USER'S GUIDE

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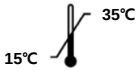
ExiPrep™ Dx Viral DNA/RNA Kit
ExiPrep™ Dx Viral DNA Kit
ExiPrep™ Dx Viral RNA Kit



REF **K-4471/K-4472/K-4473**

IVD
Viral DNA/RNA Kit
Viral DNA Kit
Viral RNA Kit

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ExiPrep™ Dx Viral DNA/RNA Kit
ExiPrep™ Dx Viral DNA Kit
ExiPrep™ Dx Viral RNA Kit

User's Guide

Version No.: 3.3 (2019-04-25)

Please read all the information in booklet before using the unit

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Safety warnings and precautions

Please inquire BIONEER's Customer Service Center to obtain a copy of the Material Safety Data Sheet (MSDS) for this product.

Before, during and after use of this kit as described in this User Manual, all potentially hazardous materials (i.e. materials that may have come in contact with clinical samples) including tubes, tips and materials should be processed and disposed of according to applicable and appropriate regulations of the municipality/government in which this product is being used.

The results yielded from this Kit may be used for preliminary analysis only. This kit is not intended for human or veterinary diagnostics.

Please read the User Manual before using this Kit. Please check the integrity of all tubes, tips and other materials supplied with this kit prior to use. Adhere to general clinical laboratory safety procedures during the experiment.

Some applications that may be performed with this kit may infringe upon existing patents in certain countries. The purchase of this kit does not include or provide a license to perform patented applications. Users may be required to obtain a license depending on country and application. We do not condone nor recommend the unlicensed use of a patented application.

Warranty and Liability

All Bioneer products undergo extensive Quality Control testing and validation. Bioneer guarantees quality during the warranty period as specified, when following the appropriate protocol as supplied with the product. It is the responsibility of the purchaser to determine the suitability of the product for its particular use. Liability is conditional upon the customer providing full details of the problem to Bioneer within 30 days.

Trademark

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Contents

1. Intended use

ExiPrep™ Dx Viral DNA/RNA Kit is an in vitro diagnostic kit designed for the extraction of viral DNA and viral RNA from human clinical samples through particular nucleic acid device, *ExiPrep*™16 Dx (A-5050), *ExiStation*™ Universal Molecular Diagnostic System (A-2200, A-2200-N, A-2200-F). This kit is a nucleic acid extraction for professional use only.

2. Overview

Designed for use with the *ExiPrep*™16 Dx (A-5050), the ***ExiPrep*™ Dx Viral DNA/RNA Kit** (K-4471, K-4472, K-4473) are the total solution for the accurate and rapid extraction of viral DNA or RNA with clinical samples. The system is designed for rapid extraction of viral DNA or RNA, delivering up to 16 extracted samples (including controls) within 1.5 hours from raw clinical samples.

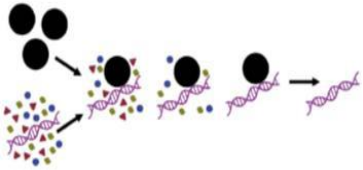
ExiPrep™ Dx Viral DNA/RNA Kit (K-4471, K-4472, K-4473) contains all buffers and consumables necessary for efficient and effective extraction of viral nucleic acids from clinical samples.

The Kit is intended for use by a qualified clinical diagnostic staff, trained to correctly and appropriately handle and manipulate clinical specimens. A user must also be equipped with basic experimental techniques required for correct execution of the experiments described in this *User's Guide*.

3. Features and principle of the test

ExiPrep™ Dx Viral DNA/RNA Kit (K-4471, K-4472, K-4473) is designed for the extraction of viral DNA or RNA from various clinical samples.

Viral DNA or RNA is extracted from clinical samples by using a lysis buffer (Buffer Cartridge ②) to disrupt viral structure. The binding buffer contains guanidine thiocyanate, which act as a chaotropic agent. The binding buffer disassociates water molecules from nucleic acids and silica magnetic beads. This induces negative charge to nucleic acid and positive to silica magnetic beads. As a result, exposed Viral DNA or RNA bind to the surface of beads. The washing buffer (Buffer Cartridge ①) rinses any impurities that may exist. The elution buffer dissolves pure Viral DNA or RNA from the beads.



[Description of Viral DNA/RNA extraction using silica magnetic bead]

4. Clinical significance

A virus is a biologically active particle consisting of a core nucleic acid and outer protein shell. Viruses have the ability to mutate constantly and produce countless subtypes. In general, viruses have a higher environmental survival rate than bacteria and can withstand disinfection better as well.

Main targets of viral infection include children or immune compromised individuals, and infection rates differ greatly depending on the region, hygiene, socio-economical status and etc. Representative viral infections include hepatitis, influenza and acute infectious gastrointestinal inflammation, etc.

There has recently been a surge in virus genome research, providing key information for the development of PCR-based diagnostics. As PCR-based diagnostics is able to detect extremely small amounts of viral nucleic acids in various samples, it is helpful in determining latent infections. Early detection is possible because assay is performed prior to antibody formation.

5. Contents of Kit

This Kit contains all reagents necessary for 96 reactions.

