bioPerfectus technologies

Jiangsu Bioperfectus Technologies

Viral Nucleic Acid Isolation Kit（Silica-Based Spin Column）

INSTRUCTIONS FOR USE

REF SDK60102 | 05.2020

50T | 4 30 | CE

IVD For *In Vitro* Diagnostic Use

Jiangsu Bioperfectus Technologies Co., Ltd.

3rd and 4th floors of Building A(G19), 4th floor of Building F(G14), Ground floor of Building G20, Shuaiyu Village, Fuye village, Sixiang town, Taizhou National Medical, Hi-tech Development Zone, 225300 Taizhou, Jiangsu,PEOPLE'S REPUBLIC OF CHINA.

http://www.s-sbio.com

EC REP MedNet EC-REP GmbH
Borkstrasse 10·48163 Muenster· Germany

1. Intended Use

The Bioperfectus Technologies Viral Nucleic Acid Isolation Kit（Silica-Based Spin Column） is specially designed for efficient purification of viral RNA and viral DNA from cell-free samples such as serum, plasma, urine, body fluids and the supernatant of viral infected cell cultures. The purified nucleic acids are ready-for-use in subsequent downstream applications of molecular biology.

2. Product Description

The sample is lysed by incubation with Lysis Solution. The Lysis Solution inactivates RNases, ensuring protection of viral nucleic acids against degradation. The lysed sample is transferred to a spin column where released viral nucleic acids immediately bind to the silica-based filter in the presence of Binding Buffer. The remaining contaminants are removed during three wash steps using Wash Buffer, whereas pure nucleic acids remain bound to the membrane. Pure viral nucleic acids are released from the spin column filter using Elution Buffer. The resulting purified nucleic acids are ready for subsequent use in downstream applications.

3. Kit Components

Contents	Numbers of preps	Volume
Lysis buffer	1	35 mL
BindingBuffer*	1	12 mL
Wash Buffer**	1	15 mL
Elution Buffer	1	3 mL
Binding Columns	50	-
Collection Tubes	50	-

*Add 28 mL Ethanol into Binding Buffer before use.
**Add 60 mL Ethanol into Wash Buffer before use.

4. Storage

1. All reagents should be stored at 4°C~30°C before the expiration date indicated on the outer kit box.

5. Materials and Devices Required but Not Provided

1. Ethanol.
2. Biosafety cabinet.
3. RNase free microcentrifuge tube.
4. Desktop centrifuge.
5. Vortex mixer.
6. Adjustable pipettes.
7. Disposable pipette tips with filters.
8. Disposable powder-free gloves.

NOTE: Please ensure that instruments have been installed, calibrated, checked and maintained according to the manufacturer's instructions and recommendations.

6. Specimens

1. The Bioperfectus Technologies Viral Nucleic Acid Isolation Kit （Silica-Based Spin Column） is specially designed for efficient purification of viral RNA and viral DNA from cell-free samples such as serum, plasma, urine, body fluids and the supernatant of viral infected cell cultrues. Store collected samples immediately and avoid cross contamination.
2. After collection, samples can be stored at 2–8°C for up to 3 days and used for extraction as quickly as possible. For long-term storage, freezing at –20°C for up to 4 months or –70°C for up to 12 months is recommended. Frozen samples must not be thawed more than five times. Repeated freeze–thawing leads to denaturation and precipitation of proteins, resulting in reduced viral titers and therefore reduced yields of viral nucleic acids.

7. General Protocol

1. Transfer 200 µLof sample to a 1.5 mL microcentrifuge tube.
2. Add 600 µL of Lysis Buffer to the sample, mix thoroughly by vortex or pipettes.
3. Incubate for 5 min at room temperature.

4. Add 600 µL of Binding Buffer (make sure ethanol added) to the sample lysate, Reason: Validity of Signature pettes.
5. Place the Binding Column in a Collection Tube. Transfer 650 µL of the lysate to the Binding Column. Centrifuge the column for 30 s at 13000 rpm. Discard the flow-through then place the Binding Column back in the Collection Tube.
6. Transfer the remaining mixture to the Binding Column. Centrifuge the column for 30 s at 13000 rpm. Discard the flow-through the place the Binding Column back in the Collection Tube.
7. Add 500 µL of Wash Buffer (make sure ethanol added) to the Binding Column. Centrifuge the column for 30 s at 13000 rpm. Discard the flow-through then place the Binding Column in the Collection Tube.
8. Repeat the step (7) again.
9. Place the Binding Column back in the Collection Tube. Centrifuge the column for 2 min at 13000RPM to dry the column matrix.
10. Place the dried Binding Column into a clean microcentrifuge tube. Add 50 µL of Elution Buffer to the center of Binding Column matrix. Incubate for at least 2 min at room temperature to ensure the Elution Buffer is absorbed by the matrix. Centrifuge for 1 min at 13000 rpm to elute the purified nucleic acids.
11. Use the purified nucleic acids immediately or store at -20°C/-80°C.

8. Warnings and Precautions

1. Carefully read this instruction before starting the procedure.
2. The kit is intended for molecular biology applications. This product is not intended for the diagnosis, prevention, or treatment of a disease.
3. Mix reagents well and centrifuge reagents before starting.
4. Keep container tightly closed.
5. Wear protective disposable powder-free gloves, laboratory coat, and eye protection when handling specimens and kit reagents.
6. Buffers provided in this system contain irritants. Avoid contact of specimens and reagents with the skin, eyes and mucous membranes. If these solutions come into contact, rinse immediately with water and seek medical advice immediately.
7. Make sure everything is RNase-free/DNase-free when handling this system.
8. Components from different batches can't be used interchangeably.
9. Do not use components of the kit after the expiration date.
10. Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in laboratory work areas.
11. Dispose of all specimens and unused reagents in accordance with local regulations.
12. Use of this product should be limited to personnel trained in the techniques of molecular biology.

9. Reference

[1] Peter R.Levisom, Stephen E. Badger, et al. Recent developments of magnetic beads for use in nucleic acid purification[J]. Journal of Chromatography A, 1998,816:107-111.
[2] Zhang HP1, Bai S, Xu L, Sun Y. Fabrication of mono-sized magnetic anion exchange beads for plasmid DNA purification [J]. J Chromatogr B Analyt Technol Biomed Life Sci. 2009 Jan 15; 877(3):127-33.

10. Appendix

Index of Symbols

IVD	In vitro diagnostic medical device
Σ	Contains sufficient for <n> tests
	Consult instructions for use
	Upper limit of temperature
REF	Catalogue number
	Date of manufacture
	Use-by date
LOT	Batch code
	Manufacturer
EC REP	Authorized representative in the European Community

11. Contact and Support

For more information about Jiangsu Bioperfectus Technologies Co. Ltd., please visit our website at: http://www.s-sbio.com or contact at E-mail: info@s-sbio.com.
For detailed programming instructions regarding the use of the Bioperfectus Technologies Viral Nucleic Acid Isolation Kit(Silica-Based Spin Column), please contact our Technical Support at E-mail: support@s-sbio.com.