

Instructions for use

PoET Master Positive Control

For use with PoET Instrument

In vitro diagnostic medical device

REF P3B-360-30

IVD CE 0483

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1. Intended use

1.1. Abstract

The control kit *PoET Master Positive Control (PoET MPC, MPC)* from *Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH* (hereinafter referred to as GFE) is a PCR positive control (PC) for the detection of HCV, HBV, HIV, HAV and B19V.

1.2. Intended use

The control kit *PoET Master Positive Control* is CE marked according to IVD Directive 98/79/EC. It serves as an accessory for the *in vitro* diagnostic tests *PoET HCV*, *PoET HBV*, *PoET HIV*, *PoET HAV* and *PoET B19V* of the PoET product line.

The PCR positive control is prepared as a separate reaction. It is used to prove that the reagents involved in the amplification reaction of the above-mentioned virus parameters are functional.

In combination with the PCR kit *PoET B19V*, the control kit *PoET Master Positive Control* can be used to make a semi-quantitative statement on the B19V concentration of the samples examined with the PCR kit *PoET B19V*.

The processing of the control kit *PoET Master Positive Control* is carried out with *PoET Instrument*.

2. Test principle

2.1. Evaluation of the validity of an analysis run

Together with the PCR kits of the PoET product line on *PoET Instrument*, the control kit *PoET Master Positive Control* implements the function of a PCR positive control.

PoET Master Positive Control contains a mixture of purified nucleic acids of hepatitis C virus (RNA), hepatitis B virus (DNA), human immunodeficiency virus-1 (RNA), hepatitis A virus (RNA) and parvovirus B19 (DNA). These viral nucleic acids (RNA and DNA) are extracted from reference materials for the respective virus. *PoET MPC* does not contain any nucleic acids of the internal control (IC).

PoET Master Positive Control is analyzed in the PCR reaction instead of the sample eluates. Please refer to the instructions for use of the PCR kit(s) used in combination with the *PoET Master Positive Control* for more detailed information on the PCR reaction.

Since the viral nucleic acids contained in *PoET MPC* correspond to the viral templates to be detected, the functionality of the PCR reagents (*enzyme mix* and *oligo mix*) used in combination with *PoET MPC* can be verified.

PoET Master Positive Control only delivers results in combination with *PoET HCV*, *PoET HBV*, *PoET HIV*, *PoET HAV* or *PoET B19V*. The results of *PoET MPC* are part of the automated evaluation of the validity of an analysis run when applying the respective PCR kit. The results of *PoET MPC* are evaluated on the basis of predefined limit values stored in the software *Calliope* of *PoET Instrument*.

2.2. Semi-quantitative evaluation for B19V

The concentration of parvovirus B19 DNA contained in the control kit *PoET Master Positive Control* and hence the detection value (Positive Point, 'PP') of *PoET MPC* for B19V is defined to correspond to a 1.3 mL EDTA plasma sample with a B19V concentration of 1041 IU/mL.

By comparing the PP value of *PoET MPC* for B19V with the PP values of the samples tested with the PCR kit *PoET B19V*, a semi-quantitative determination of the B19V concentration of the samples can be made. Please refer to the instructions for use of the PCR kit *PoET B19V* for details.

3. Reagents and materials

One control kit *PoET Master Positive Control* includes 30 tubes of *positive control* (PC).




<i>PoET Master Positive Control</i>			
GFE Reference number	P3B-360-30		
Test unit	360 µL		
Number of tests per kit	30	Total volume: 10.8 mL	
Kit component	Volume [µL]	Identifier	Cap color
<i>positive control</i>	510	PC v1	White

3.1. Storage and handling of reagents

The control kit *PoET Master Positive Control* (*PoET MPC*) is shipped on dry ice. The product should be checked upon receipt (i.e. frozen state of reagents, integrity of packaging, completeness).

The control kit *PoET MPC* is stored at $\leq 18^{\circ}\text{C}$ and is stable until the date stated on the label. After expiry of the declared shelf life, the reagents may no longer be used.

After removing the cap, the frozen *positive control* (PC) can be loaded directly onto the reagent carrier of the *PoET Instrument*. A separate thawing of the PC is not necessary.

	Expired reagents are recognized and excluded by <i>PoET Instrument</i> using the reagent barcodes.
	The reagents are intended for single use and not for repeated freezing and thawing. Any remaining reagents must be discarded after application.
	<p>Within 5 hours after removal of the reagents from the freezer the analysis has to be started on <i>PoET Instrument</i>.</p> <p>If the tubes were stored without cap for several hours, the functionality is no longer guaranteed depending on the duration and degree of evaporation.</p>

3.2. Disposal

- The component *positive control* of *PoET MPC* contains no hazardous substances or bio-hazard substances. The material safety data sheet is available on request from GFE Customer service.
- Used disposables and PCR reagent residues can be disposed of into standard commercial waste. Further information can be found in the instructions for use of the PoET PCR kits.

