

[Operation Procedures]




1. Sample pretreatment

- ◆Serum or plasma: rice yellow and clear liquid, without solid impurities, may be directly used for extraction.
- ◆Cultured cells: with the supernatant discarded after centrifugation, it is used for extraction after being resuspended in normal saline or phosphate buffer.
- ◆Saliva, alveolar lavage fluid, and nasopharyngeal aspirates: collected in accordance with related operation specifications. Thick samples must be extracted after liquidation.
- ◆Swab: including oropharyngeal swabs, nasopharyngeal swabs, reproductive tract swabs, etc. Put the swab into 0.5-1 mL normal saline or phosphate buffer and stir repeatedly for 2 minutes. Squeeze the liquid and discard the swab. Such liquid is used for subsequent extraction. The solution can be directly used for extraction if the swab is preserved in preserving solution.



2. Preparation of reagent plate


- ◆Before removing the sealing membrane, shake each plate downward to gently remove any reagents attached to the aluminum membrane, making sure that the reagents or magnetic beads are at the bottom of the plate. Adopt low speed centrifugation if necessary. Place the sample on the plate type centrifuge for 1 min at 500 rpm.
- ◆Place the reagent plate on the workbench, carefully tear off the sealing film in the diagonal direction, avoid the vibration of the pore plate and prevent the liquid from splashing out.

 Important Notes! If the aluminum film breaks during the process of tearing, rotate the reagent plate at an angle and tear it in a new direction.



3. Sample addition


- ◆Add 200 μ L of the treated sample to each reagent hole of the sample plate (samples of less than 200 μ L are recommended to make up to 200 μ L with normal saline), and then add 20 μ L of proteinase K.

 Notice:
①The 200 μ L sample should be free of obvious solid impurities. If any, the supernatant should be taken by centrifugation for extraction.
②Liquid addition sequence must not be changed. The sample is added earlier than proteinase K solution.



4. Instrument operation (Thermo Scientific KingFisher Flex, for example)

- ◆Ensure that the appropriate magnetic head and heating module are installed on the King Fisher Flex instrument;
- ◆Use BindIt software to import the extraction program "Techstar_Viral Total NA_Flex" (Please go to the techstar website <http://www.tech-star.cn/> and download from the "Downloads" page). See BindIt Software for KingFisher Instruments for details;
- ◆Start the program and follow the prompts on the instrument display to put the magnetic rod cover and reagent plate on the instrument.

 Notice: Reagent plate A1 (notch) and base A1 need to be placed correspondingly.

- ◆Start extraction process;
- ◆After the instrument operation is completed, remove the reagent plate. The liquid in the elution plate is the isolated and purified nucleic acid solution. It can be preserved at 4 °C for a short period of time, or below minus 20 °C for a long term period.



Nucleic Acid (DNA/RNA) Extraction Kit Manual

[Basic Information]

Name of the filing entity/manufacturing company: Wuxi Techstar Technology Co., Ltd.

Address: No.2 Workshop, No.117 Meiyu Road, Meicun Street, Xinwu District, Wuxi City, Jiangsu Province, China.

