Instructions for use

RealLine CMV quantitative Fla-Format

ASSAY KIT FOR THE QUANTITATIVE DETECTION OF CYTOMEGALOVIRUS (CMV) DNA USING REAL TIME PCR METHOD

In vitro Diagnostics

CE 0123

Attention!
Please read the information about quantification process carefully!

RealLine CMV quantitative (Fla Format)	**VBD1596**	**100 Tests**
valid from	**September 2019**	

BIORON Diagnostics GmbH
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Explanation of symbols used in labeling

IVD	*In vitro* diagnostic medical device
LOT	Batch code
REF	Catalogue number
	Contains sufficient for <n> tests
	Use-by-date
	Temperature limit
	Consult instructions for use
	Keep away from sunlight
	Manufacturer

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Trademarks:
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1. INTENDED USE AND INTRODUCTION

1.1. Pathogen information

Cytomegalovirus (CMV) is a ubiquitous double-stranded DNA virus belonging to the Herpesviridae family. It is transmitted by close contact between individuals, through contamination from urine, saliva, semen, cervical secretions and breast milk. CMV can establish life-long latency in the host with possible reactivations and reinfections with heterogeneous human strains of CMV.

Almost all CMV infections acquired by individuals with a normal immune response are clinically silent. Only 5% may experience a mononucleosis-like syndrome. However, in immunosuppressed patients (e.g. older adults, HIV-positive or patients after transplantation), CMV is a major cause of disease and mortality with a symptomatic infection occurring in 20 to 60% of all transplant recipients [1]. CMV coinfection is very common in HIV-infected populations, reaching levels of 90%-100%. In the setting of underlying immune deficiency, CMV is associated with a wide range of diseases, such as retinitis, pneumonitis, colitis, and other end organ diseases, as well as with indication of altered tropism of HIV, more rapid HIV disease progression and increased occurrence of AIDS-related events [2, 3]. Moreover, CMV infection is dangerous for fetus at early pregnancy stage since CMV has a teratogenic potential and may cause malformations such as migration disturbances in the brain. CMV infections acquired during delivery or via breast milk have no effect on future neurodevelopmental outcome in full-term infants, however, for pre-mature infants, sepsis-like symptoms have been claimed to occur [4].

1.2. Intended use

RealLine CMV quantitative assay kit is intended for the detection of CMV DNA in clinical specimens (whole blood, blood serum, plasma, saliva, oropharyngeal swabs, urine, urogenital swabs) using the method of real-time polymerase chain reaction (PCR) with fluorescence detection of amplified product.

The kit detects the highly conserved DNA fragment between genes RL1 and RL5A contained in CMV genome in two copies and specific to all known CMV isolates.

The extraction of DNA from clinical material can be performed using the kits:

RealLine DNA-Express (REF VBC8899)
RealLine DNA-Extraction 2 (REF VBC8897)
RealLine DNA-Extraction 3 (REF VBC8889)
RealLine Extraction 100 (REF VBC8896)

An additional step of sample processing can be managed using the kit **RealLine Hemolytic Kit** before DNA extraction if whole blood specimens are concerned. When using DNA extraction kits of other manufacturers it is highly recommended to use Internal Control sample (IC) manufactured by. BIORON Diagnostics GmbH.

For a **quantitative** determination of CMV DNA from blood serum (plasma), use the extraction kits: **RealLine DNA-Extraction 2** or **RealLine Extraction 100** and follow the instructions below.

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The results of PCR analysis are taken into account in complex diagnostics of disease.

The **Fla-Format Kit** contains 10 vials with the lyophilized Mastermix, each vial with 10 reactions, for a volume of 50 µl per reaction. The kit contains reagents required for 100 tests, including the control samples.

The kit is designed for use with block cyclers RealLine Cyclers (BIORON Diagnostics GmbH), iQ™ iCycler, iQ5™ iCycler, CFX96™ (Bio-Rad, USA), DT96 (DNA-Technology, Russia) and RealLine Cycler (BIORON Diagnostics GmbH); and rotor type cyclers Rotor-Gene® 3000, 6000 and Q (Qiagen, Germany).

The use of:

- **Extraction Kits for nucleic acids from clinical specimen from other supplier**
- **other real-time PCR devices**
- **appropriate reaction volumes, other than 50 µl**

hasto be validated in the lab by the user. The special notes regarding the internal control IC have to be strongly followed.

