



PoET Prep Reagent

(20 x 24 extractions)

REF P1B-24-20

IVD CE

Basic UDI-DI 42623533712M2

Version 3, 2024-07

Extraction kit for use with *PoET Instrument*, *in vitro* diagnostic medical device

Symbols used

	Batch code
	Reference number
	YYYY-MM Use by date (year-month)
	480 Contains sufficient for <n> tests (n = total number of IVD tests)
	+ 25 °C + 2 °C Temperature limits
	Consult instructions for use
	Caution Indication of safety-related information such as warnings or precautions
	Do not re-use
	Protect from sunlight
	Unique device identifier
	GFE logo
	Manufacturer
	<i>In vitro</i> diagnostic medical device
	This device is in conformity with the applicable requirements for CE marking of an <i>in vitro</i> diagnostic medical device

Reagents

The extraction kit *PoET Prep Reagent* consists of 20 reagent troughs of *prep reagent* (PR). One reagent trough is required for one run with ≤ 24 extractions.

Kit component	Reagent ingredients	Quantity per kit
<i>prep reagent</i> (PR)	≥ 95 % Propan-2-ol	20 x 55 mL

Safety and hazard information

Safety labeling according to Regulation (EC) No. 1272/2008

Kit component	<i>prep reagent</i> (PR)
	Danger
GHS07	GHS02
Hazardous ingredients: Propan-2-ol	
H225	Highly flammable liquid and vapour.
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.

Reagent storage and handling conditions

Storage	Transport	Use
+2 °C to +25 °C	+2 °C to +25 °C	+15 °C to + 30 °C



Start the analysis on *PoET Instrument* no later than 5 hours after removing the reagents from the storage locations. Do not open the reagents until shortly before starting the run.



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

- Do not freeze the reagents.
- Store reagents upright.
- Before use, visually inspect each reagent trough to ensure that there are no leaks. If there are signs of leakage, do not use for the test.
- Please check reagent troughs for 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.

Intended use

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

PoET Prep Reagent, together with *PoET Extraction*, is used to isolate viral nucleic acids from human plasma samples.

The extraction kits *PoET Prep Reagent* and *PoET Extraction* are processed on *PoET Instrument*.

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*.

- Peel off the *peel-seal* films of the reagent troughs before positioning them on the carriers of *PoET Instrument*. *PoET Instrument* does not have a device for automatically piercing foils.
- To avoid evaporation of the reagents, remove the *peel-seal* films only shortly before use.
- Remove the *peel-seal* films of the reagent troughs carefully to avoid spilling reagents.
- Do not combine different batches of the same reagents.
- Do not use expired reagents.

Additional materials required

The additional reagent kits, consumables and devices required for a PoET run can be found in the instructions for use of the PoET PCR kits used in conjunction with *PoET Prep Reagent*.

Warnings and precautions

- Observe the material safety data sheets (MSDS) provided by GFE, wear personal protective equipment and do not eat, drink or smoke in designated work areas.
- For *in vitro* diagnostic use only.
- Use only in conjunction with *PoET Extraction*, *PoET Instrument* and associated reagent kits and consumables.
- Inspect the product(s) upon receipt (*i.e.* packaging integrity, completeness). If there are signs of damage, these products must not be used for the test.
- Clean and disinfect all work surfaces (see IFU of the PoET PCR kits).
- Treat the specimens as potentially infectious. 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.
- Disinfect and wash your hands thoroughly after handling the specimens and reagents, and after removing the gloves. Gloves must be exchanged between handling of specimens, controls and reagents. Avoid contaminating gloves when handling specimens and controls.

Disposal

- Dispose of reagent residues according to the relevant regional and national regulations.
- Dispose of all materials that have come into contact with potentially infectious samples in accordance with the relevant regional and national regulations.

Performing the test

PoET Prep Reagent is an extraction kit for *in vitro* testing for nucleic acids of infectious agents with the corresponding PCR kits of the PoET product line. The test procedure is therefore described in the instructions for use of the PoET PCR kits.

Procedural limitations

PoET Prep Reagent was evaluated exclusively for use in combination with *PoET Extraction*, *PoET Instrument* and the PoET PCR kits.

Manufacturer and customer service



Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH
Altenhöferallee 3, 60438 Frankfurt am Main, Germany
Phone: +49 (0) 69 / 400 5513 0

If you have any questions about PoET products and training courses, please contact your local GFE representative:

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

Reporting

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

Trademark protection

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Change notes

Version	Doc.-No.	Date	Change note
3	001087	2024-07-18	<ul style="list-style-type: none"> • Fundamental revision and shortening of the IFU in accordance with IVDR Chapter III 20.4, DIN EN ISO 20417:2022 and DIN EN ISO 18113-1/-2:2013

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