Contact information: +86-510-6851 8058

Website: <http://www.tech-star.cn/>

E-mail: techstar8@163.com

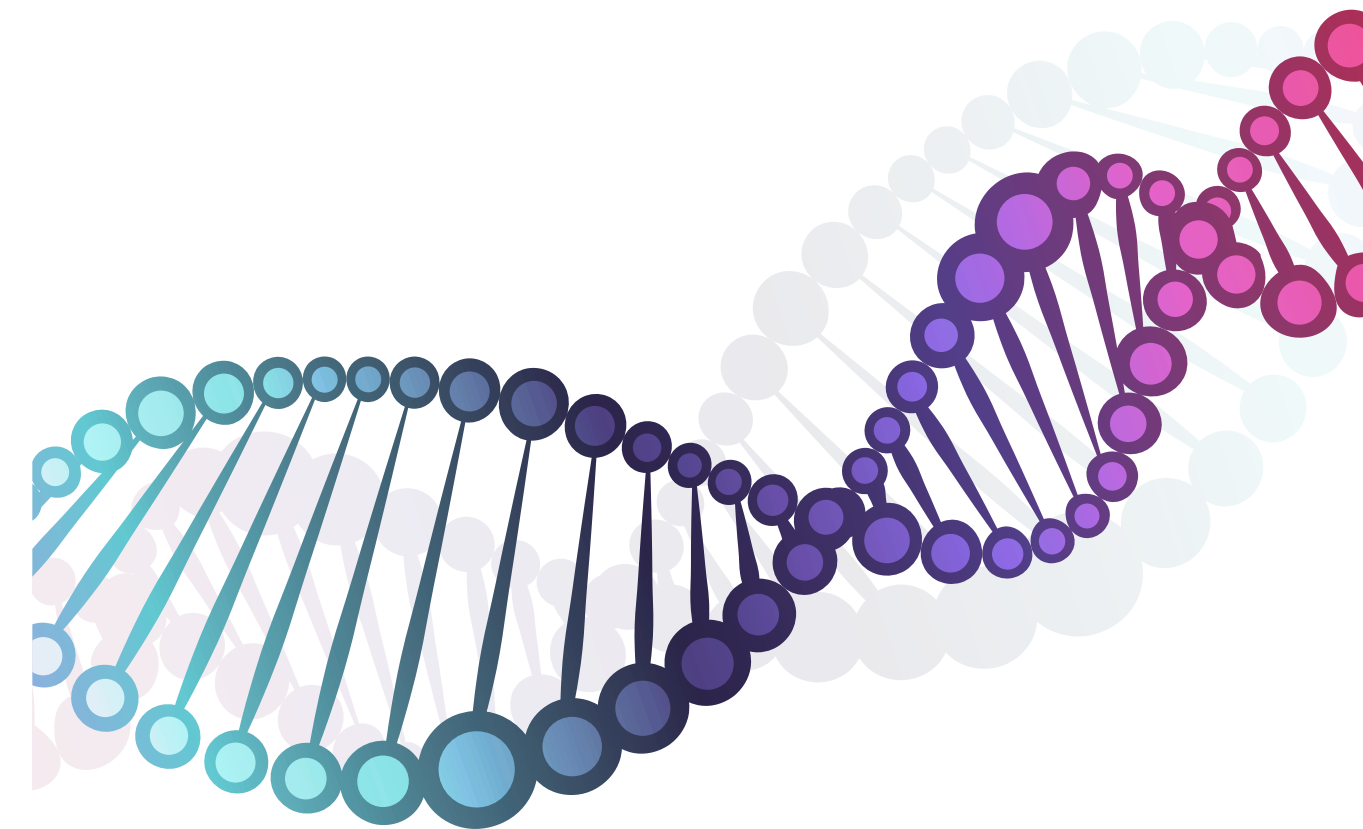
Production address: No.2 Workshop, No.117 Meiyu Road, Meicun Street, Xinwu District, Wuxi City, Jiangsu Province, China.

Production filing certificate number: [Medical device filing certificate number/product technology requirement number]

[Instruction verified and modified on] 2020.05.08

Version No.: V20200508.01

Copyright Statement: All rights reserved by Wuxi Techstar Technology Co., Ltd.



[Product name] Nucleic Acid (DNA/RNA) Extraction Kit

[Packing Specification] 96 Reactions

[Intended use] It is used for nucleic acid extraction, enrichment, purification and other steps. The processed product may be used for clinical in vitro testing.

[Transportation condition] Transportation under room temperature

[Preservation condition] Preservation under room temperature, or long-term preservation at 2-8 °C

[Period of validity] 12 months

[Applicable Instrument] Techstar YC796 automatic nucleic acid extraction system, Thermo Scientific KingFisher Flex and other 96-throughput automatic nucleic acid extractor.