4. Required equipment

4.1. Devices and software

Fully automated *PoET Instrument* including software *Calliope* and operator's manual.

4.2. Required consumables for *PoET Master Positive Control* on *PoET Instrument*

The consumables for *PoET Master Positive Control* on *PoET Instrument* are available separately from GFE. For more details, please refer to the instructions for use of the PoET PCR kits, which are used in combination with *PoET Master Positive Control*.

5. Warnings and precautions

Good laboratory practice

- Wear personal protective equipment (laboratory coat, safety glasses, laboratory gloves).
- Do not eat, drink or smoke in the laboratory.
- Treat the samples as potentially infectious as described in '*Biosafety in Microbiological and Biomedical Laboratories*' [1] and CLSI document M29A4 [2].
- If sample material is spilled, immediately disinfect with a suitable agent. Treat contaminated materials as biologically hazardous.
- Disinfect and wash your hands thoroughly after handling the samples and reagents.
- Clean and disinfect all work surfaces with suitable disinfectants, e.g. listed by German Robert Koch Institute (RKI)¹
- Eliminate potential nucleic acid contamination with DNA-ExitusPlus™ (AppliChem GmbH) or a comparably effective agent according to the manufacturer.

General information on use

- Use the control kit *PoET Master Positive Control* only in combination with *PoET HCV*, *PoET HBV*, *PoET HIV*, *PoET HAV* and/or *PoET B19V*.
- Use *PoET Master Positive Control* only in combination with *PoET Instrument* and the described accessory and other control kits as well as consumables.
- Use all reagents for *in vitro* diagnostics only
- *PoET Instrument* shall only be operated by qualified personnel trained by GFE.

¹ or other suitable guidelines, e.g. William A. Rutala, Ph.D., M.P.H., David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC): Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008; Update: May 2019

- The component *positive control* of *PoET Master Positive Control* contains no hazardous substances or biohazard substances.
- In order to prevent cross-contamination of samples or controls, all material containing samples or controls must be handled in the laboratory in accordance with the regulations for safe work.
- Store samples, controls and PCR kits separately.
- For the safe handling of the used and sealed *24well Extraction Plates* and *PCR Plates*, please follow the instructions in the operator's manual of *PoET Instrument*.
- Dispose of all materials that have come into contact with potentially infectious samples, according to the relevant regional and national regulations (see in particular also instructions for use of the *PoET* accessory kits).
- Use *PoET MPC* in the temperature range of +15 °C to +30 °C.

Reagent handling

- Remove the caps of the reagents before positioning them on the carrier of the *PoET Instrument*. *PoET Instrument* does not have a device for the automated removal of caps ('Decapper').
- Place the frozen *positive control* onto the appropriate position of the *PoET Instrument*. A separate thawing of the PC is not necessary.
- Carry out the loading and unloading of the *PoET Instrument* reagent carriers with reagents according to the specifications in the operator's manual of *PoET Instrument*. This also applies to the correct preparation of samples and controls. Any deviation from the specified procedures may affect the test performance.
- Avoid mixing up tube caps, as this can lead to contamination.
- The control kit *PoET MPC* is designed for single use. Do not reuse reagent residues.
- Do not use reagents after their shelf life has expired.

6. Processing of samples on *PoET Instrument*

The handling of *PoET Instrument* is described in detail in the operator's manual of *PoET Instrument*.

The PC is positioned on the device together with the other reagents when loading *PoET Instrument*. The PC is used by *PoET Instrument* as part of the PCR setup. For details, please refer to the instructions for use of the respective *PoET* PCR kit(s) and the operator's manual of *PoET Instrument*.

Depending on the test plan of a run on *PoET Instrument*, the PCR results are available about 3.5 hours after the start of the run.

7. Control procedures

7.1. Quality control procedures

The automated overall process consisting of sample preparation and PCR analysis is monitored by several controls. The positive control of the control kit *PoET Master Positive Control* is one of the quality control measures:

Control type	Product	Function
Internal control (IC)	<i>PoET Internal Control</i>	The IC indicates whether the processing was valid for each non-reactive sample from extraction to result.
PCR positive control (PC)	<i>PoET Master Positive Control</i>	The PCR Positive Control contains viral nucleic acids of HCV, HBV, HIV, HAV and B19V. It indicates whether the process on <i>PoET Instrument</i> from the setup of the PCR reaction, through the sealing of the <i>PCR Plates</i> to the execution of the PCR has been executed correctly.
PCR negative control (NC)	<i>PoET Negative Control</i>	<i>PoET Negative Control</i> indicates that the PCR reagents have been set up without contamination. The NC corresponds to a 'no template control' (NTC).