#	Component	Quantities	
1	Buffer Cartridge ①	6 ea	
2	Buffer Cartridge ②	6 ea	
3	Disposable filter tip	96 ea	
4	*User's Guide*	1 ea	
5	0.2ml Elution Tube	12 ea	
6	0.2ml Elution Tube Cap	12 ea	
7	Sample Loading Tube	96 ea	*ExiPrep*™16 Dx mode
	Sample Loading Tube_DNA IPC	96 ea	* *ExiStation*™ mode
	Sample Loading Tube_RNA IPC	96 ea	
8	Waste Tray	3 ea	
9	Protection Cover	12 ea	
10	Contamination Shield Filter Papers	12 ea	

***Note:**
Sample loading Tube- DNA IPC(KA-3010) / Sample loading Tube- RNA IPC (KA-3011) is an additional accessory of *ExiPrep*™ Dx Viral DNA/RNA Kit required for using the *ExiStation*™ mode. For other accessories except Sample loading Tube- DNA IPC or Sample loading Tube- RNA IPC, these are included in the *ExiPrep*™ Dx Viral DNA/RNA kit box and can be used in the operation of *ExiPrep*™ Dx mode.
However, since the accessories (Sample loading Tube- DNA IPC or Sample loading Tube- RNA IPC) are required for the *ExiStation*™ mode only and have different storage condition (refer to '6. Storage'), these are separately provided from *ExiPrep*™ Dx Viral DNA/RNA Kit.

5.1 Device used

ExiPrep™ Dx Viral DNA/RNA Kit is designed for *ExiPrep*™16 Dx and *ExiStation*™ Universal Molecular Diagnostic System. When using *ExiPrep*™ 16 Dx, refer to section 13. Nucleic acid extraction of *User's Guide* for guideline of using the device. When using *ExiStation*™ Universal Molecular Diagnostic System, refer to Bioneer's Real-Time PCR Kit *User's Guide*.

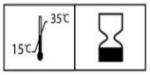
5.2 Sample Loading Tube_DNA IPC and RNA IPC

* Separate components (Sample Loading Tube_DNA IPC and Sample loading Tube_RNA IPC) are designed for *ExiStation*™ Universal Molecular Diagnostic System. When using *ExiStation*™ Universal Molecular Diagnostic System, refer to Bioneer's Real-Time PCR Kit *User's Guide*.

5.2.1 Sample Loading Tube-DNA IPC (Blue dried pellet) function: allowing monitoring of the validity of extracted DNA in Real-Time PCR and confirmation of integrity of PCR result against PCR inhibition as internal control.

5.2.2 Sample Loading Tube-RNA IPC (Yellow dried pellet) function: allowing monitoring of the validity from RNA extraction to Real-Time PCR and confirmation of integrity of PCR result against NA extraction and PCR inhibition as internal control.

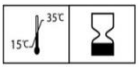
6. Storage



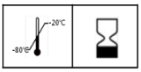
ExiPrep™ Dx Viral DNA/ RNA Kits provide buffer cartridge system.
The buffer cartridges contain binding buffer, washing buffer, elution buffer and magnetic bead solution for the nucleic acid extraction. Every Buffer cartridge is covered with sealing film to protect leakage, evaporation and cross contamination. The buffer cartridges can be stored dry at room temperature (15 – 35℃) for up to 1 year without open.

ExiPrep™ Dx Viral DNA/RNA Kits provide lyophilized enzymes such as proteinase K and carrier RNA for the convenient use.

Lyophilized proteinase K and carrier RNA are pre-loaded into Buffer cartridge ②. It can be stored at room temperature (15 – 35℃) up to 1 year without any reduced activity. Provided disposable tips, reaction tubes and elution tubes in the kit are DNase and RNase free, Please give attention to the nuclease contamination during storage.



Sample Loading Tube-DNA IPC is provided when using *ExiStation*™ mode. It can be stored at temperature between 15°C and 35°C up to 1 year.



Sample Loading Tube-RNA IPC is provided when using *ExiStation*™ mode. It can be stored at temperature between −80°C and −20°C up to 1 year.

7. Required materials

- Disposable powder-free gloves
- Appropriate volume pipettes
- Sterilized, filtered pipette tips

- 1.5 ㎖ microcentrifuge tubes
- Vortex mixer
- Desktop centrifuge
- *ExiPrep*™16 Dx (Cat. No.: A-5050, Bioneer Corp., Republic of Korea)

8. Starting Volume

Sample type	Starting Volume	Elution Volume
Serum	400 ㎕	50 – 100 ㎕
Plasma	400 ㎕	50 – 100 ㎕
CSF	400 ㎕	50 – 100 ㎕
Urine	400 ㎕	50 – 100 ㎕
BAL	400 ㎕	50 – 100 ㎕
Cell free body fluid	400 ㎕	50 – 100 ㎕
Saliva	400 ㎕	50 – 100 ㎕
Swab	1 ea	50 – 100 ㎕

9. Before you begin

We recommend that several precautionary measures are taken to ensure proper results are obtained.

9.1 Appropriate bench use

Pressurized benches are divided into **positive pressure** and **negative pressure** benches. **Positive pressure** benches (e.g. clean benches etc.) are workspaces where filtered air flows outward, thus keeping a clean environment within the workspace. **Negative pressure** benches (e.g. Biosafety Cabinets, fume hoods etc.) send air from the laboratory space outside. In other words, air flows inward. This air flow prevents dangerous substances from contaminating the laboratory environment.

When opening sterilized containers such as Buffer Cartridges included within the kit, the work should be conducted in a positive pressure environment to prevent environmental contaminants from entering and fouling the sterile supplies. Also, before removing supplies from the positive pressure environment, please take appropriate measures to assure that sterility of the materials is preserved when introduced into a static-pressure environment.

