



PoET Extraction

(4 x 24 extractions)

REF P1A-24-04

IVD

Basic UDI-DI 42623533711LY

Version 4, 2024-05

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)



96

Contains sufficient for <n> tests
(n = total number of IVD tests)



+ 8°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



In vitro diagnostic medical device



This device is in conformity with the applicable requirements for CE marking of an *in vitro* diagnostic medical device

Reagents

The extraction kit *PoET Extraction* consists of eight components: one reagent troughs each of *lysis buffer* (LB), *sample diluent* (SD), *wash buffer a* (WBa) and *wash buffer b* (WBb) as well as one tube each of *NA elution buffer* (NEB, green cap), *beads* (B, red cap), *proteinase K 1* (P-1, yellow cap) and *proteinase K 2* (P-2, yellow cap).

One set of all eight components is required for one run with 24 extractions.

Kit component	Reagent ingredients	Quantity per kit
<i>lysis buffer</i> (LB)	≥ 40 – < 45 % guanidine thiocyanate, ≥ 0,3 – < 0,5 % NP-40, tris buffer, H ₂ O	4 x 37,4 mL
<i>sample diluent</i> (SD)	tris buffer, H ₂ O	4 x 36,0 mL
<i>wash buffer a</i> (WBa)	≥ 30 – < 35 % propan-2-ol, guanidine hydrochloride, tris buffer, H ₂ O	4 x 26,6 mL
<i>wash buffer b</i> (WBb)	≥ 75 – < 80 % ethanol, tris buffer, H ₂ O	4 x 55,0 mL
<i>NA elution buffer</i> (NEB)	tris buffer, H ₂ O	4 x 4,24 mL
<i>beads</i> (B)	magnetic particles	4 x 0,44 mL
<i>proteinase K 1</i> (P-1)	proteinase tritirachium album serine, glycerine, tris buffer, CaCl ₂ , H ₂ O	4 x 4,26 mL
<i>proteinase K 2</i> (P-2)	proteinase tritirachium album serine, glycerine, tris buffer, CaCl ₂ , H ₂ O	4 x 4,26 mL

Safety and hazard information

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

Kit component	<i>lysis buffer</i> (LB)
	Danger
GHS07	GHS09
GHS05	
Hazardous ingredients: Guanidine thiocyanate	
H302+H332	Harmful if swallowed or if inhaled.
H314	Causes severe skin burns and eye damage.
H411	Toxic to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.
P260	Do not breathe spray, vapours, mist.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing, eye protection, face protection.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER, a doctor.
P391	Collect spillage.

Intended use

PoET Extraction 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 Extraction, together with *PoET Prep Reagent*, is used to isolate viral nucleic acids from human plasma samples. In addition, the reagent *sample diluent* contained in *PoET Extraction* is used to fill samples up to the volume required for processing with *PoET Instrument*.

The extraction kits *PoET Extraction* and *PoET Prep Reagent* 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*.



Kit component		<i>wash buffer a (WBa)</i>
		Danger
GHS07	GHS02	
Hazardous ingredients: Propan-2-ol		
H225	Highly flammable liquid and vapour.	
H315	Causes skin irritation.	
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.	
P303+P361	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.	
+P353		
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.	
P305+P351	IF IN EYES: Rinse cautiously with water for several minutes.	
+P338	Remove contact lenses, if present and easy to do. Continue rinsing.	
P312	Call a doctor if you feel unwell.	
P241	Use explosion-proof electrical equipment.	

Kit component		<i>wash buffer b (WBb)</i>
		Danger
GHS07	GHS02	
H225	Highly flammable liquid and vapour.	
H319	Causes serious eye irritation.	
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.	
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	
P337+P313	If eye irritation persists: Get medical advice/attention.	
P403+P235	Store in a well-ventilated place. Keep cool.	
P501	Dispose of contents and container in accordance with local and national regulations.	

Kit component		<i>proteinase K 1 and K 2 (P-1/P-2)</i>
	Danger	
GHS08		
Hazardous ingredients: Proteinase Tritirachium album serine		
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.	
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER, a doctor.	

Reagent storage and handling conditions

Storage	Transport	Use
+2 °C to +8 °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 tube/ reagent trough to ensure that there are no leaks. If there are signs of leakage, do not use for the test.
- Please check tubes and 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 tube/trough surface and/or caps of the tubes/*peel-seal* films of the reagent troughs.
- Remove the caps and peel off the *peel-seal* films of the reagents before positioning them on the carriers of *PoET Instrument*. *PoET Instrument* does not have a device for automatically removing caps ('Decapper') or piercing foils.
- To avoid evaporation of the reagents, remove the tube caps and *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 Extraction*.



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 Prep Reagent*, *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).
- Do not allow *lysis buffer* to get in contact with sodium hypochlorite solution (bleach). This mixture can produce a highly toxic gas.
- 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 Extraction 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 Extraction was evaluated exclusively for use in combination with *PoET Prep Reagent*, *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

PoET[®] und *Calliope*[®] are registered names owned by GFE. Other registered names, trademarks etc. used in this document belong to their respective owners.

Change notes

Version	Doc.-No.	Date	Change note
4	001085	2024-05-23	<ul style="list-style-type: none"> Update of the hazardous substance labeling of guanidine thiocyanate and NP-40 in the <i>PoET Extraction lysis buffer</i> 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

© 2024, GFE, all rights reserved