8. Evaluation and validity of the results

The evaluation is performed automatically by the software *Calliope*. The software analyzes the fluorescence signals of all PCR reactions, including the controls, and evaluates whether the overall result is valid for the test parameter and for each individual sample.

If one of the criteria of the validity check for the PCR controls is not met, the PoET run will be assessed as invalid for the affected test parameter.

Depending on the number of samples and the test parameters with which the samples are analyzed, a predefined number of PCR positive controls per PCR plate is applied by *PoET Instrument*.

When evaluating the results of the PCR positive control(s), the parameters 'Positive Point' (PP) and 'Quotient' (Q) are calculated from the fluorescence signals. In order for PC results to be considered valid, they must not exceed specified PP values and must not fall below specified Q values. The PC limit values for each test parameter are stored in the software *Calliope*.

The software *Calliope* applies the following case rules to the evaluation:

Case	Positive control (PC) result for test parameter	Assessment
1	All PC on the same PCR plate are reactive and meet PP and quotient limit values*.	Overall PC result is valid
2	<i>Only in case of multiple PCs per test parameter on one PCR plate:</i> One PC is not reactive or does not meet PP and/or Q limit values*.	Overall PC result is valid
3	Two or more / all PCs on the same PCR plate are not reactive or do not meet PP and/or Q limit values*.	Overall PC result is invalid

*PP ≤ limit value, Q ≥ limit value

When using *PoET Master Positive Control* (MPC) together with *PoET B19V*, a reference value is calculated via the software. Using this value, a semi-quantitative statement about the B19V concentrations of the samples can be made. Further information on the evaluation can be found in the instructions for use of *PoET B19V*.

9. Procedural limitations

The control kit *PoET Master Positive Control* is intended exclusively for use with the PoET PCR kits *PoET HCV*, *PoET HBV*, *PoET HIV*, *PoET HAV* and *PoET B19V*.












10. Performance characteristics

The performance characteristics of *PoET Master Positive Control* can only be determined together with the associated PoET PCR kit(s). For detailed information, please refer to the instructions for use of the respective kit.

11. Changes in analytical procedure and performance

In the event of significant changes in the analytical procedure and / or in the analytical performance of the reagents, corresponding information will be passed on by the manufacturer to the users immediately. This also applies to the measures resulting from these changes. If necessary, this may include the recall of the *in vitro* diagnostic medical devices.

12. Explanation of symbols

	Symbol for 'Batch code'
	Symbol for 'Reference number'
 YYYYY-MM	Symbol for 'Use by date' (year-month)
 -18°C	Symbol for 'Upper limit of temperature'
	Symbol for 'Consult instructions for use'
	Symbol for 'Caution' Indication of safety-related information such as warning or precaution
	Symbol for 'Do not re-use'
	Symbol for ' <i>In vitro</i> diagnostic medical device'
 0483	Symbol for conformity to the European Directive 98/79/EC (IVDD) on <i>in vitro</i> diagnostic medical devices and identification number of the notified body
	Symbol for 'Manufacturer'
	GFE manufacturer logo

13. List of abbreviations

B19V	Parvovirus B19
DNA	Deoxyribonucleic acid
EDTA	Ethylenediaminetetraacetic acid
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCV	Hepatitis B virus
HIV	Human immunodeficiency virus
IC	Internal control
IFU	Instructions for use
IU	International units
MPC	<i>PoET Master Positive Control</i>
NC	<i>PoET Negative Control (PCR negative control)</i>
NTC	No template control
PC	PCR positive control
PCR	Polymerase chain reaction
PP	Positive Point
Q	Quotient
RKI	Robert Koch Institute
RNA	Ribonucleic acid

14. Technical service

Questions regarding the control kit *PoET Master Positive Control* can be directed to GFE Customer service:

Email: service@gfeblut.de

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

15. References

- [1] Lewis & Wilson, Deborah. (2009). Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. HHS Publication No. (CDC) 21-1112 Revised December 2009
- [2] Protection of Laboratory Workers From Occupationally Acquired Infections, 4th Edition; Clinical and Laboratory Standards Institute; May 2014; ISBN Number: 1-56238-962-9

16. Exclusion of liability and trademark protection

All registered names, trademarks, etc. used in this document are not to be considered legally unprotected, even if they are not specifically marked.

17. Change history

Version	Date [YYYY-MM-DD]	Remarks
Version 1	2020-10-06	Initial release
Version 2	2021-02-24	<ul style="list-style-type: none">• Chapter 5: Linguistic revision and restructuring• Chapter 8: More detailed explanation of the validity criteria and evaluation for the PC, removal of the table for semi-quantitative evaluation of B19V with reference to IFU of the PCR kit <i>PoET B19V</i>

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

Altenhöferallee 3, D-60438 Frankfurt/Main, Germany

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

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