[Product Introduction]

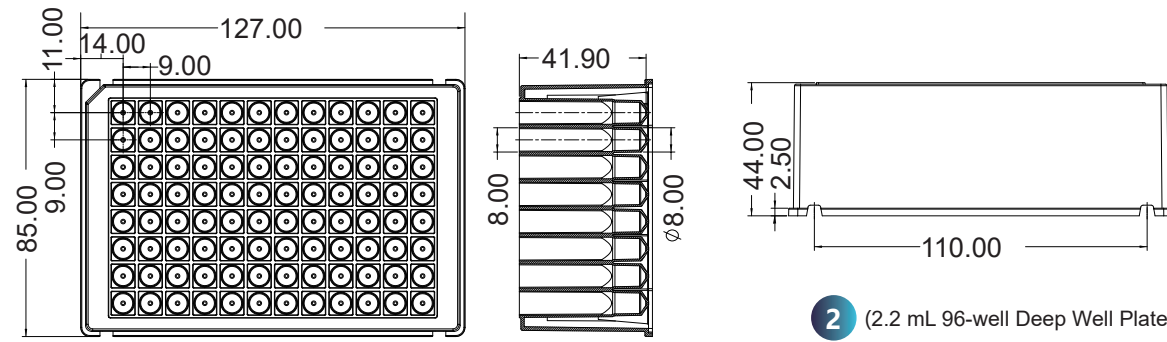
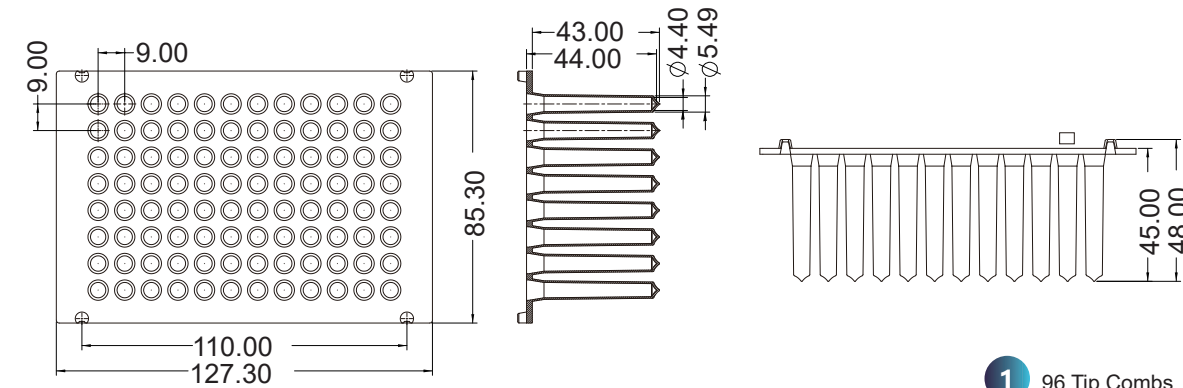
In conjunction with the 96-throughput full-automatic nucleic acid extraction instrument, the reagent kit serves to extract genomic DNA/RNA of pathogenic microorganisms from serum or plasma, cultured cells, saliva, alveolar lavage fluid, nasopharyngeal aspirates, and swab samples. The reagent kit is provided with the magnetic bead and buffer solution system featuring unique separation functions, with the special chemical group on the magnetic bead surface exerting extremely strong enrichment forces to DNA/RNA under given conditions for reversible release of DNA/RNA when conditions change, so as to separate and purify DNA/RNA as soon as possible and minimize impurities such as the protein. The DNA/RNA extracted by this kit can be widely used in various downstream molecular biology experiments, such as sequencing, genetic typing and qPCR.

