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

*Instructions for use*

# PoET Extraction

*For use with PoET Instrument*

*In vitro diagnostic medical device*

REF **P1A-24-04**

IVD CE

## Table of contents

# 1. Intended use

## 1.1. Abstract

The kit *PoET Extraction* from *Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH* (hereinafter referred to as GFE) is an extraction kit for the isolation of viral nucleic acids from blood plasma.

## 1.2. Intended use

*Intended purpose*

The extraction kit *PoET Extraction* is an accessory for *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 and provide viral nucleic acids from human plasma samples. In addition, the reagent *sample diluent* contained in *PoET Extraction* is used to replenish samples to the volume required for processing with *PoET Instrument*.

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

*PoET Extraction* 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 trained and 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*.

# 2. Test principle

*PoET system*

The extraction kit *PoET Extraction* is a stand-alone reagent product in the PoET system, consisting of the *PoET Instrument* and the PoET reagent kits, a fully automated solution for the extraction, amplification and detection of nucleic acids (nucleic acid amplification technology, NAT) of pathogens in human body fluids in IVD high throughput screening or in individual samples.

*Principle of PoET Extraction*

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

The extraction takes place in the following steps:

1. Lysis of viruses by means of *lysis buffer* (LB) and *proteinase K1/K2* (P-1, P-2) under the influence of heat.
2. Precipitation and binding of viral nucleic acids to magnetic *beads* (B) under chaotropic conditions by adding *PoET Prep Reagent*.
3. Cleaning of the bound nucleic acids by two washing steps with *wash buffer a* (WBa) and *wash buffer b* (WBb).
4. Detachment of the viral nucleic acids from the magnetic *beads* with *NA elution buffer* (NEB).
5. Provide the eluted nucleic acids in *NA elution buffer* for PCR.

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 (IFU) of the respective PCR kits of the PoET product line.

## 4. Reagents

One extraction kit *PoET Extraction* includes 4 reagent troughs of each *lysis buffer* (LB), *wash buffer a* (WBa), *wash buffer b* (WBb) and *sample diluent* (SD) as well as 4 tubes of each *NA elution buffer* (NEB), *beads* (B), *proteinase K 1* (P-1) and *proteinase K 2* (P-2).

The reagents for nucleic acid extraction are 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 batches of 24 or 48 (equivalent to 2 tests of 24 reactions).

**Table 1: Labelling and composition**

| ***PoET Extraction*** | | | |
|---|---|---|---|
| GFE Reference number | P1A-24-04 | | |
| Basic UDI-DI | 42623533711LY | | |
| UDI | (01) 04262353370001(17)YYMMDD(10)1AYYXX | | |
| Number of reactions per test | 24 | | |
| Number of tests per kit | 4 | | |
| Total number of reactions (∑) | 96 | | |
| **Kit component** | **Volume [mL]** | **Identifier** | **Primary packaging (closure type)** |
| *lysis buffer* | 37,4 | LB v1 | Reagent trough (peel-seal film) |
| *wash buffer a* | 26,6 | WBa v1 | Reagent trough (peel-seal film) |
| *wash buffer b* | 55,0 | WBb v1 | Reagent trough (peel-seal film) |
| *sample diluent* | 36,0 | SD v1 | Reagent trough (peel-seal film) |
| *NA elution buffer* | 4,24 | NEB v1 | Screw tube (green cap) |
| *beads* | 0,44 | B v1 | Screw tube (red cap) |
| *proteinase K 1* | 4,26 | P-1 v1 | Screw tube (yellow cap) |
| *proteinase K 2* | 4,26 | P-2 v1 | Screw tube (yellow cap) |

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 format YYMMDD and (10) batch number in format 1AYYXX.

The symbols are explained in Chapter 14.

## 4.1. Transport and storage of reagents

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

*PoET Extraction* is stored upright at +2°C to +8°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 tubes and 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 tube/trough surface and/or caps of the tubes/peel-seal films of the reagent troughs.
- Please ensure that the reagent tubes and 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 *PoET Instrument* using the reagent barcodes. |
|  | Comply with the storage conditions for *PoET Extraction*. The use of incorrectly stored reagents is prohibited, as their efficiency may be severely impaired. |
|  | 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. |
|  | The maximum on-board stability of *PoET Extraction* is designed to match the PCR kits. Information on this can be found in the corresponding IFU of the PCR kits.<br>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. |

### 4.3. Disposal of reagents

- Some components of *PoET Extraction* contain hazardous substances. Conditions for the disposal of reagents can be found in the supplied MSDS.
- The *lysis buffer* contains guanidine thiocyanate. Do not allow *lysis buffer* to contact sodium hypochlorite solution (household bleach). This mixture can produce a highly toxic gas.
- 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 local 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 Extraction*, 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,<br>4x 24well Extraction Plate<br>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 *PoET Instrument* is not allowed.