On the other hand, when handling clinical samples (especially of high pathogenicity), it is critical for the safety of the operator and other staff members that all related work (i.e. de-capping, pipetting, capping of clinical samples and containers) be conducted within a negative pressure bench and preferably, a filtered bench rated for the classification of pathogens that are being handled, such as a properly-rated biosafety cabinet.

9.2 Sample allocation

Although the product contains all necessary consumables for a successful experiment, the number of consumables supplied within assume that at least two strips worth (16 wells) be run at a time.

We recommend at the very least that samples be run by 8-well strip units to prevent the unfortunate circumstance of consumables running out before reagents. If the situation dictates that one or two samples be run (e.g. emergency samples), please contact your local BIONEER agent to order additional consumables.

9.3 Cleaning and maintenance of accessories

The greatest source of contamination is human-induced. To prevent unintended contamination of reagents, we recommend that the following guidelines be implemented in cleaning and maintaining the various accessories involved with kit use.

⚠ Discard all liquids, plastic consumables, used wipers etc. in appropriate biohazard containers according to local and national regulations.

Hole Puncher (8 Hole Punch)

The hole puncher may be a source of contamination after repeated use. Adhere to the following cleaning guidelines to prevent potential contamination from occurring.

1. Take out Hole Puncher from initialized *ExiPrep*™16 Dx.
2. Clean the punching edges with cleaning liquids capable of degrading nucleic acids (e.g. 5% nitric acid etc.)

   ⚠ The punching edges are extremely sharp and may cause injury when handled without caution.
3. Rinse with distilled water.
4. Air dry completely in a positive pressure bench.
5. Insert Hole Puncher into *ExiPrep*™16 Dx.

Contamination shield

1. Take out Contamination Shield from initialized *ExiPrep*™16 Dx.
2. Rinse with a lint-free cloth or wiper with distilled water.
3. Air dry completely in a positive pressure bench.
4. Insert Contamination Shield into *ExiPrep*™16 Dx.

Elution tube rack

1. Wash with cleaning agents (e.g. ethanol, soap etc.). Use a cotton-tip applicator to clean the inside of the wells if necessary.
2. Rinse with distilled water.
3. Tap the rack upside-down on an absorptive surface to expel residual water from the wells.
4. Air dry completely in a positive pressure bench.

Sample tube rack

1. Dispose the sample tubes in an appropriate waste container.
2. Wash with cleaning agents (e.g. ethanol, soap etc.). Use a cotton-tip applicator to clean the inside of the wells if necessary.
3. Rinse with distilled water.
4. Tap the rack upside-down on an absorptive surface to expel residual water from the wells.
5. Air dry completely in a positive pressure bench.

10. Warning and precautions

■ Buffer Cartridge ①

Risk·Hazard Classification :
Volatile liquid : Class 2
Extreme eye damage/eye irritation : Class 2
Carcinogen : Class 1A
Reproductive Cell Mutation : Class 1B
Reproductive toxicity : Class 1A
Specific target organ toxicity (single exposure) : Class 3 (Respiratory system irritation)
Specific target organ toxicity (single exposure) : Class 3 (Anesthetic)
Specific target organ toxicity (repeat exposure) : Class 1
Risk·Hazard phrase : H225, H319, H335, H336, H340, H350, H360, H372
Prevention : P201,P202, P210, P233, P240, P241, P242, P243, P260, P261, P264, P270, P271, P280, P281
Response : P303+P361+P353, P304+P340, P305+P351+P338, P308+P313, P312, P314, P337+P313, P370+P378
Storage : P403+P233, P403+P233, P403+P235, P405 / Disposal : P501

■ Buffer Cartridge ②

Risk·Hazard Classification :
Volatile liquid : Class 2
Acute toxicity (oral) : Class 4
Skin corrosion/irritation : Class2
Extreme eye damage/eye irritation : Class 2
Carcinogen : Class 1A
Reproductive Cell Mutation : Class 1A
Reproductive toxicity : Class 1A
Specific target organ toxicity (single exposure) : Class 3 (Respiratory system irritation)
Specific target organ toxicity (single exposure) : Class 3 (Anesthetic)
Specific target organ toxicity (repeat exposure) : Class 1
Risk·Hazard phrase : H225, H302, H315, H319, H335, H336, H340, H350, H360, H372
Prevention : P201,P202, P210, P233, P240, P241, P242, P243, P260, P261, P264, P270, P271, P280, P281
Response : P301+P312, P302+P352, P303+P361+P353, P304+P340, P305+P351+P338, P308+P313, P312, P314, P321, P330, P332+313, P337+P313, P370+P378
Storage : P403+P233, P403+P235, P405 / Disposal : P501

11. Specimen handling

 All samples must be treated as potential biohazards.

11.1 Specimen collection

ExiPrep™ Dx Viral DNA/RNA Kit is optimized for viral DNA/RNA extracted from various clinical samples. Viral DNA/RNA should be isolated from clinical sample within one day after collection.

⚠ Only use preservative-free containers.

11.2 Sample storage

The clinical samples can be stored up to a day at 2 – 8 °C. For longer period of storage, the clinical samples should be stored at −80 ~ −20 °C in aliquots.

11.3 Sample transport

All samples should be transported in a shatterproof transport container to prevent potential infection from sample leakage. Samples should be transported according to local or national guidelines regarding biohazard transportation.

