

*Instructions for use*

# PoET Prep Reagent

*For use with PoET Instrument*

*In vitro diagnostic medical device*

**REF** P1B-24-20

**IVD** CE

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## 1. Intended use

### 1.1. Abstract

The kit *PoET Prep Reagent* from *Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH* (hereinafter referred to as GFE) is a reagent kit to support the kit *PoET Extraction*.

### 1.2. Intended use

#### Intended purpose

The extraction kit *PoET Prep Reagent* is an accessory for *in vitro* testing for nucleic acids of infectious agents with the corresponding PCR kits of the PoET product line.

The use of *PoET Prep Reagent*, together with *PoET Extraction*, is part of the process to isolate and provide viral nucleic acids from human plasma samples.

The processing of the extraction kits *PoET Extraction* and *PoET Prep Reagent* is carried out with *PoET Instrument* from GFE.

*PoET Prep Reagent* is a CE marked class A *in vitro* diagnostic accessory for professional use in accordance with Regulation (EU) 2017/746.

#### Intended users

The application must be carried out by pre-trained and qualified laboratory personnel who have been instructed and trained in *in vitro* diagnostic procedures and have successfully completed GFE's training.

## 2. Test principle

#### PoET system

The extraction kit *PoETcolo Prep Reagent* is a stand-alone reagent product in the PoET system, consisting of the *PoET Instrument* and the PoET reagent kits for fully automated extraction, amplification and detection of nucleic acids (nucleic acid amplification technology, NAT) of infectious agents.

#### Principle of PoET Prep Reagent

*PoET Prep Reagent* is used in combination with *PoET Extraction* as a ready-to-use system for the extraction of viral nucleic acids.

The explanation of the extraction process can be found in the instructions for use (IFU) of *PoET Extraction*.

The nucleic acid extracts obtained with the extraction kits *PoET Extraction* and *PoET Prep Reagent* are optimized for the amplification and detection processes of PoET PCR kits with *PoET Instrument* from GFE.

## 3. Information on viral pathogens

Information on the viral pathogens can be found in the instructions for use of the respective PCR kits of the PoET product line.

## 4. Reagents

One extraction kit *PoET Prep Reagent* includes 20 reagent troughs of *prep reagent* (PR).

The reagents for nucleic acid extraction is packaged for single use. In order to use the reagents (*PoET Extraction* and *PoET Prep Reagent*) as efficiently as possible, samples and controls should be processed in series of 24 or 48 (equivalent to 2 tests of 24 reactions).

**Table 1: Labelling and composition**

<b><i>PoET Prep Reagent</i></b>			
GFE Reference number	P1B-24-20		
Basic UDI-DI	42623533712M2		
UDI	(01)04262353370018(17)YYMMDD(10)1BYYXX		
Number of reactions per test	24		
Number of tests per kit	20		
Total number of reactions ( $\Sigma$ )	480		
<b>Kit component</b>	<b>Volume [mL]</b>	<b>Identifier</b>	<b>Primary packaging (closure type)</b>
<i>prep reagent</i>	55	PR v1	Reagent trough (peel-seal film)

The UDI (Unique Device Identifier) consists of UDI-DI (Device Identifier) and UDI-PI (Production Identifier). It is composed as follows: (01) UDI-DI, (17) expiration date in YYMMDD format and (10) batch number in 1BYYXX format.

The symbols are explained in Chapter 14.

### 4.1. Transport and storage of reagents

The extraction kit *PoET Prep Reagent* is shipped at +2°C to +25°C. The product should be checked upon receipt (i.e. integrity of packaging, completeness).

*PoET Prep Reagent* is stored upright at +2°C to +25°C and is stable until the date stated on the label.




Conditions for the safe storage of reagents can be found in the material safety data sheets (MSDS).



Do not freeze the reagents.

### 4.2. Handling of reagents

- Please check the reagent troughs for liquid level and possible coloring, turbidity or precipitate formation of the contents before use.
- Take care to ensure that no reagent drops have formed above the actual liquid level on the inner trough surface and/or peel-seal films of the reagent troughs.
- Please ensure that the reagent troughs do not show any signs of leakage before use.
- Precautions in handling of the reagents are listed in Chapter 6.