### 5.3. Required accessory kits

- *PoET Prep Reagent* [GFE Reference number P1B-24-20]
- *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) according to 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)[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 *PoET Extraction* only in combination with *PoET Prep Reagent*.
- Use *PoET Extraction* 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, which have successfully completed the operator`s training on *PoET Instrument*.
- 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 Extraction* in the temperature range from +15°C to +30°C.

[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

**Handling of reagents**

- Remove the caps and 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 removal of caps (‘*Decapper*’) or 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.
- Avoid mixing up tube caps, as this can lead to contamination.
- *PoET Extraction* is designed for single use. Do not reuse reagent residues.
- Do not exchange or combine reagents of different batch numbers of *PoET Extraction*.
- Do not use reagents after their shelf life has expired.

## 6.1. Safety and hazard statements

| Component | Dangerous ingredients | Safety and hazard warnings* |
|---|---|---|
| *lysis buffer (LB)* | Guanidinium thiocyanate | **Achtung**<br>***Warning***<br>  <br>Signal word GHS07<br>H302+H332 - Harmful if swallowed or if inhaled.<br>H412 - Harmful to aquatic life with long lasting effects.<br>P264 - Wash hands thoroughly after handling.<br>P301+P312 – IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.<br>P304+P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing.<br>P312 - Call a POISON CENTER/doctor if you feel unwell.<br>P330 - Rinse mouth.<br>P501 - Dispose of contents/containers in accordance with local and national regulations. |

| Component | Dangerous ingredients | Safety and hazard warnings* |
|---|---|---|
| *wash buffer a (WBa)* | Propane-2-ol | **Gefahr**<br>***Danger***<br>   <br>Signal word GHS02 GHS07<br>H225 – Highly flammable liquid and vapor.<br>H315 - Causes skin irritation.<br>H319 - Causes serious eye irritation.<br>H336 - May cause drowsiness or dizziness.<br>P210 - Keep away from heat, hot surfaces, sparks, open flames or other ignition sources. No smoking.<br>P303+P361+P353 – IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.<br>P304+P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing.<br>P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P312 - Call a POISON CENTER/doctor if you feel unwell.<br>P241 - Use explosion-proof electrical equipment. |

*Safety marking according to GHS Regulation of the EU[4].

| Component | Dangerous ingredients | Safety and hazard warnings* |
|---|---|---|
| *wash buffer b (WBb)* | Ethanol | **Gefahr**<br>***Danger***<br>  <br>  <br>Signal word GHS02 GHS07<br>H225 – Highly flammable liquid and vapor.<br>H319 - Causes serious eye irritation.<br>P210 - Keep away from heat, hot surfaces, sparks, open flames or other ignition sources. No smoking.<br>P280 - Wear protective gloves/protective clothing/eye protection/face protection.<br>P303+P361+P353 – IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.<br>P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P337+P313 – If eye irritation persists: Get medical advice/attention.<br>P403+P235 - Store in a well-ventilated place. Keep cool.<br>P501 - Dispose of contents/containers in accordance with local and national regulations. |

| Component | Dangerous ingredients | Safety and hazard warnings* |
|---|---|---|
| *proteinase K 1 / K 2 (P-1, P-2)* | Proteinase, Tritirachium album serine |  <br>GHS08<br>H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled<br>P304+P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing.<br>P342+P311 – If experiencing respiratory symptoms: Call a POISON CENTER/doctor. |

| Component | Dangerous ingredients | Safety and hazard warnings* |
|---|---|---|
| *sample diluent (SD)* | No hazardous substance | |
| *beads (B)* | No hazardous substance | |
| *NA elution buffer (NEB)* | No hazardous substance | |

*Safety marking according to GHS Regulation of the EU[4]

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

## 7.1. Sample material

- In the validation studies of *PoET Extraction* and *PoET Prep Reagent* together with the PoET PCR kits, human EDTA plasma was used as sample material. All performance-related information is based on this material, which is therefore recommended for use with *PoET Instrument*.
- Blood samples taken from heparin blood collection tubes, as well as samples from heparinized persons, may not be used, as heparin can impair the PCR analysis [3].

Treat all samples as potentially infectious.