2. KIT CONTENTS

Universal Positive Control sample (UPC) certified according the reference standard 1st WHO International Standard for Human Cytomegalovirus (CMV) (NIBSC code 09/162)	1 vial, 1 ml;
Master Mix for PCR (MM), lyophilized	10 tubes (10 tests each)
Recovery Solution (RS)	2 vials, 2 ml each
Passport with concentration of CMV in the UPC (Universal positive control) at a sticker in the upper lid of the box	

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3. PRINCIPLE OF THE METHOD

The Real time PCR is based on the detection of the fluorescence, produced by a reporter molecule, which increases as the reaction proceeds. Reporter molecule is dual-labeled DNA-probe, which binds to the target region of pathogen DNA specifically. Fluorescent signal increases due to the fluorescent dye and quencher separating by Taq DNA-polymerase exonuclease activity during amplification. PCR process consists of repeated cycles: temperature denaturation of DNA, primer annealing and complementary chain synthesis.

Threshold cycle value – Ct – is the cycle number at which the fluorescence generated within a reaction crosses the fluorescence threshold, a fluorescent signal rises significantly above the background fluorescence. Ct depends on initial quantity of pathogen DNA template.

The use of **Internal Control (IC)** prevents generation of false negative results associated with possible loss of DNA template during specimen preparation. IC indicates if PCR inhibitors occur in the reaction mixture. IC template should be added in each single sample (including control samples) prior to DNA extraction procedure. The amplification and detection of IC does not influence the sensitivity or specificity of the target DNA PCR.

Note: IC is a component of the NA extraction kits of RealLine series. Internal Control is added to the sample during NA isolation step and is used throughout the whole process of NA extraction, amplification, detection.

4. SPECIFICATIONS

The range of detectable concentrations: 300 to 10^8 IU CMV DNA/ml.

4.1. **The analytical specificity** of "RealLine CMV" assay kit is ensured by the selection of the primers and probes. The primers and probes were checked for possible homologies to all sequences published in gene banks by sequence comparison analysis.

The analytical specificity of the CMV DNA detection is determined using the Standard Reference Panel of negative sera not containing causative agents of various infectious diseases, as a percentage of the samples determined by the kit as negative. Specificity equals 100 %.

4.2. The analytical sensitivity is determined on five samples containing 24 IU of CMV DNA in the sample, prepared from Standard Reference Sample, SRS CMV DNA, as a percentage of the samples determined by the kit as positive. Sensitivity equals 100 %.

4.3. The **coefficient of variation** (CV in %) is calculated for the logarithm values of the CMV DNA concentrations in six SRS samples. The coefficient of variation is not more than 10 %.

4.4. The **"linearity"** test - characterizes the coincidence (in %) of the measured value and the prescribed value (calculated with allowance for the dilution factor) of the CMV DNA concentration logarithm in a sample prepared by dilution from SRS. The "linearity" is in the range of 90-110%.

4.5. **Diagnostic sensitivity** of the CMV DNA detection.
Clinical tests were conducted on 153 clinical samples from 128 patients diagnosed with cytomegalovirus infection (20 samples of whole blood; 47 blood plasma and 25 blood serum samples, where 25 serum and plasma samples were obtained from the same patients; 8 urogenital swabs, 24 samples of saliva, 16 urine samples).
Clinical tests showed 100 % sensitivity (interval 97.7 % -100 %, with a confidence level of 90 %);

4.6. **Diagnostic specificity** of the CMV DNA detection.
Clinical tests were conducted on 92 CMV negative clinical samples from 67 healthy blood donors (20 samples of whole blood; 25 blood plasma and 47 blood serum samples, where 25 serum and plasma samples were obtained from the same patients).
Clinical tests showed 100 % specificity (interval 97.4 % -100%, with a confidence level of 90 %).

Analysis by the CE-marked reference kit showed full match of results.

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5. LIMITATIONS

- This assay must not be used with the clinical specimen directly. Appropriate nucleic acids extraction methods have to be conducted prior to using this assay.
- The presence of PCR inhibitors (e.g. heparin) may cause underquantification, false negative or invalid results.
- When monitoring a patient the same extraction method must be used in all determinations. Otherwise, results may not be relative.
- Results should be interpreted with consideration of clinical and laboratory findings.
- Reliable results depend on adequate specimen sampling.
- Negative results indicate lack of detectable DNA in the examined sample type, but do not exclude the infection or disease.
- Positive results indicate active or asymptomatic infection; viral load and a clinical history and symptoms should be taken into account.
- Potential mutations within the target regions of the CMV genome covered by the primers and/or probes used in the kit may result in underquantification and/or failure to detect the presence of the pathogens.