	Expired reagents are recognized and excluded by <i>PoET Instrument</i> using the reagent barcodes.
	The reagents are intended for single use. Any remaining reagents, as well as unopened reagents that have been stored outside the specified temperature, must be discarded.
	<p>The maximum on-board stability of <i>PoET Prep Reagent</i> is designed to match the PCR kits. Information on this can be found in the corresponding IFU of the PCR kits.</p> <p>If the reagents were stored without cap/peel-seal film for several hours, the functionality is no longer guaranteed depending on the duration and degree of evaporation.</p>

### 4.3. Disposal of reagents

- The component *prep reagent* contains a hazardous substance. Conditions for the disposal of the reagent can be found in the supplied MSDS.
- The contents and containers of the reagents as well as the *Extraction Plate Sets* that come into contact with the reagents during use must be disposed of in accordance with the relevant regional and national regulations. Further information on how to dispose of the *Extraction Plate Sets* can be found in the operator's manual of *PoET Instrument*.
- When using *PoET Prep Reagent*, PCR plates and PCR reagent residues as well as consumables that have come into contact with them are produced. These must be disposed of in accordance with the relevant regional and national regulations. Further information can be found in the instructions for use of the PoET PCR kits.

## 5. Required equipment

### 5.1. Devices and software

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


### 5.2. Required consumables

The consumables for the application of the extraction kits *PoET Extraction* and *PoET Prep Reagent* on *PoET Instrument* are available separately from GFE.

**Table 2: Consumables for the extraction kits**

Article	Name on label	Manufacturer	GFE Reference number
Extraction Plate Set	Extraction Plate Set, 4x 24well Extraction Plate 1x Tip-Plate	GFE	43001-0703

Please refer to the corresponding instructions for use and the operator's manual of *PoET Instrument* for the consumables required for the PoET PCR kits and PCR control kits.

	The use of other than the consumables specified in the operator's manual of <i>PoET Instrument</i> is not allowed.
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### 5.3. Required accessory kits

- *PoET Extraction* [GFE Reference number P1A-24-04]
- *PoET Internal Control* [GFE Reference number P1C-1440-60]

### 5.4. Additional equipment required

- Centrifuge for the extraction of plasma from primary tubes (EDTA-K2 blood collection systems with gel barrier) meeting the specifications of the tube manufacturer. See also operator's manual of *PoET Instrument*.

## 6. 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)<sup>1</sup>
- Eliminate potential nucleic acid contamination with DNA-ExitusPlus™ (AppliChem GmbH) or a comparably effective agent according to the manufacturer.

### General information on use

- Use *PoET Prep Reagent* only in combination with *PoET Extraction*.
- Use *PoET Prep Reagent* only in combination with *PoET Instrument* and the associated reagent kits (PCR and accessory kits) and consumables.
- Use all reagents for *in vitro* diagnostics only.
- *PoET Instrument* shall only be operated by qualified personnel trained by GFE.
- 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.
- Use *PoET Prep Reagent* in the temperature range from +15°C to +30°C.



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<sup>1</sup> 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

## Handling of reagents

- Carefully peel off the peel-seal films of the reagents before positioning them onto the carriers of the *PoET Instrument*. *PoET Instrument* does not have a device for the automated piercing of films.
- 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.
- *PoET Prep Reagent* is designed for single use. Do not reuse reagent residues.
- Do not exchange or combine reagents of different batch numbers of *PoET Prep Reagent*.
- Do not use reagents after their shelf life has expired.


### 6.1. Safety and hazard statements

Component	Dangerous ingredients	Safety and hazard warnings*		
<i>prep reagent (PR)</i>	Propane-2-ol	<b>Danger</b>		
		Signal word	GHS02	GHS07
		H225 – Highly flammable liquid and vapor. H319 - Causes serious eye irritation. H336 - May cause drowsiness or dizziness. P210 - Keep away from heat, hot surfaces, sparks, open flames or other ignition sources. No smoking. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.		

\*Safety marking according to GHS Regulation of the EU[3].

## 7. Collection, handling, storage and disposal of plasma samples

Information on the collection, handling, storage and disposal of plasma samples can be found in the instructions for use of the kit *PoET Extraction* and the respective *PoET PCR* kits.