11.4 Interfering substances

The clinical samples may contain several PCR inhibitors. During extraction of Viral DNA/RNA, PCR inhibitors should be removed to get reliable detection of DNA and RNA.

11.5 Pretreatment of specimens

i. Body Fluids

- Types of specimen: Bronchoalveolar lavage (BAL), Pleural fluid, Saliva, etc.
- Specimen volume required: > 5 ㎖
- Storage conditions and period: can be stored at 4°C up to 7 days.
  And for longer storage put into a freezer.
- Materials: Table top centrifuge (operates up to 13,000 rpm), vortex mixer 10 N NaOH,
  1X PBS buffer (pH 6.8 – 7.2)

■ Pretreatment procedure

① After vortex vigorously a specimen-containing tube, transfer 5 – 10 ㎖ of the specimen to a conical tube.

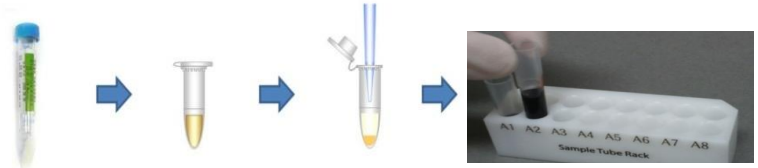
⚠In case of a sticky specimen, solubilize it by adding 200 ㎕ of 10N NaOH and incubating 15 minutes at room temperature. With any floating material, remove it before use.

② Centrifuge at 3,000 rpm for 20 minutes and remove the supernatant completely by using a pipette.

③ Add 1 ㎖ of 1X PBS buffer and vortex 30 seconds. Transfer the mixed solution into 1.5 ㎖ microcentrifuge tube and centrifuge at 9,000 rpm for 5 minutes. Remove the supernatant completely by using a pipette.
⚠In case of forming a white layer on top of the pellet, remove the layer along with the supernatant.

④ Mix well with the addition of 400 ㎕ of Resuspension Buffer, 1x PBS or normal saline by using a pipette.

⑤ Spin down at 6,000 rpm for 5 seconds and use the supernatant for ensuing nucleic acid extraction. For the nucleic acid extraction, you need 400 ㎕ of the supernatant on *ExiPrep*™16 Dx.



(Sample loading tube)

ii. Viral Swabs

- Unit of specimen: each
- Method for specimen collection: Use only sterilized swabs. Insert a sterilized swab into a targeted area about an inch deep and take specimen with a careful rotating motion. Store it in a proper container until use.

■ **Taking a nasal swab:** Insert a swab into the nostril as deep as possible –up to one third of nose to ear length– rolling it gently and take specimen of a visible size.

■ **Taking a throat swab:** Use a sweeping motion to swab the posterior pharyngeal wall and tonsillar pillars and take specimen of a visible size. Be careful not to touch the uvula.

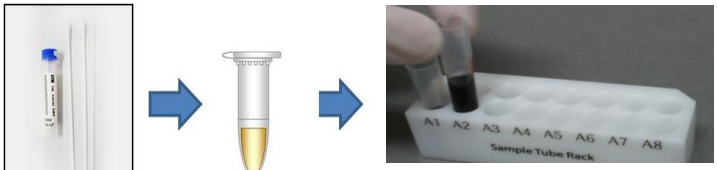
- Storage conditions and period: can be stored at 4°C up to 3 days and for longer. Storage Put into a freezer.
- Materials: Table top centrifuge (operates up to 13,000 rpm), vortex mixer, 1x PBS (pH 6.8~7.2)

■ Pretreatment procedure

① Add 1 ㎖ of transport buffer, 1x PBS or normal saline and vortex vigorously that viruses on the swab are detached well into the solution.

② Transfer 500 ㎕ of the sample to an 1.5 ㎖ microcentrifuge tube and centrifuge at 6,000 rpm for 5 seconds.

③ Take the supernatant for ensuing nucleic acid extraction. For the nucleic acid extraction, you need 400㎕ of the supernatant on *ExiPrep*™ 16 Dx.



(Sample Loading tube)

iii. Sputum

- Specimen volume required: > 1 ㎖
- Storage conditions and period: can be stored at 4 C up to 7 days.
  And for longer storage put into a freezer.
- Materials: Table top centrifuge (operates up to 13,000 rpm), vortex mixer, 10N NaOH,
  1X PBS buffer (pH 6.8~7.2)

■ Pretreatment procedure

① Add 1/10 volume of 10 N NaOH to the sputum in a container and vortex vigorously for 3 minutes.

② Incubate at 25°C for 15 minutes.

⚠With very sticky sputum, increase the volume of NaOH up to 2 times or the incubation time up to 30 minutes.
When increasing the NaOH volume does not work, you may transfer the mixture to a conical tube to add the same amount of PBS or DEPC water and vortex.

③ Vortex vigorously for 1 minute and transfer the mixed solution into 1.5 ㎖ microcentrifuge tube.

④ Centrifuge at 9,000 rpm for 5 minutes. Remove the supernatant completely by using a pipette.

⚠In case of forming a white layer on top of the pellet, remove the layer along with the supernatant to

leave only the pellet.

⑤ Wash cell pellet by adding 1 ㎖ of 1X PBS and vortexing. Centrifuge at 9,000 rpm for 5 minutes and remove the supernatant completely by using a pipette. Repeat this washing 2 – 3 times.
⚠In case of forming a white layer on top of the pellet, remove the layer along with the supernatant to leave only the pellet.