6. WARNING AND PRECAUTIONS

- For In vitro use only.
- The kits must be used by skilled personnel only.
- When handling the kit, follow the national safety requirements for working with pathogens.
- To prevent contamination, the stages of DNA isolation and PCR test run must be spatially separated.
- Avoid microbial and nuclease contamination of reagents when removing aliquots from reagent vials.
- Wear protective disposable gloves, laboratory coats and eye protection when handling specimens and kit reagents.
- Every workplace must be provided with its own set of variable-volume pipettes, necessary auxiliary materials and equipment. It is prohibited to relocate them to other workplaces.
- The use of sterile disposable pipette tips is recommended.
- Never use the same tips for different samples.
- Do not pool reagents from different lots or from different vials of the same lot.
- Dispose unused reagents and waste in accordance with country, federal, state and local regulations.
- Do not use the kit after the total expiration date on the side label of the box.

7. ADDITIONAL MATERIALS AND DEVICES REQUIRED BUT NOT SUPPLIED

- real time PCR system, like described in paragraph1
- DNA-Extraction Kit: **RealLine Express, RealLine DNA-Extraction 2, RealLine DNA-Extraction 3** or **RealLine Extraction 100**
- Internal Control reagent (VBC8881) and Negative Control Sample, if the kit is used with the extraction kits of other suppliers,
- Plates or Tubes suitable for the used device with caps or a sealing foil for PCR
- safety laminar box;
- refrigerator;
- half-automatic variable-volume single-channel pipettes;
- disposable medical non-sterile powder-free gloves;
- disposable pipette tips with aerosol barrier;
- biohazard waste container.

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8. PREPARATION OF THE SPECIMENS

*Each group of samples undergoing the procedure of DNA isolation must include a **Positive Control sample (PC)** from this kit and a **Negative Control sample (NC)** which is a component of the DNA extraction kit.*

We strongly recommend the implementation of the Internal Control IC, the Negative Control NC and Positive Control PC samples to the extraction procedure, for quantitative determination use 3 Positive Control Samples.

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When using a kit of another supplier for the extraction of nucleic acids as recommended in p1, add **20 µl** of **IC (VBC8881)** to each tube.

- For NC use **100 µl** of the Negative Control Sample.
- For the PC use **70 µl** of Negative Control Sample and **30 µl** of Positive Control to the tube marked PC.

The assay is performed on extracted DNA specimens obtained from the clinical material using one of the DNA extraction kits listed in p.1.2, according to the Instruction Manual. If an extraction kit with magnetic particles is used, keep the tubes with extracted DNA in the magnetic rack.

In case of quantitative determination, the DNA extraction is conducted from 100 µl of blood serum or 100 µl of plasma specimen (*with EDTA as anticoagulant*) using **RealLine Extraction 100** kits. For analysis of whole blood the specimen volume should be 250 µl, each specimen must undergo the preliminary treatment with **RealLine Hemolytic** kit. Specimens are then ready to undergo the DNA extraction procedure with **RealLine Extraction 100** kit. Each group of specimens should include 3 PC and 1 NC. Elution volume is 200 µl.

Store the extracted DNA at (2 – 8) °C for no more than 24 hours.
After initial opening, store PC at (2 – 8) °C for no more than 1 month or in 50 µl aliquots at minus (18 – 24) °C during 3 months.

9. PROCEDURE

9.1. Preparation of the kit components

Prior to the test, take the kit out of the refrigerator, open the package, take the necessary number of tubes with the **Master Mix for PCR (MM)**, taking into account prepared specimens and control samples. For qualitative detection, 1 NC and 1 PC are required; for quantitative detection, 3 PC and 1 NC are required. Keep the tubes at (18 – 25) °C for at least 30 min. Put the remaining tubes immediately back into the foil pouch, squeeze the air out and tightly close with the clip.

Attention! Each tube with MM is intended for 10 tests.

After initial opening of the package, store MM at (2 - 8) °C for no more than 3 months.
To prepare diluted Master Mix for PCR, add 300 µl of Recovery Solution (RS) to each tube with MM. Mix gently, keep at (18 – 25) °C for 15 min, and then mix again.

