient of variation (%)</th>
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<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Standard Deviation</td>
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<tr>
<td>1</td>
<td>5.0 X 10^7</td>
<td>7.7 X 10^6</td>
</tr>
<tr>
<td>2</td>
<td>5.0 X 10^7</td>
<td>8.0 X 10^6</td>
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<td>3</td>
<td>1.9 X 10^7</td>
<td>3.6 X 10^6</td>
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<tr>
<td>4</td>
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</tr>
<tr>
<td>5</td>
<td>1.6 X 10^5</td>
<td>3.7 X 10^4</td>
</tr>
<tr>
<td>6</td>
<td>4.2 X 10^4</td>
<td>8.7 X 10^3</td>
</tr>
<tr>
<td>7</td>
<td>1.1 X 10^4</td>
<td>3.6 X 10^3</td>
</tr>
<tr>
<td>8</td>
<td>7.5 X 10^2</td>
<td>4.3 X 10^2</td>
</tr>
</tbody>
</table>

* Samples were tested five times on five different days.
### TABLE 3. Results of intra-assay testing

<table>
<thead>
<tr>
<th>Sample no.</th>
<th>Copies of CMV DNA/ml detected $^b$</th>
<th>Coefficient of variation (%)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Standard Deviation</td>
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<tr>
<td>1</td>
<td>5.8 $\times 10^6$</td>
<td>3.9 $\times 10^5$</td>
</tr>
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<td>2.3 $\times 10^4$</td>
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<td>1.3 $\times 10^4$</td>
<td>2.9 $\times 10^3$</td>
</tr>
<tr>
<td>4</td>
<td>9.9 $\times 10^2$</td>
<td>3.5 $\times 10^2$</td>
</tr>
</tbody>
</table>

$^b$ Samples were tested five times each in a single run.
TABLE 4. Results obtained by the artus® CMV LC PCR Kit and the CMV HHV6,7,8 R-gene Quantification kit routinely used

<table>
<thead>
<tr>
<th>artus® CMV LC PCR Kit</th>
<th>CMV HHV6,7,8 R-gene Quantification kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Positive 53</td>
</tr>
<tr>
<td>Negative</td>
<td>Positive 35</td>
</tr>
<tr>
<td>Total</td>
<td>Positive 88</td>
</tr>
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</table>
TABLE 5. Comparison of results obtained by different test systems for quantitation of CMV DNA. Results are expressed in copies per ml.

<table>
<thead>
<tr>
<th>Sample no</th>
<th>EZ1/artus&lt;sup&gt;a&lt;/sup&gt;</th>
<th>EZ1/R-gene&lt;sup&gt;b&lt;/sup&gt;</th>
<th>MPC/artus&lt;sup&gt;c&lt;/sup&gt;</th>
<th>MPC/R-gene&lt;sup&gt;d&lt;/sup&gt;</th>
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<td>&lt;150&lt;sup&gt;f&lt;/sup&gt;</td>
</tr>
<tr>
<td>2</td>
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<td>tnd</td>
<td>&lt;150&lt;sup&gt;f&lt;/sup&gt;</td>
</tr>
<tr>
<td>3</td>
<td>tnd</td>
<td>tnd</td>
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<td>&lt;150&lt;sup&gt;f&lt;/sup&gt;</td>
</tr>
<tr>
<td>4</td>
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</tr>
<tr>
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<td>540</td>
<td>tnd</td>
<td>&lt;150&lt;sup&gt;f&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup> BioRobot EZ1 workstation/artus<sup>®</sup> CMV LC PCR Kit

<sup>b</sup> BioRobot EZ1 workstation/CMV HHV6,7,8 R-gene Quantification kit

<sup>c</sup> MagNa Pure Compact instrument/artus<sup>®</sup> CMV LC PCR Kit

<sup>d</sup> MagNa Pure Compact instrument/CMV HHV6,7,8 R-gene Quantification kit

<sup>e</sup> tnd, target not detected

<sup>f</sup> under the lower limit of quantification; i.e. weak positive
FIGURE 1. Linearity of the results for a 0.5-log-unit dilution series of a high-titer routine clinical sample obtained by the new molecular assay. The diagonal line represents the line of identity.
FIGURE 2: Results of the Probit analysis to determine the lower limit of detection of the artus® CMV LC PCR Kit for the detection of CMV DNA in EDTA whole blood samples after sample preparation with the BioRobot EZ1 workstation.
FIGURE 3: Correlation between the results (copies/ml) of the artus® CMV LC PCR Kit and the CMV HHV6,7,8 R-gene Quantification kit. The black line represents the regression curve; the grey line represents the identity line.

3a: Correlation of all quantified samples

3b: Correlation of all quantified samples within ±1.0 log unit

\[
y = 0.8869x + 0.4543 \quad R^2 = 0.8539
\]

\[
y = 0.9249x + 0.2357 \quad R^2 = 0.9099
\]
FIGURE 4: Log deviation between the results (copies/ml) of the artus® CMV LC PCR Kit and the CMV HHV6,7,8 R-gene Quantification kit.