[List of Product Composition]

Product Name	Quantity	Volume	Type of Deep Well Plate
96 Tip Combs	1	/	96 Tip Combs
Sample Plate	1	500 μL×96 well	2.2 mL 96-well Deep Well Plate
Magnetic Bead Plate	1	200 μL×96 well	
Wash Plate I	1	600 μL×96 well	
Wash Plate II	2	600 μL×96 well×2 pcs	
Elution Plate	1	600 μL×96 well	
Proteinase K	2	1mL x 2 pcs	/



[Product composition size]



[Precautions]

- As a disposable product, this product cannot be reused.
- Preservation of the reagent plate or reagent in low-temperature places such as the refrigerator may lead to relatively high solution viscosity or sediments. For such sediments found before operation, please heat the reagent plate or reagent at 37 °C and mix it gently to dissolve the sediments. Bubbles must be prevented during mixing.
- Repeated freezing and thawing of the reagent plate are forbidden, otherwise the magnetic bead may be damaged.
- If the aluminum film breaks during the process of tearing, rotate the reagent plate at an angle and tear it in a new direction.
- Please operate carefully, as the solution contains a guanidine salt protein denaturant, which is corrosive. If it accidentally splashes on the skin, please rinse with plenty of water.
- The reagent plate must be used within 30 minutes after unsealing, as long-term placement may affect the extraction effect;
- To prevent reduced activity of proteinase K, sample is added to the sample plate before addition of proteinase K.
- Each eluent hole is preloaded with a volume of 100 μL. A larger elution volume requires supplement of a certain volume of TE in accordance with the instrument.
- Fresh sample extraction is recommended. Repeated freezing and thawing of samples may lead to significantly decreased quantity of the nucleic acid.
- As RNA is easily degradable, please use Rnase-free consumables. The nucleic acid must be used shortly after extraction and purification. If not, please store at minus 20 degrees Celsius. Long-term storage is recommended below minus 70 degrees Celsius.

[Requirement for use]

- If a custom extraction process is needed, the procedure should follow the sequence of "Taking tip combs → Sample lysis → Transfer beads → Bind nucleic acid → Wash I → Wash II → Wash III → Nucleic acid elution → Discard beads". The recommended magnetization time for "Wash I" and "Nucleic acid elution" is not less than 60 seconds, while the magnetization time for the other steps is not less than 30 seconds. For other settings, please refer to the relevant instrument manual.
- The collection, transportation and preservation of samples shall comply with relevant specifications.
- All samples, considered as a potential biological hazard, must be prevented from contact with skin or mucous membranes. Sample processing and operation should meet relevant laws and regulations, such as the General Guidelines for Biosafety of Microbial Biomedical Laboratories and the Regulations on Medical Waste Management.
- Discarded consumables and tips generated during the experiment are treated as medical waste.
- Kits with damaged packaging or liquid leakage must not be used.

[Faults and solutions]

Fault phenomenon	Possible cause	Recommended measures
Low or inconsistent output	Before unpacking, magnetic beads are adsorbed on the side wall or aluminum film	Before opening the magnetic bead plate, check whether the magnetic beads are all gathered at the bottom of the plate. If they are absorbed on the side wall or aluminum film, tap and knock them down to the bottom and then open the plate.
	After unpacking, some magnetic beads are found on the aluminum film	For wet beads, carefully pipette the liquid from the aluminum membrane back into the corresponding hole. For dry beads, re-wet them with nuclease-free water, and then carefully pipette the liquid from the aluminum membrane back into the corresponding hole.
	There are air bubbles in the reagent plate	Eliminate air bubbles with low speed centrifugation method before use.

[Symbol description]



Automatically invalid after one-time use



Do not use the product, if the package has been damaged or opened



Refer to the instruction for details



Refer to the instructions for details

[Quality assurance]

- For quality problems resulted from manufacturing within the warranty period under the conditions of preservation, transportation and use specified in this instruction, users may contact the Company or its designated agent.
- Material cost, logistic expenses and travel expenses due to product damages resulted from operations in violation of the instruction within the warranty period are borne by the user.
- Indicators and functions described herein may be changed or modified without prior notice.