Store diluted MM at (2 - 8) °C for no more than 7 days.

After initial opening, store Recovery Solution at (2 - 8) °C for no more than 3 months.

9.2. Prepare an appropriate number of 0.2 ml tubes and plate for PCR. Label each tube for each specimen and control.

Attention!

Labels should be placed on the caps of tubes for rotor-type cyclers. For block-type cyclers labels should be placed on the lateral side of the tubes.

9.3. Add **25 µl** of prepared Master Mix to each 0.2 ml tube.

9.4. Add **25 µl** of corresponding extracted DNA solution (*from the tubes placed in the magnetic rack*) to each tube using a separate pipette tip with filter. Do not touch the pellet! Tightly close the tubes.

9.5. Place the tubes into the Real Time PCR system.

9.6. Program Real Time PCR system:

For Rotor-Gene® 3000 (6000, Q):

Stage 1:	50°C	2min	
Stage 2:	95°C	2min	
Stage 3:	94°C	10 sec	50 cycles
	60°C*	40 sec	
* Measure the fluorescence at 60°C			

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For RealLine Cycler, iQ™ iCycler, iQ™5 iCycler, CFX™96, DT-96:

Stage 1:	50°C	2min	
Stage 2:	95°C	2min	
Stage 3:	94°C	10 sec	50 cycles
	60°C*	20 sec	
* Measure the fluorescence at 60°C			

9.7. Select the amplification detection channels:

- Collect data through **FAM** channel (RealLine Cycler, iQ5 iCycler, CFX96, DT-96, Rotor-Gene 3000) and ***Green*** channel (Rotor-Gene 6000, Rotor-Gene Q) for the detection of amplification signal of **IC DNA**;

- Collect data through **ROX** channel (RealLine Cycler , iQ5 iCycler, CFX96, DT-96, Rotor-Gene 3000), and ***Orange*** channel (Rotor-Gene 6000, Rotor-Gene Q) for the detection of amplification signal of **CMV DNA**;

9.8. Program the positions of test tubes with samples, positive and negative controls according to the instruction manual for the Real Time PCR system in use and run the program.

10. DATA ANALYSIS AND INTERPRETATION

10.1 The program should detect in **Positive Control** sample:

- increase of the IC DNA amplification signal along channel **FAM** (*Green*) and determine the threshold cycle, IC **Ct**;
- increase of the *Cytomegalovirus DNA* amplification signal along channel **ROX** *(Orange)* and determine the **Ct** value;

10.2 For **NC** the program should detect the increase of the amplification signal of IC DNA along channel **FAM** (*Green*) and determine the threshold cycle, IC **Ct**. No significant **ROX** *(Orange)* fluorescent increase should appear (*no Cytomegalovirus DNA amplification*).

If **Ct** value for NC through **ROX** *(Orange)* channel **is less than or equal to 40,** this indicates the presence of contamination (see paragraph 10.7).

10.3 For each sample the program should detect the increase of the amplification signal of IC DNA along channel **FAM** (*Green*) and determine IC **Ct**.

10.4 Calculate (IC **Ct**)$_{av}$ as an average IC **Ct** of all analyzed samples (including PC and NC).

IC **Ct** values that differ by more than 2 cycles from the (IC **Ct**)$_{av}$ should be ignored. Recalculate the (IC **Ct**)$_{av}$ for the remaining values after the screening.

10.5 The sample is considered **positive**, i.e. contains *Cytomegalovirus DNA*, when **Ct** value via **ROX** *(Orange)* channel for this sample is **less than or equals to 40.**

10.6 The sample is considered **negative** (not containing *Cytomegalovirus DNA*), if **Ct** value via **ROX** *(Orange)* channels for this sample is **above 40** or is not determined.

If IC **Ct** value for such sample differs from the (IC **Ct**)$_{av}$ value by more than 2 cycles, the result is regarded as equivocal. A repeated analysis of the sample, starting with the DNA isolation step is necessary.

10.7 If Ct value for NC through “ROX”/ “Orange” channel **is less than or equals to 40,** it indicates the presence of contamination. In this case, all positive results of this individual PCR run are considered **unreliable**. Actions are required to identify and eliminate the source of contamination, and repeat the analysis of all specimens of this run that were identified as positive. Specimens that showed negative results in this run should be considered negative.

