

PoET CMV Positive Control

Control kit

for use with *PoET Instrument*

For *in vitro* diagnostic use

REF P3G-180-30

IVD CE 0123

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1 Intended use

1.1 Intended purpose

PoET CMV Positive Control is a control kit for the PCR kit *PoET CMV* for professional use.

PoET CMV Positive Control is applied as a separate reaction. It serves as a PCR positive control to demonstrate the functionality of the reagents involved in the amplification of CMV DNA.

PoET CMV Positive Control is processed automatically on *PoET Instrument*.

1.2 Intended users

The application has to be carried out by qualified laboratory personnel who have been instructed and trained in *in vitro* diagnostic procedures and have successfully completed the operator's training on *PoET Instrument*.

2 Background

2.1 Assay principle

The control kit *PoET CMV Positive Control* (CMV PC) has the function of a PCR positive control (PC) and is used in conjunction with the PCR Kit *PoET CMV* and *PoET Instrument*.

PoET CMV Positive Control contains synthetic nucleic acids of human cytomegalovirus (CMV). Since the synthetic nucleic acids contained in *PoET CMV Positive Control* correspond to the amplified CMV sequences, the functionality of the PCR kit *PoET CMV* can be verified.

PoET CMV Positive Control only delivers results in combination with *PoET CMV*. The results are part of the automated evaluation of the validity of a PoET run when applying *PoET CMV*. The results are evaluated on the basis of predefined limit values stored in the software *Calliope* of *PoET Instrument* (see Chapter 6.3.1).

3 PoET system overview

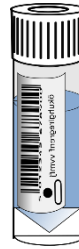
The PoET system is a fully automated solution for the extraction, amplification and detection of nucleic acids of pathogens in human body fluids in IVD high throughput screening or in individual samples. It consists of several different products which are available separately.

| PoET system | | |
|------------------------|--|---|
| <i>PoET Instrument</i> | PoET reagents | disposables |
| | <ul style="list-style-type: none"> • PoET PCR kits • PoET controls • PoET extraction reagents | <ul style="list-style-type: none"> • PCR plates • extraction plates • sample tubes • pipette tips |

4 Reagents

The control kit *PoET CMV Positive Control* contains 30 units (tubes) of *positive control CMV* (PC_CM).

| PoET CMV Positive Control | |
|----------------------------------|---------------|
| GFE reference number | P3G-180-30 |
| Basic UDI-DI | 42623533725MB |



| Kit component | Identifier | Primary packaging | Reagent ingredients | Quantity per kit |
|-----------------------------|------------|-----------------------------|--|--|
| <i>positive control CMV</i> | PC_CM v1 | tube with screw cap (white) | H ₂ O; tris buffer; synthetic nucleic acids | 30 x 370 µL total volume (30 x 180 µL usable volume) |

4.1 Reagent handling conditions

| Material | Storage | Transport | Use |
|----------------------------------|----------|-----------|------------------|
| <i>PoET CMV Positive Control</i> | ≤ -18 °C | ≤ -18 °C | +15 °C to +30 °C |



The reagents are intended for single use. Any reagents remaining after application must be discarded.



The analysis on *PoET Instrument* has to be started at the latest 5 hours after taking the reagents out of storage. Functionality of the reagents cannot be guaranteed, if the reagents have been stored open for several hours.



Do not use expired reagents. *PoET Instrument* monitors reagent barcodes and will not allow to start a run with expired reagents.

4.2 Additional materials required

These reagents and disposables for use on *PoET Instrument* are available separately from GFE:

| Material | Reference number |
|------------------------------|---------------------|
| <i>PoET Extraction</i> | P1A-24-04 |
| <i>PoET Prep Reagent</i> | P1B-24-20 |
| <i>PoET Internal Control</i> | P1C-1440-60 |
| <i>PoET CMV</i> | P2G-28-30 |
| <i>PoET Negative Control</i> | P3A-500-30 |
| <i>1000µL-CO-RE II Tips</i> | 235905 |
| <i>300µL-CO-RE II Tips</i> | 235903 |
| <i>Extraction Plate Set</i> | 43001-0703 |
| <i>PCR Plate</i> | SP-0362 |
| <i>13 mL Tube & Cap*</i> | 60.541.004 & 65.714 |

*Optional. Please refer to the operator's manual of *PoET Instrument* for additional information about primary and secondary tubes.



The use of other disposables on *PoET Instrument* is not permitted.

4.3 Instrumentation and software required

| Material | Reference number |
|---|------------------|
| <i>PoET Instrument</i> incl. software <i>Calliope</i> | P9A |

5 Warnings and precautions

5.1 General precautions

- Use for *in vitro* diagnostics only.
- Only use in combination with *PoET CMV* and *PoET Instrument* as well as the associated reagent kits and disposables.
- Clean and disinfect all work surfaces according to the 'Guideline for Disinfection and Sterilization in Healthcare Facilities' (1) or comparable methods.
- Eliminate potential nucleic acid contamination with DNA-ExitusPlus™ (AppliChem GmbH) or a comparably effective agent according to the manufacturer.
- Treat the specimens as potentially infectious as described in 'Biosafety in Microbiological and Biomedical Laboratories' (2) and CLSI document M29A4 (3). If specimen material is spilled, immediately disinfect with an appropriate agent. Treat contaminated materials as biologically hazardous.
- If spillages of samples or reagents occur on *PoET Instrument*, follow the instructions in the operator's manual of *PoET Instrument* to clean and decontaminate its surface.