## 7.2. Sample drawing & pretreatment

- The venipuncture is to be carried out with commercially available EDTA-K2 blood collection systems with gel barrier (e.g. Sarstedt or Becton Dickinson) according to the manufacturer's specifications.
- The EDTA blood tubes (primary blood tubes) have to be mixed immediately by inverting five to eight times according to the manufacturer's specifications
- The whole blood samples in the EDTA-K2 gel barrier blood collection tubes must be separated by centrifugation into the cellular and plasma components within 48 hours according to the manufacturer's specifications.
- *PoET Instrument* requires a volume of up to 1.5 ml plasma for processing. Depending on the test method, significantly lower volumes can be used. Further information can be found in the operator's manual of *PoET Instrument*.

The primary tubes must be filled sufficiently. Take care to ensure that no gel components or blood cells contaminate the plasma. This can lead to an impairment of the performance of the test procedure.

## 7.3. Sample transport

Sample material has to be shipped exclusively in shatterproof transport containers in order to reduce the risk of leakage of sample material and, as a result, the risk of infection. Sample material must be packed and shipped in compliance with applicable national or international regulations covering the transport of medical samples.

The permissible time and temperature of the transport for the samples have to comply with the storage conditions (see Chapter 7.4).

## 7.4. Sample storage

The whole blood samples in the EDTA-K2 blood collection tubes must be separated into the cellular and plasma components within 48 hours. The samples can usually be transported and stored at a temperature of 0°C to +35°C until separation. For details on storage and transport conditions of whole blood samples please refer to the instructions for use of the respective PoET PCR kits.

Information on virus stability in EDTA plasma can be found in the instructions for use of the respective PCR kits.

The test performance may be affected by freezing and thawing or prolonged storage of the samples.

## 7.5. Provision of samples for *PoET Instrument*

Sample material stored in the refrigerator can be used and analyzed directly. The handling of frozen and thawed sample material has not been validated. Therefore, no information is available for frozen and thawed sample material. If frozen plasma is to be used, it is recommended to thaw the plasma at +37 °C in a water bath to prevent the formation of precipitates that could affect the test performance.

## 7.6. Disposal of samples

Human plasma samples are classified as potentially infectious materials. Disposal must be carried out in accordance with the applicable regional and national regulations.

# 8. Processing of samples on *PoET Instrument*

## 8.1. General information for working with *PoET Instrument*

The handling of *PoET Instrument* is described in detail in the operator's manual of *PoET Instrument.* The following is the summarized test procedure*:*

- Before starting the run: turn on the device and PC and carry out maintenance program according to the instructions on the screen
- Running the test:
  - Select processing mode
  - Load samples
  - Assign testing orders (test type and test parameters)
  - Load *PoET Instrument* with reagents and consumables
  - Start run
  - Check results
  - Unload consumables and disposal of waste

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.

## 8.2. Process Overview

*PoET Instrument* allows the simultaneous processing of different GFE PCR kits depending on the number of samples to be analyzed. Nucleic acid extraction is carried out for externally formed sample pools, sample pools created on *PoET Instrument* and for individual samples in different processing modes (Pooling and screening mode; Screening mode). These modes are explained in detail in the operator's manual of *PoET Instrument*.

*PoET Instrument* processes a sample input volume of up to 1300 µL for extraction, which is transferred to the extraction plate (*24well Extraction Plate*). For samples and sample pools with a volume lower than 1300 µL, *PoET Instrument* supplements the volume directly in the extraction plate to 1300 µL with the reagent *sample diluent*. After addition of *PoET Internal Control* and the reagents *lysis buffer* and *proteinase K 1 & K 2* as well as the magnetic *beads*, the chaotropic virus lysis is carried out with the help of the extraction modules of *PoET Instrument*. By adding *PoET Prep Reagent*, nucleic acids (DNA and RNA) are precipitated. Under these conditions, the nucleic acids are bound to the *beads*. The *beads* with the bound nucleic acids are magnetically separated from the liquid by magnets on the extraction module, which mechanically drive into the *Tip-Plates*. For further purification of the bound nucleic acids, two different wash buffers (*wash buffer a* and *wash buffer b*) are used. For each washing step, the respective *Tip-Plate* including the *beads* is transferred to a new *24well Extraction Plate* filled with wash buffer. By removing the magnetic field at the *Tip-Plate* ('extending' the magnets from the sleeves), the *beads* can be homogenized by mixing movements of the *Tip-Plate* in the wash buffer. Subsequently, the *beads* are magnetically collected again and the process steps are repeated with the second wash buffer. In the last step of extraction, the nucleic acids are detached from the *beads* in the *NA elution buffer* (NEB) by heating the reaction batches. For this purpose, the *beads* are transferred into a *24well Extraction Plate* filled with NEB and re-suspended with the help of the *Tip-Plate*. After incubation, the *beads* are collected and removed. The plate now contains the nucleic acids dissolved in NEB. The contents of this eluate plate are further processed as part of the PCR setup.