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10.8 Quantitative calculation of the results

For quantitative analysis, calculate the concentration of CMV DNA in the analysed specimens according Annex III

10.8.1. If the calculated value of the DNA concentration of CMV in the sample is in the range of 300 to 10^8 IU of CMV DNA the result is determined as positive, indicating the obtained concentration of CMV DNA in the sample (in IU/ml).

10.8.2. If the calculated value of the CMV DNA concentration is greater than 10^8 IU, the result should be interpreted as positive with a CMV DNA concentration **greater than 10^8 IU/ml.**

10.8.3. If the calculated value of the CMV DNA concentration is less than 300 IU/ml, the result should be interpreted as **positive** with CMV DNA concentration **less than 300 IU/ml.**

10.9 The analyzed sample is counted as negative (not containing CMV DNA), if the **Ct** for the sample is above **40** or not determined.

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11. STORAGE AND TRANSPORTATION

- Store the assay kit at (2 - 8) °C in the manufacturer's packing.
- Transport at (2 – 8) °C, transportation up to 25 °C for up to 10 days is allowed.
- Do not freeze the kit!
- Do not pool reagents from different lots or from different vials of the same lot.
- Strictly follow the Instruction manual for reliable results.
- Do not use kits with damaged inner packages and get in contact with BIORON Diagnostics GmbH.

- **Storage and shelf life of solutions and components of the kit after initial opening:**
  Positive Control sample: 1 month at (2 – 8) °C.
  Ready Master Mix (MM): unused MM at (2 – 8) °C up to 3 month after opening the foil.
  Diluted MM: at (2 – 8) °C for 7 days.
  Recovery Solution: at (2 – 8) °C for 3 months.

12. REFERENCES

1. Jenkins F.J., Rowe D.T., Rinaldo C.R. Jr. Herpesvirus Infections in Organ Transplant Recipients. 2003. *Clinical and diagnostic laboratory immunology*, 10, 1–7.
2. Effros R.B. The silent war of CMV in aging and HIV infection. 2015. Mech. Ageing Dev., 158, 46-52.
3. Griffiths P.D. CMV as a cofactor enhancing progression of AIDS. 2006. Journal of Clinical Virology, 35, 489–492.
4. Malm G., Engman M.L. Congenital cytomegalovirus infections. 2007. Seminars in Fetal & Neonatal Medicine, 12, 154-159.

ANNEX I: Settings for RealLine Cycler and DT96:

for these cyclers the measurement exposure must be adjusted. Choose the **Operation with the device** mode in the **Settings** menu, select the item **Measurement exposition:**

- **FAM** to **250**
- **HEX** and **ROX** to **1000**

Confirm that the current exposure value is saved by pressing **YES**

Attention! The specified exposure values are applicable only for RealLine kits and, if necessary, must be changed for other purposes.

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ANNEX II: Programming the Device and Analysis of Results using Rotor-type Cyclers:

Rotor-Gene 3000, Rotor-Gene 6000, Rotor-Gene Q (Qiagen, Germany)

Hereinafter, detection channels and terms corresponding to different versions of devices and software are listed in the following order: Rotor-Gene 3000 (Rotor-Gene 6000, Rotor-Gene Q).

Program real-time PCR cycler.

1) Click **"New"** button.
2) Select an **"Advanced"** template from the tab of the New Run wizard. Click **"New"** button.
3) Select **36-Well Rotor** type, check that No Domed 0.2 ml Tubes are used. Click **"Next"** button.
4) In the new window, determine Reaction volume as **50 µl**. Click **"Next"** button.
5) The temperature profile of real time PCR should be set. Click **"Edit Profile"** button.

Step 1:	50°C	2 min	
Step 2:	95°C	2 min	
Step 3:	94°C	10 sec	50 Cycles
	60°C*	40 sec	

* measurement of fluorescent at 60 °C in FAM and ROX

6) Then temperature profile is set, click **"OK"** button.
7) In the **"New Run Wizard"** window click **"Calibrate"** *("Gain optimization")* button. The window **"Auto Gain Calibration Setup"** opens. In the line **"Channel Settings"** choose **"ROX"** *(Orange)*, click **"Add"**. Set **"Tube Position"** 1, **"Min Reading"** 5, **"Max Reading"** 10, click "**OK**". In the line **"Channel Settings"** choose **"FAM**" *(Green)*, click **"Add"**. Set **"Tube Position"** 1, **"Min Reading"** 5, **"Max Reading"** 10, click **"OK"**
8) Tick off **"Perform Calibration Before 1st Acquisition"**. Click **"Close"** button.
9) Click **"Next"** button, start the amplification process by clicking **"Start Run"** button.
10) Save a file in the Rotor-Gene/templates folder, named RealBest with **.ret* extension. In subsequent work RealBest template would be presented in New run wizard.
11) Save reaction result file with Rotor-Gene Run File **.rex* extension.
12) Record the positions of the controls and specimens according to the instruction manual of the operating device. Click **"Start run"** button.

