

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.

Indications and contra-indications for use of the reagent

Purification and immobilization of a single-stranded PCR product is used prior to determine the nucleotide sequence of the studied genetic locus by *in vitro* diagnostics using the pyrosequencing method.

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
Binding Buffer	colorless clear liquid	250	1 vial
Cleansing Solution	colorless clear liquid	500	4 vials
10x Denaturation Solution*	colorless clear liquid	200	1 vial
10x Washing Buffer*	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: **H₂O 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.

 Warning	Cleansing Solution Contains substance: isopropyl alcohol H226: 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 and other ignition sources. No smoking. P261: Avoid breathing vapours. P264: Wash your hand thoroughly after handling. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P403+P233: Store in a well ventilated place. Keep container tightly closed. P501: Dispose of contents in accordance with national regulation.
	10x Denaturation Solution Danger Contains substance: sodium hydroxide H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage. P264: Wash hands thoroughly after handling. P280: Wear protective gloves and protective clothing. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower. P321: Specific treatment (see skin corrosion in the SDS). P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P405: Store locked up. P501: Dispose of contents in accordance with national regulation.

6. WORKING CONDITIONS

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

Interfering substances and limitations of using test material samples

The information about potential interfering substances and limitations of using test material samples is specified in the Instruction manual to the kit for genotyping the single-nucleotide polymorphisms based on the pyrosequencing technology.

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.

Please contact our Authorized representative in the European Community if side effects, undesirable reactions, facts and circumstances that pose a threat to the life and health of citizens and medical workers are identified during the use of the reagent kit.

List of Changes Made in the Instruction Manual

VER	Location of changes	Essence of changes
24.04.20 VA	Through the text	The text formatting was changed
	Footer	The phrase "Not for use in the Russian Federation" was added
22.03.21 MM	—	The name, address and contact information for Authorized representative in the European Community was changed
01.08.23 EM	1. Intended use	"Indications and contra-indications for use of the reagent" subsection was added
	6. Sampling and handling	"Interfering substances and limitations of using test material samples" subsection was added
	12. Quality control	The Authorized representative in the European Community was specified for the contact in case of undesirable effects when using the reagent
11.06.24 PM	5. General precautions	Information about hazards was rewritten according to the Regulation (EU) 2020/878

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