

# PEERO-prep reagent kit for sample preparation



For Professional Use Only

## Instruction Manual

### KEY TO SYMBOLS USED

|  |   |  |                                   |
|--|---|--|-----------------------------------|
|  | Catalogue number                                    |  | Caution                           |
|  | Batch code  |  | Contains sufficient for <n> tests |
|  | <i>In vitro</i> diagnostic medical device           |  | Use-by Date                       |
|  | Version   |  | Consult instructions for use      |
|  | Temperature limit                                   |  | Keep away from sunlight           |
|  | Manufacturer  |  | GHS05: Corrosion                  |
|  | Date of manufacture                                 |  | GHS02: Flame                      |
|  | Authorized representative in the European Community |  | GHS07: Exclamation mark           |

**FBIS CRIE** Federal Budget Institute of Science "Central Research Institute for Epidemiology"

### 1. INTENDED USE

**PEERO-prep** reagent kit for sample preparation is intended for product preparation for pyrosequencing using the Vacuum Prep Workstation.

**NOTE:** The results of PCR analysis are taken into account in complex diagnostics of disease.

### 2. PRINCIPLE AND PROCEDURE

The reagent kit is used for binding the PCR product, cleansing the reaction mixture, and denaturation of amplicons with the use of the Vacuum Prep Workstation. Streptavidin Sepharose High Performance (GE Healthcare) reagent is additionally required for binding the PCR product.

### 3. CONTENT

**PEERO-prep** reagent kit for sample preparation is produced in 1 form:

K15-1611-40-CE.

**PEERO prep** reagent kit includes:

| Reagent                           | Description            | Volume, ml | Quantity |
|-----------------------------------|------------------------|------------|----------|
| <b>Binding Buffer</b>             | colorless clear liquid | 250        | 1 vial   |
| <b>Cleansing Solution</b>         | colorless clear liquid | 500        | 4 vials  |
| <b>10x Denaturation Solution*</b> | colorless clear liquid | 200        | 1 vial   |
| <b>10x Washing Buffer*</b>        | colorless clear liquid | 200        | 1 vial   |

\* – for optimal preparation of template DNA for Pyrosequencing analysis only 1x Buffers and Solutions should be used. (See section D. "Product Preparation to Pyrosequencing" from the instruction manual to the kit for genotyping the single-nucleotide polymorphisms based on the pyrosequencing technology, manufactured by FBIS CRIE).

**NOTE:** Correct results when working with **PEERO-prep** reagent kit for sample preparation are guaranteed only in the case of using the additional reagent for sample preparation: **H<sub>2</sub>O sterile, manufactured by FBIS CRIE.**

### 4. ADDITIONAL REQUIREMENTS

See the instruction manual to the kit for genotyping the single-nucleotide polymorphisms based on the pyrosequencing technology manufactured by FBIS CRIE.

### 5. GENERAL PRECAUTIONS

The user should always pay attention to the following:

- Use sterile pipette tips with aerosol filters and use a new tip for every procedure.
- Store and handle amplicons away from all other reagents.
- Thaw all components thoroughly at room temperature before starting an assay.
- When thawed, mix the components and centrifuge them briefly.
- Use disposable protective gloves, laboratory coats, and protect eyes while samples and reagents handling. Thoroughly wash hands afterwards.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in laboratory work areas.
- Do not use a kit after its expiration date.
- Dispose of all samples and unused reagents in compliance with the local regulations.
- Samples should be considered potentially infectious and handled in a biological cabinet in accordance with appropriate biosafety practices.
- Clean and disinfect all samples or reagents spills using a disinfectant, such as 0.5 % sodium hypochlorite or another suitable disinfectant.
- Avoid samples and reagents contact with the skin, eyes, and mucous membranes. If these solutions come into contact, rinse the injured area immediately with water and seek medical advice immediately.
- Safety Data Sheets (SDS) are available on request.
- Use of this product should be limited to personnel trained in DNA amplification techniques.
- Workflow in the laboratory must be one-directional, beginning in the Extraction Area and moving to the Amplification and Detection Area. Do not return samples, equipment, and reagents to the area where the previous step was performed.

|                    |   |
|--------------------|---|
| <br><b>Warning</b> | Cleansing Solution<br>Contains substance: isopropyl alcohol<br>H226: Flammable liquid and vapour.<br>H319: Causes serious eye irritation.<br>H336: May cause drowsiness or dizziness<br>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br>P261: Avoid breathing vapours.<br>P264: Wash your hand thoroughly after handling.<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>P403+P233: Store in a well ventilated place. Keep container tightly closed.<br>P501: Dispose of contents in accordance with national regulation. |
| <br><b>Danger</b>  | 10x Denaturation Solution<br>Contains substance: sodium hydroxide<br>H314: Causes severe skin burns and eye damage.<br>P264: Wash hands thoroughly after handling.<br>P280: Wear protective gloves and protective clothing.<br>P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.<br>P321: Specific treatment (see skin corrosion in the SDS).<br>P363: Wash contaminated clothing before reuse.<br>P501: Dispose of contents in accordance with national regulation.   |

### 6. WORKING CONDITIONS

**PEERO prep** reagent kit should be used at 18–25 °C.

### 7. PROTOCOL

See section D. "Product Preparation to Pyrosequencing" from the instruction manual to the kit for genotyping the single-nucleotide polymorphisms based on the pyrosequencing technology manufactured by FBIS CRIE.

### 8. TRANSPORTATION

**PEERO prep** reagent kit for sample preparation should be transported at 2–8 °C for no longer than 5 days.

### 9. STABILITY AND STORAGE

All components of **PEERO-prep** reagent kit for sample preparation are to be stored at 2–8 °C when not in use. All components of **PEERO-prep** reagent kit are stable until the expiration date on the label. The shelf life of reagents before and after the first use is the same, unless otherwise stated.

### 10. QUALITY CONTROL

In compliance with Federal Budget Institute of Science "Central Research Institute for Epidemiology" ISO 13485-Certified Quality Management System, each lot of **PEERO-prep** reagent kit for sample preparation has been tested against predetermined specifications to ensure consistent product quality.

**List of Changes Made in the Instruction Manual**

| VER            | Location of changes | Essence of changes  |
|----------------|---------------------|---|
| 24.04.20<br>VA | Through the text    | The text formatting was changed   |
|                | Footer              | The phrase "Not for use in the Russian Federation" was added  |
| 22.03.21<br>MM | —                   | The name, address and contact information for Authorized representative in the European Community was changed |

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