Results of IC DNA amplification

1) Click **"Analysis"** button, choose **"Quantitation"** from the list, choose **"Cycling A. FAM"** *(«Cycling A. Green»)*, click **"Show"** button.
2) Click **"OK"** button, and cancel automatic **Threshold** determination.
3) Click **"Linear scale"** button. Settings should change to **"Log. scale**".
4) In the ***Quantitation analysis*** menu buttons **"Dynamic tube"** and **"Slope Correct"** should be pressed.
5) Click **"More Settings"** *(Outlier Removal)* **button,** determine **NTC threshold** value as **5 %**.
6) In the column **"CT Calculation"** *(right part of the window)* determine **"Threshold"** value as **0.04**.
7) In the result table *("Quant. Results" window)* **Ct** will be displayed.

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Results of CMV DNA amplification

1) Click **"Analysis"** button, choose **"Quantitation"** from the list, choose **"Cycling A. ROX"** *("Cycling A. Orange")* click, **"Show"** button.
2) Click **"OK"** button, and cancel automatic **Threshold** determination.
3) Click **"Linear scale"** button. Settings should change to **"Log. scale"**.
4) In the **Quantitation analysis** menu buttons **"Dynamic tube"** and **"Slope Correct"** should be pressed.
5) Click **"More Settings"** *(Outlier Removal)* **button,** determine **NTC threshold** value as **5 %**.
6) In the column **"CT Calculation"** *(right part of the window)* determine **"Threshold"** value as **0.04**.
7) In the result table ***("Quant. Results"** window)* Ct will be displayed.

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ANNEX III: QUANTITATIVE ANALYSIS OF THE RESULTS

- Quantitative analysis of CMV DNA should be performed according to the formulas given below.

- For PC samples, the Ct value of which is within the range indicated in the insert card of this kit, calculate first the adjusted values of Ct CMV with taking into account the efficiency of DNA extraction, controlled by IC. For this, use the formula:

$$\mathbf{Z_{PC} = Ct\ PC + (Ct\ IC_{av} - Ct\ IC_{PC}),}$$

Where:
Z_{pc} – adjusted value of Ct CMV for the PC sample;
Ct IC_{av} - the average value of Ct IC, calculated for all samples (see the instruction);
Ct PC and Ct IC - values Ct of the analysed PC sample obtained from channels **ROX** and **FAM**, correspondently.

- Calculate the average value for the adjusted threshold cycle of PC (Z_{PCav}). Eliminate the results from PC samples, where Z_{PC} differs by more than 2 from the value of Z_{PCav}. After that, re-calculate Z_{PCav} for the remaining samples.

- Calculate the amount of CMV DNA in each analysed sample (Q_n) using the formula:

$$\mathbf{Q_n = C_{PC} \times 2^{Xn}\ (IU)}$$

Where:
$\mathbf{X_n = Z_{PCav} - Z_n}$;
Z_{PCav} is the average value of Z for the PC samples;
C_{PC} - concentration of CMV DNA in universal PC, indicated on the label inside the box of the kit in **IU** / **ml**;
n - sample number;
$\mathbf{Z_n}$ - adjusted value of Ct for the analysed sample, calculated by the formula:

$$\mathbf{Z_n = Ct\ CMV_n + (Ct\ IC_{av} - Ct\ IC_n).}$$

- Finally, calculate the concentration of Cn CMV DNA for each sample:

  - when isolated from 100 µl: $\mathbf{C_n = 10 \times Q_n}$
  - when isolated from 250 µl : $\mathbf{C_n = 4 \times Q_n}$

The resulting concentration of the CMV DNA will be expressed in IU / ml.

For further information and help, ask us at e. We can provide you with a calculation sheet for an easy evaluation of your data.

SPACE FOR YOUR NOTES:

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