- Dispose of all materials that have come into contact with potentially infectious specimens and/or reagents, according to the relevant regional and national regulations.
- Material safety data sheets (MSDS) are provided by GFE.
- Wear personal protective equipment (laboratory coat, eye protection, laboratory gloves). Do not eat, drink or smoke in designated work areas.
- Disinfect and wash your hands thoroughly after handling the specimens and reagents, and after removing the gloves. Gloves must be changed between handling of specimens, controls and reagents. Avoid contaminating gloves when handling specimens and controls.

5.2 Reagent handling

- Handle all reagents, controls, and specimens according to good laboratory practice in order to prevent carryover of specimens or reagents.
- Store specimens, controls and PCR kits separately.
- Store all reagents, controls and specimens upright and at specified temperatures.
- PoET PCR kits and controls are shipped on dry ice. For safe handling and disposal follow the local instructions and guidelines.
- Check the product(s) after receipt (i.e. frozen state of PCR kits and controls, integrity of packaging, completeness). If there is any evidence of unfreezing or damage, do not use these products for testing.
- PCR reagents are photosensitive. Take care to store and handle them protected from light sources.
- Avoid interchanging tube caps to prevent cross-contamination.
- The reagents are designed for single use. Do not reuse reagent residues.
- Do not combine different batches of the same reagents.
- Do not use reagents after their shelf life has been expired.
- Extraction reagents contain hazardous substances. Store, handle and dispose of them safely, according to the MSDS and Chapter 6.6 of this IFU.

6 Performing the test

PoET CMV Positive Control is a control kit for *PoET CMV*. The test procedure is therefore described in detail in the instructions for use (IFU) of *PoET CMV*.

6.1 Requirements for performing the test

- Only personnel trained and qualified as proficient in the use of PoET products and in handling of infectious materials should perform this procedure.
- Closely follow the procedures and guidelines provided to ensure that the test is performed correctly. Any deviation from the procedures and guidelines may affect test performance.
- Use this product only for its intended purpose.
- Use only the specified reagents and disposables.
- Use in the temperature range of +15 °C to +30 °C.

6.2 Preparations before use

- PCR kits and PCR controls can be loaded frozen on *PoET Instrument*.
- Before use, visually inspect each reagent tube to ensure that there are no signs of leakage. If there is any evidence of leakage, do not use that material for testing.
- Remove the caps of the reagent tubes before positioning on the carriers of *PoET Instrument*. *PoET Instrument* does not have a device for the automated removal of caps ('Decapper').
- In order to avoid evaporation of reagents, remove the tube caps only shortly before use.

6.3 Quality control measures and validity of results

The entire process from sample preparation to PCR analysis is monitored by several controls:

| Control type | Product | Function |
|---------------------------|----------------------------------|--|
| Internal control (IC) | <i>PoET Internal Control</i> | IC is added to each sample at the beginning of the process. For each non-reactive sample, IC indicates whether the processing from extraction to the result is valid. |
| PCR positive control (PC) | <i>PoET CMV Positive Control</i> | PCs are set up as individual reactions. The PCR positive control contains synthetic nucleic acids of CMV. The PC proves that the reagents involved in the amplification of CMV are functional. |
| PCR negative control (NC) | <i>PoET Negative Control</i> | NCs are set up as individual reactions. The PCR negative control indicates that the PCR reagents are free of contaminations, which might act as templates for the respective target virus amplification. |

Based on the PP and Q values of the controls *Calliope* evaluates, whether the overall result is valid for the sample batch and for each individual sample.

6.3.1 Validation of PCR positive controls (PCs)

PCR positive controls are set up as separate reactions. They serve to demonstrate that the reagents involved in the amplification reaction of the nucleic acids of the respective target virus are functional. PC results have to be 'reactive' for the target virus and must meet the predefined limits for PP and Q values. The limit values are stored in the software *Calliope*.

If more than one PC reaction is set up for the same target virus on one PCR plate, only one PC is allowed to be 'not reactive' for the target virus or to exceed the PP value limit or to stay below the Q value limit.

| Case | PC result for target virus | Assessment |
|------|---|------------------------------|
| 1 | All PC on the same PCR plate are reactive and meet PP and Q limit values. | Overall PC result is valid |
| 2 | Only in case of > one PC per target virus on the same PCR plate: One PC is not reactive or does not meet PP and/or Q limit values. | Overall PC result is valid |
| 3 | ≥ Two or all PC on the same PCR plate are not reactive or do not meet PP and/or Q limit values. | Overall PC result is invalid |

In case of an overall invalid PC result, the PoET run will automatically be assessed as invalid for the corresponding sample batch.

