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

Instructions for use

PoET Negative Control

For use on PoET Instrument

In vitro diagnostic medical device

REF **P3A-500-30**

IVD CE

Content

1. Intended purpose

1.1. Short description

The control kit *PoET Negative Control* (*PoET NC*, NC) from Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH (hereinafter referred to as GFE) is a negative control for quality monitoring of PCR reactions.

1.2. Intended purpose

The control kit *PoET Negative Control* is CE marked according to IVD Directive 98/79/EC. It serves as an accessory for the *in vitro* diagnostic tests of the PoET product line for the detection of viral nucleic acids (DNA or RNA).

The PCR negative control is prepared as a separate reaction. It is used to prove that the reagents involved in the amplification reaction are not contaminated with the nucleic acids to be detected. It does not serve as a negative control for the overall process, but exclusively as a no template control (NTC) in the PCR reaction.

The processing of the control kit *PoET Negative Control* is carried out with *PoET Instrument* from GFE.

2. Information and functionality of the test

The control kit *PoET Negative Control* serves as a no template control (NTC) to check for contamination when use with the PoET PCR kits on the *PoET Instrument*.

The *PoET Negative Control* contains an aqueous buffer solution free of viral nucleic acids.

PoET Negative Control is used in place of the eluate of the samples to be tested in the PCR reaction. Since PoET NC is free of viral nucleic acids (templates) and nucleases, the PCR reagents used (*enzyme mix* and *oligo mix*) can be checked for contaminating nucleic acid sequences. This allows *PoET Negative Control* to be used to evaluate the validity of the amplification and detection results of the PCR. Detailed information on the exact procedure can be found in the instructions for use of the PCR kits used in combination with the control kit *PoET NC*.

By definition, negative controls must show a non-reactive test result. Reactive results lead to invalidation of the results of the respective affected parameter of a PCR plate in a PoET run.

The data evaluation after the PCR run on the *PoET Instrument* is carried out automatically by the software *Calliope*. Further details on the evaluation are described in the *PoET Instrument* operator's manual.

3. Reagents and materials

The contents of the *PoET Negative Control* kit include 30 tubes of *negative control*.

PoET Negative Control			
GFE Reference number	P3A-500-30		
Test unit	500 µL		
Number of tests per kit	30	Total volume: 15 mL	
Kit component	**Volume [µL]**	**Description**	**Cap color**
negative control	650	NC v1	White

3.1. Reagent storage

The control kit *PoET Negative Control* (*PoET NC*) is shipped in dry ice. Upon receipt, the product should be checked for the following:

- frozen state of the reagent
- integrity of the outer packaging and individual reagent tubes
- completeness regarding the number of reagent tubes

The control kit *PoET NC* is stored at ≤ -18°C and is valid until the date indicated on the label.

3.2. Reagent handling

- Before use, check the reagent tubes for proper filling.
- Ensure that no drops of reagent are hanging above the actual liquid level on the walls and/or lid of the reagent tubes.
- The *negative control* (NC) can be placed directly on the corresponding position of the carrier system of the *PoET Instrument* in its frozen state after removing the lid. Separate thawing of the NC is not necessary.
- Reagents must not be used after the declared expiration date.

	Expired reagents are recognized and excluded by *PoET Instrument* based on the reagent barcodes.
	The reagents are intended for single use only and not for repeated freezing and thawing. Any remaining reagents must be discarded after application.
	A maximum of 5 hours may elapse between removal from the freezer and the start of the analysis run on the *PoET Instrument*. If the tubes have been stored open for several hours, an adequate fill level may no longer be guaranteed depending on the duration and degree of evaporation.

3.3. Disposal

- The component *negative control* of the control kit *PoET Negative Control* does not contain hazardous substances or biohazardous materials. The material safety data sheet is available upon request from GFE customer service.
- Contents and containers of reagents must be disposed of in accordance with applicable regional and international regulations.
- The use of *PoET Negative Control* generates PCR plates and PCR reagent residues as well as consumables that have come into contact with them. These must be disposed of in accordance with applicable regional and international regulations. Further instructions 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 for *PoET Instrument*.

4.2. Required consumables for application

The consumables for using *PoET Negative Control* on the *PoET Instrument* are available separately from GFE. Information on the required items can be found in the instructions for use of the PoET PCR kits used in combination with the control kit *PoET NC*.

5. Warnings and precautions

Good laboratory praxis

- Wear personal protective equipment (lab coat, safety goggles, laboratory gloves).
- Do not eat, drink, or smoke in laboratory work areas.
- Treat samples as potentially infectious, as described in " *Biosafety in Microbiological and Biomedical Laboratories*" [1] and the CLSI document M29-A4 [2].
- Immediately disinfect any spilled sample material with an appropriate agent. Treat contaminated materials as biologically hazardous.
- Disinfect and thoroughly wash hands after handling samples and reagents.
- Clean and disinfect all work surfaces with disinfectants listed by the Robert Koch Institute (RKI).
- Eliminate potential nucleic acid contamination with DNA-ExitusPlus™ (AppliChem GmbH) or a similarly effective agent according to the manufacturer's specifications.