	Treat all samples as potentially infectious.
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## 8. Processing of samples on *PoET instrument*

The operation of *PoET Instrument* is described in detail in the operator's manual of *PoET Instrument*. The process of nucleic acid extraction is shown in the instructions for use of *PoET Extraction*.

Depending on the test plan of a run on *PoET Instrument*, the PCR results are available about 3 hours after the start of the run.

## 9. Control procedures

In the automated extraction process on *PoET instrument*, an internal control (*PoET Internal Control*) is used to evaluate the validity of the results of the tested samples.

Further information on control procedures can be found in the instructions for use of *PoET Internal Control* and the PoET PCR kits and PCR control kits used in combination.

## 10. Evaluation and validity of the results

The evaluation and validity of the results for *PoET Prep Reagent* is only carried out together with the PCR kits from GFE used in combination and is therefore described in the instructions for use of the respective PoET PCR kits.

## 11. Procedural limitations

- *PoET Prep Reagent* is intended exclusively for use with *PoET Extraction* and PoET PCR and control kits on *PoET Instrument*.
- Please refer to the instructions for use of *PoET Extraction* for further information.

## 12. Performance characteristics















The performance characteristics of the extraction kit *PoET Prep Reagent* can only be assessed together with *PoET Extraction* and the PoET PCR kits used in combination. For this reason, the performance characteristics are described in the instructions for use of the respective PoET PCR kits.

## 13. 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.



## 14. Explanation of symbols

	Symbol for 'Reference number'
	Symbol for 'Sufficient for <n> tests' (n = total number of IVD tests)
	Symbol for 'Batch code'
 YYYY-MM	Symbol for 'Use by date' (year-month)
	Symbol for 'Temperature limits'
	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 'Keep away from sunlight'
	Symbol for ' <i>In vitro</i> diagnostic medical device'
	Symbol of conformity with Regulation (EU) 2017/746 on <i>in vitro</i> diagnostic medical devices
	Symbol for 'Unique Device Identification'
	Symbol for 'Manufacturer'
	GFE manufacturer logo

## 15. Hazard pictograms

	GHS02 Flammable
	GHS07 Warning

## 16. List of abbreviations

DNA	Deoxyribonucleic acid
EDTA	Ethylenediaminetetraacetic acid
GFE	Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH
IFU	Instructions for use
NAT	Nucleic acid amplification technology
PCR	Polymerase chain reaction
UDI	Unique Device Identifier
UDI-DI	UDI device identifier
UDI-PI	UDI production identifier

## 17. Contact

### 17.1. Technical service

Questions regarding the product *PoET Prep Reagent* can be addressed to GFE Customer service:

Email: [service@gfeblut.de](mailto:service@gfeblut.de)

Web: <https://www.gfeblut.de>

### 17.2. Reporting of serious incidents

Regulation (EU) 2017/746 requires all serious incidents involving the device to be reported to the manufacturer and the competent authority. Please send your notification in writing to us as manufacturer to the e-mail address given in Chapter 17.1

## 18. 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
- [3] Regulation (EC) No 1272/2008 of the European Parliament and of the Council; of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006

## 19. 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.

## 20. Version history

Version	Date [YYYY-MM-DD]	Remarks
1	2021-03-29	Initial release
2	2022-05-20	<ul style="list-style-type: none"><li>• Chapter 1 Intended use: Adaptation of intended use in accordance with Regulation (EU) 2017/746</li><li>• Chapter 2 Test principle: overview of PoET system inserted</li><li>• Chapter 4 Reagents: UDI and reference to Chapter 14 (Explanation of symbols) inserted</li><li>• Chapter 9 Control procedures: shortened with reference to PCR kit IFUs</li><li>• Chapter 10 Evaluation and validity of the results: newly inserted with reference to IFU of the PCR kits</li><li>• Chapter 14 Explanation of symbols: reference to Regulation (EU) 2017/746 inserted at CE symbol; addition of UDI symbol</li><li>• Chapter 17: Renamed into 'Contact', divided into Chapter 17.1: Technical service and newly added Chapter 17.2 Reporting of serious incidents</li></ul>

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