⑥ Mix well with the addition of 400 ㎕ of Resuspension Buffer, 1x PBS or normal saline by using a pipette.

⑦ Spin down at 6,000rpm for 5 seconds and use the supernatant for ensuing nucleic acid extraction. For the nucleic acid extraction, you need 400 ㎕ of the supernatant on *ExiPrep*™16 Dx.

iv. Stool

- Specimen amount: 50 ㎎ ~ 200 ㎎ / 200 ㎕
- specimen collection: Take 1 – 2 g / 2 ㎖ of stool that appears to have pus, blood or mucus. Transfer it to a clean and dry container.
- Storage condition and period: can be stored at 4°C up to 3 days.
- Materials required: Table top centrifuge (operates up to 13,000 rpm),Vortex mixer, Shaking incubator (60℃), stool lysis buffer(not supplied), proteinase K(not supplied)

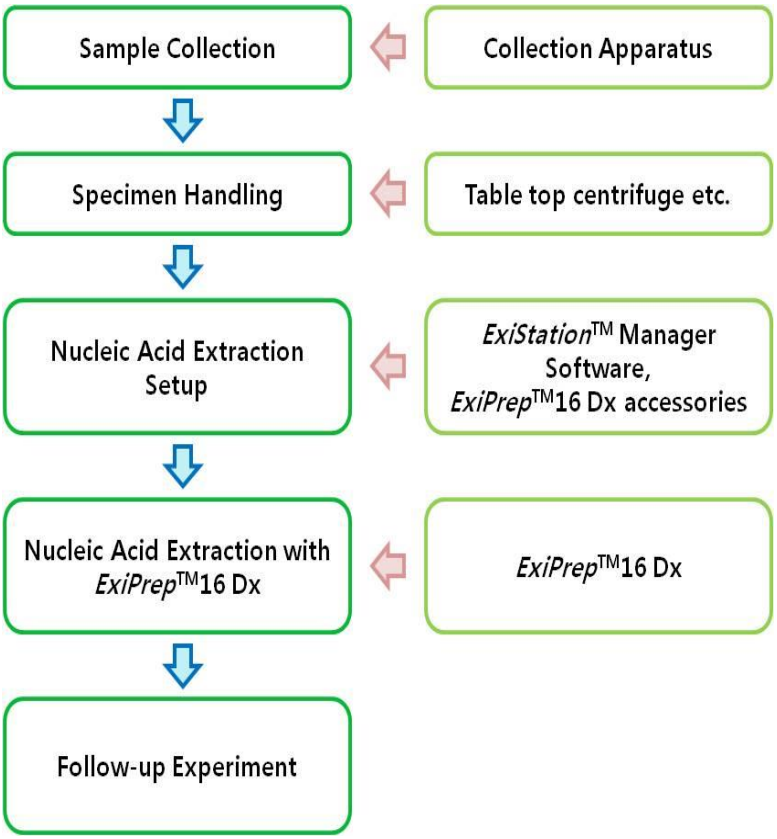
■ Pretreatment procedure

① Transfer 50 – 200 ㎎ of specimen into an 1.5 ㎖ tube. Add 400 ㎕ of stool lysis buffer to the tube.

② Vortex the tube vigorously for 3 minutes.

③ Spin down at 6,000 rpm for 5 seconds and use the supernatant for ensuing nucleic acid extraction. For the nucleic acid extraction, you need 400 ㎕ of the supernatant on *ExiPrep*™16 Dx.

12. Experimental flow chart



13. Nucleic acid extraction

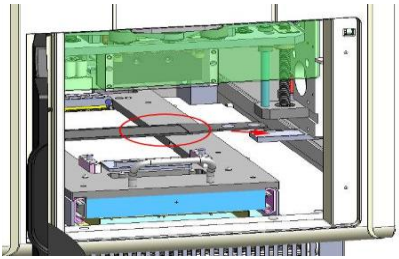
For extraction of nucleic acids, please follow the instructions below on how to use the *ExiPrep*™ Dx Viral DNA/RNA kit and the *ExiPrep*™16 Dx or the *ExiStation*™. The extraction process includes sample preparation, extraction process setup, pipetting samples and executing the extraction by operating the *ExiPrep*™16 Dx or the *ExiStation*™. The extracted Viral DNA/RNA is automatically loaded into the Elution tubes.

13.1 Experimental setup

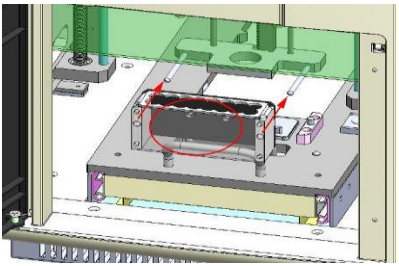
① Turn on the *ExiPrep*™16 Dx by pressing the main power button located at the front of the instrument. Press the 'STARTING' image displayed on the LCD to initiate instrument startup.

② Press the 'MISC SET' button on the LCD screen. Attach the filter paper onto the Contamination Shield. Attach the prepared Contamination Shield then the Tip Protector in the instrument. Press the 'MISC Set' button again.