General usage instructions

- Use the *PoET Negative Control* only in combination with the PCR kits of the PoET product line.
- The control kit *PoET Negative Control* is intended only for use with the *PoET Instrument* and the described accessory kits, other control kits, and consumables.
- Use all reagents exclusively for *in-vitro* diagnostics.
- The *PoET Instrument* should only be operated by qualified personnel trained by GFE.
- In order to prevent cross-contamination of samples or controls, handle all materials containing samples or controls according to laboratory safety regulations.
- Store samples, controls, and PCR kits separately.
- Follow the instructions in the *PoET Instrument* operator's manual for the safe handling of used and sealed extraction plates and PCR plates.
- Dispose of all materials that have come into contact with potentially infectious samples in accordance with applicable regional and international regulations (see in particular the instructions for use of the sample preparation kits *PoET Extraction* and *PoET Prep Reagent*).
- Use the control kit *PoET Negative Control* within a temperature range of +15°C to +30°C.

Handling reagents

- Remove the cap of the *negative control* from *PoET Negative Control* before placing it on the carrier systems of the *PoET Instrument*. The *PoET Instrument* does not have a device for automated cap removal ("Decapper").
- Place the *negative control* in its frozen state on the appropriate position of the carrier system. Separate thawing of the NC is not necessary.
- Load and unload the *PoET Instrument* reagent carriers with reagents according to the instructions 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 impair test performance.
- Avoid mixing up tube caps, as this may lead to contamination.
- The NC of *PoET Negative Control* is designed for single use. Do not reuse residues.
- Do not use reagents after their expiration date.

6. Processing samples on the *PoET Instrument*

The procedure is described in detail in the operator's manual of *PoET Instrument*. The NC is positioned on the device along with the other reagents when loading the *PoET Instrument*. The use of the NC is automated as part of the PCR setup by the *PoET Instrument*. For details on the procedure, please refer to the instructions for use of the respective PoET PCR kits and the operator's manual of *PoET Instrument*. Depending on the test plan for a run on the *PoET Instrument*, PCR results are available approximately 3.5 hours after the start of the run.

7. Control procedures

7.1. Quality control measures

The automated overall process, consisting of sample preparation and PCR analysis, is monitored by several controls. The *negative control* of the control kit *PoET Negative Control* serves as PCR negative control as one of the quality control measures:

Control type	Product	Function
Internal Control (IC)	*PoET Internal Control*	The IC indicates whether the processing from extraction to result was valid for each sample.
PCR positive control (PC)	Multiparameter control (*PoET Master Positive Control*) or single parameter PCR positive control	The PC contains viral nucleic acids of the parameters to be detected (e.g., multiparameter control *PoET Master Positive Control*: nucleic acids of HCV, HBV, HIV, HAV, and B19V) and indicates successful amplification, ensuring correct conditions for PCR from setup, sealing of PCR plates, to execution on the *PoET Instrument*.
PCR negative control (NC)	*PoET Negative Control*	The NC indicates that the PCR reagents were set up contamination-free. The NC corresponds to a "No Template Control" (NTC).

8. Evaluation and validity of the results

The evaluation is performed by the software *Calliope*. The software analyzes the fluorescence signals of all PCR reactions, including the controls, and assesses whether the result is valid.

If the PCR controls do not meet the validity criteria, the PCR results of the samples for the affected test parameter on the PCR plate are declared invalid.

Depending on the number of samples and test parameters analyzed, *PoET Instrument* sets a predetermined number of PCR negative controls (*negative control*) per PCR plate.

For NC results to be considered valid, the signals for the test parameters to be determined and the internal control must not be reactive. If multiple NC are used on a PCR plate, a maximum of one NC may be reactive for the test parameter to be determined or the internal control.

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

Case	***negative control*** **(NC) for test parameter and IC**	**Evaluation**
1	All NC per PCR plate are non-reactive	NC result is valid
2	Only for multiple NC per test parameter on a PCR plate: Maximum of one NC is reactive	NC result is valid
3	Two or more as well as all NCs per PCR plate are reactive	NC result is invalid

9. Procedure limitations

The control kit *PoET Negative Control* is exclusively intended for use in combination with the GFE PCR kits of the PoET product line (e.g., *PoET HCV, PoET HBV, PoET HIV, PoET HAV, PoET B19V, PoET HEV*).

10. Performance characteristics

The performance characteristics of *PoET Negative Control* can only be determined together with the associated PoET PCR kits. For detailed information, please refer to the instructions for use of the respective kits.

11. Change in the analytical procedure and performance

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

12. Explanation of symbols

LOT	Symbol for ‘Batch code’
REF	Symbol for “Reference number’
JJJJ-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 warnings and precaution
	Symbol for ‘Do not re-use’
IVD	Symbol for ‘*In vitro* diagnostic medical device’
CE	Symbol for conformity with European Directive 98/79/EG on *in vitro* diagnostic medical devices
	Symbol for ‘Manufacturer’
	GFE manufacturer logo

13. Abbreviations

B19V	Parvovirus B19
DNA	Deoxyribonucleic acid
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HEV	Hepatitis E virus
HIV	Human immunodeficiency virus
IC	Internal control
IFU	*Instructions for use*
NC	*PoET Negative Control*
NTC	No Template Control
PC	PCR Positive Control
PCR	Polymerase Chain Reaction
RKI	Robert Koch Institute
RNA	Ribonucleic acid
RT	Reverse Transcription

14. Technical Service

Questions regarding the product *PoET Negative Control* can be addressed to GFE customer service:

E-Mail: 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. Disclaimer and trademark protection

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

17. Revision history

Version	Date [YYYY-MM-DD]	Remarks
Version 1	2021-03-22	First release

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