After the nucleic acid extraction, the automatic PCR setup for virus detection takes place. Further information on the PCR setup and the data evaluation can be found in the instructions for use of the respective PoET PCR kits as well as in the operator's manual of *PoET Instrument*.

# 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 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 Extraction* 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 Extraction* is intended exclusively for use together with *PoET Prep Reagent* and PoET PCR and control kits on *PoET Instrument*.
- If possible, EDTA blood collection tubes taken specifically for this test should be used as sample material for NAT tests. Samples and sample tubes already used for other tests could be contaminated and therefore affect the PCR result.
- The primary tubes must be sufficiently filled. If the primary tubes are insufficiently filled, gel components or blood cells can be transferred to the sample pool or the extraction reaction. As a result, the performance of the test procedure may be impaired.
- The detection of human viruses depends on the amount of virus-specific nucleic acids contained in the sample. In the case of a very low viral load (below the detection limit of the test), this cannot be reliably detected by the respective PCR kit.
- Incorrect sampling, untested interfering substances and improper sample storage and preparation can negatively affect the stability of viruses and nucleic acids and impair the result of PCR. In addition, the plasma may contain inhibiting substances that interfere with extraction or PCR reaction.
- Blood samples taken from heparin blood collection tubes, as well as samples from heparinized individuals, should not be used because heparin can interfere with PCR.
- In rare cases, samples with a very high viral load may carry over during sample preparation on *PoET Instrument*. Detection of a PCR result with early amplification signal may thus lead to weakly reactive results in further samples in the same run.

## 12. Performance characteristics

The performance characteristics of *PoET Extraction* can only be assessed together with *PoET Prep Reagent* 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

| | |
|---|---|
| REF | Symbol for ‘Reference number’ |
| Σ 96 | Symbol for ‘Sufficient for <n> tests’ (n = total number of IVD tests) |
| LOT | Symbol for ‘Batch code’ |
| YYYY-MM | Symbol for ‘Use by date’ (year-month) |
| +2°C +8°C | Symbol for ‘Temperature limits’ |
| | Symbol for ‘Consult instructions for use’ |
| | Symbol for ‘Caution’<br>Indication of safety-related information such as warning or precaution. |
| | Symbol for ‘Do not re-use’ |
| | Symbol for ‘Keep away from sunlight’ |
| IVD | Symbol for ‘*In vitro* diagnostic medical device’ |
| CE | Symbol of conformity with Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices |
| UDI | Symbol for ‘Unique Device Identification’ |
| | Symbol for ‘Manufacturer’ |
| | GFE manufacturer logo |

## 15. Hazard pictograms

| | |
|---|---|
|  | GHS02<br>Flammable |
|  | GHS07<br>Warning |
|  | GHS08<br>Systemic health hazards |

## 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 |
| RNA | Ribonucleic acid |
| 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 Extraction* can be addressed to GFE Customer service:

Email: 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] Ding M, Bullotta A, Caruso L, Gupta P, Rinaldo CR, Chen Y. An optimized sensitive method for quantitation of DNA/RNA viruses in heparinized and cryopreserved plasma. J Virol Methods. 2011;176 (1-2):1-8. doi:10.1016/j.jviromet.2011.05.012

[4] 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 | • Chapter 1 Intended use: Adaptation of intended use in accordance with Regulation (EU) 2017/746<br>• Chapter 2 Test principle: overview of PoET system inserted<br>• Chapter 4 Reagents: UDI and reference to Chapter 14 (Explanation of symbols) inserted<br>• Chapter 9 Control procedures: shortened with reference to PCR kit IFUs<br>• Chapter 10 Evaluation and validity of the results: newly inserted with reference to IFU of the PCR kits<br>• Chapter 14 Explanation of symbols: reference to Regulation (EU) 2017/746 inserted at CE symbol; addition of UDI symbol<br>• Chapter 17: Renamed into ‘Contact’, divided into Chapter 17.1: Technical service and newly added Chapter 17.2 Reporting of serious incidents |
| 3 | 2023-03-20 | • Chapter 2 detailed description of *PoET System* inserted<br>• Chapter 4.3 linguistic adaptation (replace „regional“ by „local”)<br>• Chapter 6 adaptation of wording: note regarding the handling of *PoET Instrument* inserted<br>• Chapter 6.1 Nonylphenol-ethoxylat and hazard pictogram GHS09 removed, H412-phrase replaced by H411 because of changed classification of lysis buffer<br>• Chapter 15 hazard pictogram GHS09 removed |

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