['MISC SET' on *ExiPrep*™16 Dx LCD panel]



[Placing the Contamination Shield on the projecting part (red arrow)]



[Inserting two holding shafts (red arrows) into the Tip Protector]

Prep tools

- Setup Tray
- Hole Punch
- Sample Tube Rack
- Elution Tube Rack
- Disposable Tip Rack

Consumables

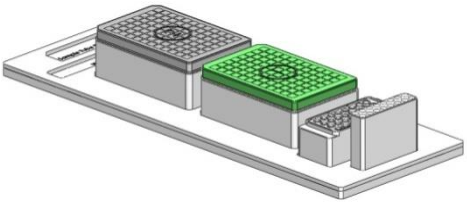
- Buffer Cartridges ① and ②
- Sample Loading Tubes
- Disposable Tips
- Elution Tubes
- Elution Tube Caps
- Protection Cover
- Waste Tray

③ The preparation process is as follows:

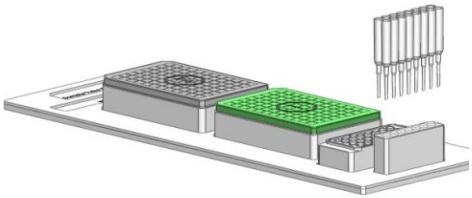
Check materials –> Buffer Cartridge Preparation –> Preparing the Elution Tube Rack –> Tip Loading –> Clinical Sample Loading –> Loading the Instrument

④ Place '**Setup tray**' on a flat surfaced desk.

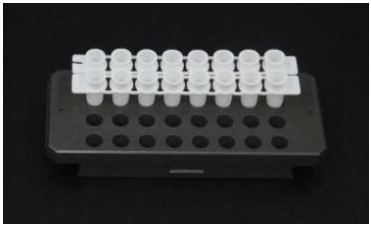
⑤ On the Setup tray, put on the '**Buffer Cartridge ①, ②**', '**Disposable tip rack**', **'Elution tube rack'**.



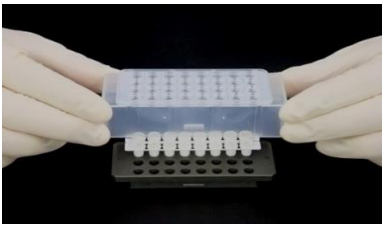
⑥ Fill the appropriate number of **Disposable Tips** in the **Disposable Tip Rack**.



⑦ Insert appropriate numbers of the Elution Tubes or Diagnostic Kit Tubes into the **Elution Tube Rack**. We recommend marking each strip of the elution strips with the corresponding column number.



⑧ Fasten the **Protection Cover** onto the elution tube rack.



13.2 Loading controls and samples

13.2.1 Buffer Cartridge Preparation

① Remove the shrink-wrap enclosing the both **Buffer Cartridges ① and ②**.

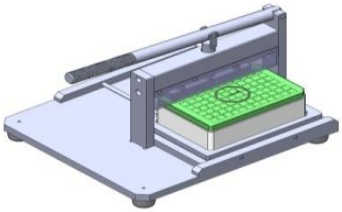
⚠ If using a blade (e.g. knife or scissors), please be careful not to hurt yourself.

② Clean the surface (preferably a positive pressure bench e.g. clean bench) where work will be performed.

⚠ Inspect the wells of the **Buffer Cartridges** and make sure all liquids are at the bottom of the wells. If necessary, grab the **Buffer Cartridges** and snap your wrist to bring down liquids that may be present on the well walls.

③ Remove the lids on **Buffer Cartridges ① and ②**.

④ Punch holes with the **Hole Punch** according to sample number.

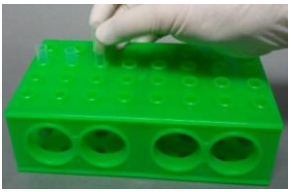


⑤ Cover **Buffer Cartridges ① and ②** with the lids after hole punching is complete.

13.2.2 Sample Loading

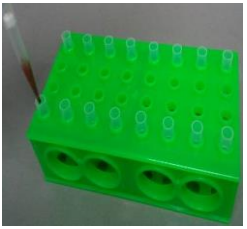
① Clean the negative pressure surface (e.g. biosafety cabinet etc.) on which the nucleic acid extraction preparation will be performed.

② Take out the necessary number of Sample Tubes and insert them into a separate rack with at least 20 mm spacing between the holes.
Molecular diagnostic with ExiStation System uses lyophilized IPC (Internal Positive Control) in Sample Loading tube. IPC used in ExiStation molecular diagnostic system verifies nucleic acid extraction and amplification.
(KA-3010: Sample loading tube-DNA IPC/ KA-3011: Sample loading tube-RNA IPC)

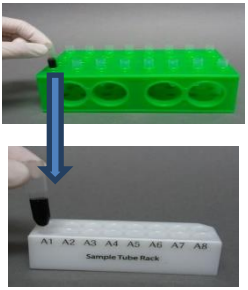


③ Take the original clinical sample containers.

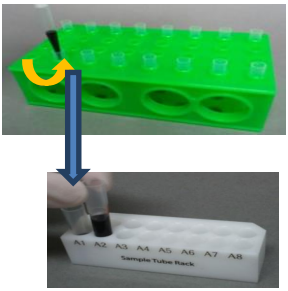
④ De-cap the original clinical sample containers and pipette 400 ㎕ sample into a Sample Loading Tube. ⚠Insert mix well because of specimen's viscosity.



⑤ Move the filled Sample Tube into the **Sample Tube Rack**.
⚠ Insert the Sample Tubes vertically to prevent spilling.



⑥ De-cap another original clinical sample container and pipette 400 ㎕ sample into the next available sample loading tube.