6.4 Interpretation of results

A valid sample batch in an individual *PoET Instrument* run may include both valid and invalid sample results.

Sample results are only valid if the respective PCR controls (PC, NC) of the corresponding sample batch are valid and no processing errors occurred.

For more details, please refer to the IFU of *PoET CMV*.

6.5 Procedural limitations

- *PoET CMV Positive Control* has been evaluated only for use in combination with *PoET Instrument* and the PCR kit *PoET CMV*.

6.6 Disposal

- PCR positive controls do not contain any hazardous substances.
- Dispose of reagent residues according to the relevant regional and national regulations.
- Dispose of all materials that have come into contact with potentially infectious specimens and/or reagents, according to the relevant regional and national regulations.

7 Overview of reagents and materials

| Material | Manufacturer | Reference number | Storage conditions |
|----------------------------------|--------------|------------------|-------------------------|
| <i>PoET CMV</i> | GFE | P2G-28-30 | ≤ -18 °C |
| <i>PoET CMV Positive Control</i> | GFE | P3G-180-30 | ≤ -18 °C |
| <i>PoET Extraction</i> | GFE | P1A-24-04 | +2 °C to +8 °C, upright |
| <i>PoET Prep Reagent</i> | GFE | P1B-24-20 | +2 °C to +8 °C, upright |
| <i>PoET Internal Control</i> | GFE | P1C-1440-60 | ≤ -18 °C |
| <i>PoET Negative Control</i> | GFE | P3A-500-30 | ≤ -18 °C |

| Material | Manufacturer | Reference number |
|--|----------------------|---------------------|
| <i>PoET Instrument incl. software Calliope</i> | GFE | P9A |
| <i>1000 µL CO-RE II Tips</i> | Hamilton Bonaduz AG | 235905 |
| <i>300 µL CO-RE II Tips</i> | Hamilton Bonaduz AG | 235903 |
| <i>Extraction Plate Set</i> | GFE | 43001-0703 |
| <i>PCR Plate</i> | Azenta Life Sciences | SP-0362 |
| <i>13 mL Tube & Cap</i> | Sarstedt AG & Co. | 60.541.004 & 65.714 |

Please refer to the operator's manual of *PoET Instrument* for additional information. All items are supplied by GFE.

8 Manufacturer and service contacts



Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH

Altenhöferallee 3, 60438 Frankfurt/Main, Germany

Phone: +49 (0) 69 / 400 5513 0

Fax: +49 (0) 69 / 400 5513 21

Questions concerning PoET products and training courses can be addressed to your local GFE representative:

Web: <https://www.gfeblut.de/contact-us/>

8.1 Reporting

Inform your local competent authority and GFE if any serious incidents occur when using this product. The summary of the safety and performance report can be found using the following link: <https://ec.europa.eu/tools/eudamed>. Until the EUDAMED database is fully functional, please contact your local GFE representative.

9 Trademarks and patents



















- *PoET* and *Calliope* are registered names owned by GFE.
- The *SuperScript® III reverse transcriptase* included in the PCR kits is a product manufactured and licensed by Life Technologies by Thermo Fisher Scientific.
- During the application of the PCR kits, the PCR plates (*PCR Plates*) "*FrameStar® 96 (cut corner A12)*" with barcode [Reference number SP0362] are used. These are subject to the following license limitation: "*FrameStar® is covered by one or more of the following US patents or their foreign counterparts, owned by Eppendorf AG: US Patent Nos. 7,347,977 and 6,340,589. FrameStar® is a registered trademark owned by Azenta Life Sciences*".
- Other registered names, trademarks, etc. used in this document are not to be considered legally unprotected, even if they are not specifically marked.

10 References

1. Rutala WA. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. 2008;163.
2. Wilson DE, Chosewood LC. Biosafety in Microbiological and Biomedical Laboratories.
3. Callihan DR, Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections: approved guideline. 2014.

11 Symbols

The following symbols are used in labelling of GFE products:

| | | | |
|---|---|---|---|
|  | Batch code |  | Serial number |
|  | Reference number |  | Date of manufacture |
|  YYYY-MM | Use by date (year-month) |  | Unique device identifier |
|  840 | Contains sufficient for <n> tests (n = total number of IVD tests) |  | GFE manufacturer logo |
|  -18°C | Upper temperature limit value |  | Manufacturer |
|  +2°C | Temperature limits |  | Protect from sunlight |
|  | Consult instructions for use |  | <i>In vitro</i> diagnostic medical device |
|  | Attention Indication of safety-related information such as warning or precaution |  | Conformity to the European Requirements on <i>in vitro</i> diagnostic medical devices |
|  | Do not re-use |  | Conformity to the European Requirements on <i>in vitro</i> diagnostic medical devices and identification number of the Notified Body (0123) |

12 Revision history

| Version | Document ID | Date [YYYY-MM-DD] | Remarks |
|---------|-------------|-------------------|---|
| 1 | 001172 | 2023-03-09 | initial release |
| 2 | 001172 | 2024-02-26 | Removal of the term "accessory" from chapter 1.1. and 6. Template: FB 001183_V01 |