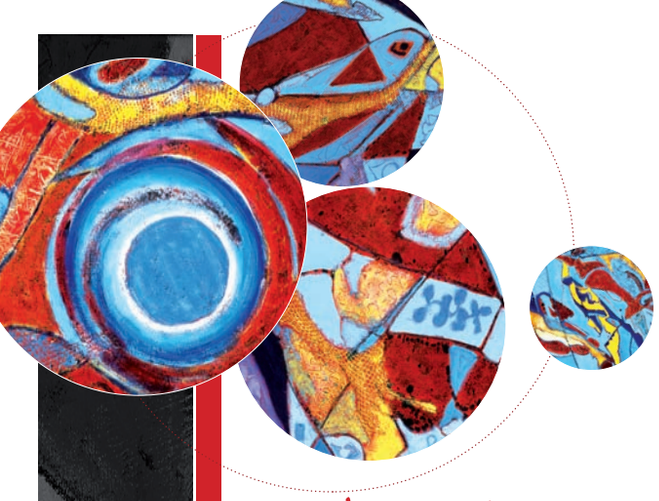

ARGENE

# Cytomegalovirus Whole Blood

QCMD proficiency panels 2012

## Panel composition

This EQA panel for the detection of CMV consisted of 7 samples containing various concentrations and strains of CMV in whole blood, and 1 negative sample.

## Material and methods

The QCMD panel was prepared using NucliSENS® easyMAG® (bioMérieux) for sample extraction with Specific B Whole blood v1 protocol.
Subsequently, the samples were analysed by real-time PCR using **CMV R-gene®** (bioMérieux - ref.: 69-003B) on Dx Real Time System (Bio-Rad).

## Results and discussion

| | QCMD Results | | | | | CMV R-gene® Results | | | |
|---|---|---|---|---|---|---|---|---|---|
| Panel code | Sample Content | Sample status * | Concentration (copies/mL) | Concentration ($Log_{10}$ copies/mL) | Concentration ($Log_{10}$ IU/mL) | Concentration ($Log_{10}$ copies/mL) | Delta $Log_{10}$ (copies/mL) | Concentration ($Log_{10}$ IU/mL) | Delta $Log_{10}$ (IU/mL) |
| CMVWB 12-01 | CMV (AD169) Whole Blood | Frequently detected | 8,128 | 3.91 | 3.79 | 3.62 | -0.29 | 3.57 | -0.22 |
| CMVWB 12-02 | CMV (FM65) Whole Blood | Frequently detected | 86,298 | 4.94 | 4.77 | 4.73 | -0.21 | 4.68 | -0.09 |
| CMVWB 12-03 | CMV (AD169) Whole Blood | Detected | 966 | 2.99 | 2.84 | 2.62 | -0.37 | 2.58 | 0.26 |
| CMVWB 12-04 | CMV (AD169) Whole Blood | Frequently detected | 8,414 | 3.93 | 3.78 | 3.71 | -0.22 | 3.67 | -0.11 |
| CMVWB 12-05 | CMV (FM65) Whole Blood | Detected | 912 | 2.96 | 2.86 | 2.79 | -0.17 | 2.74 | -0.12 |
| CMVWB 12-06 | CMV Negative Whole Blood | Negative | Negative | Negative | Negative | Negative | NA | Negative | NA |
| CMVWB 12-07 | CMV (AD169) Whole Blood | Frequently detected | 43,954 | 4.64 | 4.64 | 4.39 | -0.25 | 4.35 | -0.29 |
| CMVWB 12-08 | CMV (AD169) Whole Blood | Detected | 380 | 2.58 | 2.55 | 2.09 | -0.49 | 2.04 | -0.51 |

*«*Sample status is assigned by peer-group consensus, based on the qualitative results returned by all participants. It is not a measure of the 'strength' of a positive sample nor is it technology-dependent, and is used solely for the scoring of the EQA data. The rationale for the sample status is:*
*Frequently detected: More than 95% of datasets recorded the correct positive result.*
*Detected: Between 65% and 95% of datasets recorded the correct positive result.» QCMD-2012-general-announcement*

- **The 7 positive CMV samples of CMVWB 2012 Panel are detected with CMV R-gene®.**
- **The negative sample is undetected as expected with CMV R-gene®.**
- **The results show the good sensitivity and specificity of the CMV R-gene® - ref.: 69-003B.**
- **An excellent correlation between QCMD quantification results and CMV R-gene® quantification results is observed, with delta log ranging from 0.17 to 0.49 in copies/mL and from 0.09 to 0.51 in IU/mL.**

## Sensitivity of CMV R-gene®

Analytical sensitivity of the CMV R-gene® (bioMérieux) kit has been evaluated through a limit dilution method with CMV positive samples. The results indicate there is a :

- 95% probability of detecting CMV in whole blood containing 555 copies / mL in whole blood
- 5% probability of detecting CMV in whole blood containing 30 copies / mL in whole blood

*"The data presented in this document illustrates the performance of the CMV R-gene® assay when testing the CMVWB DNA EQA 2012 QCMD panel. The results are not representative of the QCMD EQA program report and full details on the QCMD EQA program can be obtained from the QCMD website (www.qcmd.org )".*

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