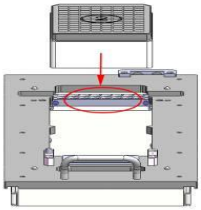
⑦ Repeat steps **4 ~ 6** until all samples are loaded.
⚠If for any reason glove contamination by sample is suspected, immediately exchange gloves to prevent contamination of samples.

⑧ Place the **Sample Tube Rack** and **Waste Tray** onto the **Setup Tray**.

13.2.3 Loading the Instrument

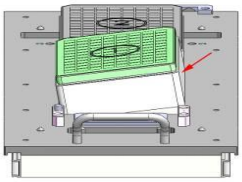
① Open the door of the *ExiPrep*™16 Dx and pull the Base Plate out completely.

② Starting from the Buffer Cartridges, place each component one-by-one into the Base Plate as described below.



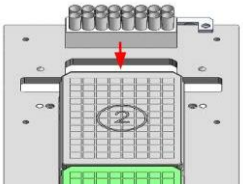
(1) Place the Buffer Cartridge ② on the heating block of the base plate.

⚠:If Buffer Cartridge ② is not properly placed on the heating block, it may cause an experiment failure or an instrument malfunction.



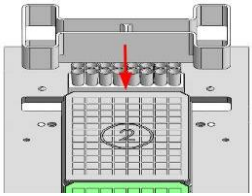
(2) Place the Buffer Cartridge ① on the base plate.

⚠:Place the Buffer Cartridge ① by putting the cartridge to the left side of the base plate and press right-hand side of the Cartridge to press the Cartridge to secure.

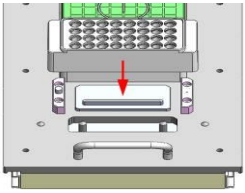


(3) Place the Sample tube rack on the base plate.

⚠:Be careful that the Sample tube rack's front and rear sides are properly placed.

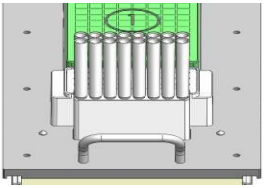


(4) Place the Waste tray in between the Sample tube rack and the Buffer Cartridge ②.



(5) Place the Elution tube rack on the base plate.

⚠Check the Protection Cover is properly secured on the elution tube rack.



(6) Place the Disposable tip rack on the base plate.

⚠ Make sure that the tips, holes and tubes are in alignment.

③ Remove the lids from the Buffer Cartridges.

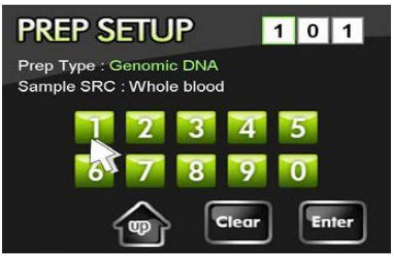
④ Slide the Base plate in the instrument and close the door of the *ExiPrep*™16 Dx.

⚠ Make sure that the lids of the Buffer Cartridges are removed and all components are in the correct positions. If unused wells are present, place the lids face down on top of the instrument until sample prep is complete.

13.3 Running the Equipment

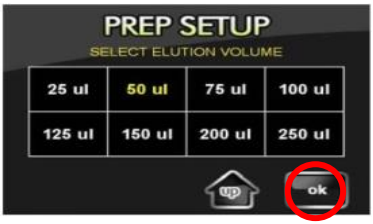
① Press the '**START**' button to access the *PREP SETUP* screen.

② Refer to the **"List of protocol numbers"** in this Kit Manual to select the three-digit protocol number applicable to your desired nucleic acid and sample source type.



③ Verify the '**Prep Type**' and '**Sample SRC**' of the three-digit code you have entered.

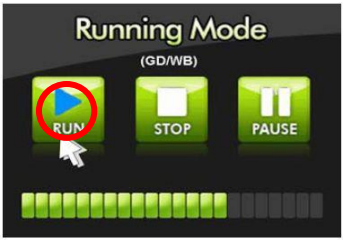
④ Press the '**Enter**' button to access the '**Elution Volume**' selection menu.



⑤ Select the elution volume and press the '**OK**' button to complete *PREP SETUP*.

⑥ Check that all racks and Buffer Cartridges are placed in their respective locations on the Base Plate according to the **CHECK LIST** on the LCD touch screen and Press the '**OK**' button to initiate the extraction process.

⑦ Verify the name of the target nucleic acid type and sample source type on the Running Mode screen, and press the **'RUN'** button.



⑧ After the extraction run is complete, pull out the Base Plate carefully and remove the Buffer Cartridges and all racks from the Base Plate. After removing all accessories, push the Base Plate back in

completely and close the door.

⑨ Press the '**START**' button to initiate UV sterilization. The sterilization process takes 5 minutes. Progress can be checked through the progress bar.

⚠ If you do not close the door to ensure UV Lamp is not lit.

⑩ Remove the contamination protection accessories (Tip protector, Contamination shield).

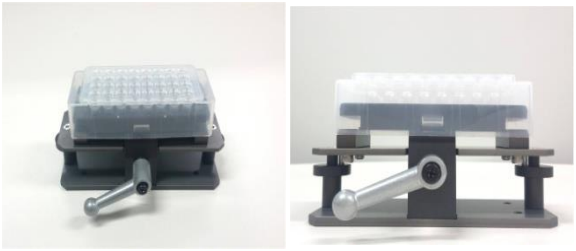
13.4 Preparing for follow-up work

In order to logically process the samples from up to *ExiPrep*™16 Dx without confusing the order or identity of samples, please follow the instructions below (perform in a UV-sterilized static-pressure environment):

① Open the door of the *ExiPrep*™16 Dx after the nucleic acid extraction process is complete, and remove the **Elution Tube Rack**.

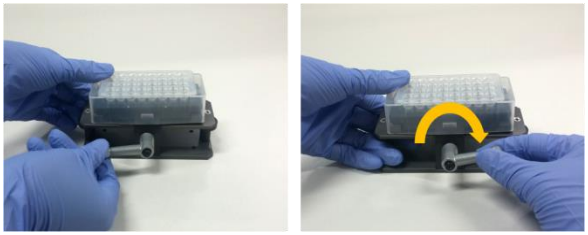
② Please remove Protection Cover according to **Protection Cover Separation Tool** utility method.

1) Take out Elution Tube Rack from *ExiPrep*™16 Dx and place it on top of Protection Cover Separation Tool.
Note: When placing Elution Tube Rack on Protection Cover Separation Tool, the lever must be facing left-hand side.



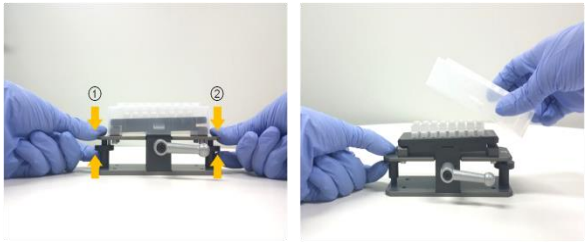
(Picture of Elution Tube Rack on top of Protection Cover Separation Tool)

2) Firmly hold down Protection Cover and Separation Tool with one hand. Rotate the lever in a clockwise 180° with the other hand.
Note: Rotate the lever until Elution Tube Rack is firmly fixed to Protection Cover Separation Tool.



(Picture of lever rotation for fixing Elution Tube Rack to Protection Cover Separation Tool)

3) Press down both sides of Separation Tool as shown in the picture below. This action will push Protection Cover upwards so that Elution Tube Rack can be removed with ease.
Tip: Hold down Protection Cover with one hand. Then press down each side of Separation Tool consecutively to prevent any liquid from splashing.



(Picture of pressing down each side of Separation Tool and removing Protection Cover from Separation Tool)

③ Cap the elution tubes with the supplied Elution Tube caps and perform a brief spin-down. Observe the level of liquid within the elution tubes. The level of liquid, albeit small, should be even.

Make note of samples that have uneven amounts of liquid, as it may be indicative of erroneous sample extraction. Exclude the samples from further analysis and re-perform the extraction process.

④ Remove all consumables and components from the instrument, starting with the Buffer Cartridges and various racks, and discard all liquids and consumables in their appropriate containers.

⚠: If un-used wells are present in the Buffer Cartridges, wipe the film surface of the Buffer Cartridges with a lint-free cloth or wipe wet with 70% ethanol. Replace the lids on the Buffer Cartridges and keep them in a positive pressure bench (*e.g.* clean bench) until later use.

⑤ Press the 'MISC Set' button, remove the Tip Protector and Contamination Shield, and press the 'MISC Set' button again.

⑥ Push the Base Plate back in and shut the instrument door. then the UV sterilization will begin automatically.

14. List of protocol number

1. Viral DNA (K-4472)

No.		Target	Sample source
4	34	viral DNA	New Viral

2. Viral RNA(K-4473)

No.		Target	Sample source
5	34	viral RNA	New Viral

3. Viral DNA/RNA(K-4471)

No.		Target	Sample source
6	34	viral DNA/ RNA	New Viral

15. Troubleshooting

Low yield of viral DNA/ RNA

- Did you add sufficient amount of samples? The yield is dependent on the sample type and amount. Sometimes overload sample may decrease the yield.
- Did you completely lysis the samples? Incomplete lysis decreases the yield and purity.
- Did you shake your Buffer cartridge ② before use? Incomplete suspension of the magnetic bead may decrease the yield and purity.

Co-eluted magnetic particle

- Sometimes magnetic particle co-eluted with your viral DNA/RNA after viral DNA/RNA extraction. Co-eluted magnetic particle cannot bind viral DNA and RNA in elution buffer and it will not decrease the yield and purity.
- Co-eluted magnetic particles can easily separate by simple centrifugation.

16. Remarks

- Please store the nucleic acid extraction kit at room temperature.
- Do not reuse reagents and take care not to mix used and fresh reagents.
- Please use gloves and wear a mask when handling clinical samples, and use sterilized filter tips for all pipetting steps.

17. References

K.-H. Heermann. et al. (1994). Journal of Virological Methods., 50., 43-57.

Samira Fafi-Kremer. et al. (2004), Journal of Clinical Virology.,30, 157-164.

Sue-Hwa Lin. et al. (2008). Protein Expression and Purification., 62 , 223-229.

Penella J. Woll. et al. (2009). Clinica Chimica Acta., 404, 100-104

18. Explanation of symbols

	Catalog Number		Contains sufficient for (n) tests
	USE BY		Temperature Limitation
	Batch code		Caution
	Manufacturer		Biological risks
	DO NOT REUSE		Consult Instructions For Use
	In Vitro Diagnostics Medical Device		Conformite Europeenne Mark
	Authorized representative in the European Community		

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