



# MPure Viral/Pathogen Nucleic Acids Extraction Kit A

## Instructions For Use



REVISION DATE: 2016-06  
MSAJ50031-ENG-1

**REF** 8AJ50-048 (48 Tests)

### TRADE NAME AND INTENDED USE

The **MP Diagnostics MPure Viral/Pathogen Nucleic Acids Extraction Kit A** is used with the **MPure-12 aNAP System** for extraction of viral and bacterial DNA/RNA from cell-free samples, e.g. serum, plasma, and other cell-free body fluids.

### APPLICATION

Nucleic acids extracted from **MPure Viral/Pathogen Nucleic Acids Extraction Kit A** can be used in a number of downstream applications including: Polymerase Chain Reaction (PCR), quantitative PCR (qPCR), Next-Generation Sequencing (NGS), Microarray, Restriction Fragment Length Polymorphism (RFLP) and Southern Blot Analysis.

### DESCRIPTION OF SYMBOLS USED

The following are graphical symbols used in or found on MP Biomedicals products and packaging. They are explained in more detail in the European Standard ISO 15223-1:2012.



Use by



*In vitro* diagnostic medical device



Temperature Limitation



Batch Code  
*Synonym:*  
Lot Number  
Batch Number



Authorized representative in the European Community



Contains sufficient for <n> tests



Consult Instructions for Use



Catalogue Number  
Batch Code  
*Synonym :*  
Reference Number  
Re-order Number



Manufacturer

### KIT COMPONENTS

Components	Quantity
<b>CARTRIDGE</b>   <b>RG</b> Reagent Cartridge	48 pieces (24x2)
<b>CHAMBER</b>   <b>RX</b> Reaction Chamber	48 pieces (24x2)
<b>TIP</b>   <b>HOL</b> Tip Holder	48 pieces (24x2)
<b>TIP</b>   <b>FIL</b> Filter Tip	50 pieces
<b>PIN</b>   <b>P</b> Piercing Pin	50 pieces
<b>TUBE</b>   <b>SP</b> Sample Tube (2 ml)	50 pieces
<b>TUBE</b>   <b>EL</b> Elution Tube (1.5 ml)	50 pieces
<b>RNA</b>   <b>CA</b> RNA Carrier (1 mg)	1 vial
<b>Barcode Paper</b>	1 copy
<b>Selection Guide</b>	1 copy
<b>Instructions For Use</b>	1 copy

### REAGENT CARTRIDGE CONTENT



- Well-1: Proteinase K solution = 40 µl
- Well-2: Lysis Buffer 4 = 720 µl
- Well-3: Binding Buffer 1 = 1000 µl
- Well-4: Magnetic Bead Solution = 800 µl
- Well-5: Washing Buffer 1 = 1000 µl
- Well-6: Washing Buffer 2 = 1000 µl
- Well-7: Washing Buffer 3 = 1000 µl
- Well-8: RNase-free water = 1000 µl
- Well-9: RNase-free water = 1000 µl
- Well-10: BL2B Buffer = 400µl

### WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For Professional use only.

#### Handling Requirements

1. Do not use kits beyond the expiry date.
2. Do not handle the reagents with bare hands. Avoid contact from your skin, eyes, or mucous membranes. If contact occurs, wash the affected area

immediately with large amounts of water. If spillage of the reagents occurs, dilute the spill with water before wiping it up.

- Avoid mixing the reagents with sodium hypochlorite solution or strong acids. Otherwise, a highly toxic gas will be produced.

#### Laboratory Procedures

- Treat all samples and waste as if potentially infectious, practice safe laboratory procedures. As sensitivity and titer of the pathogens in the sample varies, the operator needs to optimize the pathogen inactivation by boiling, using Lysis Buffer or taking the appropriate measures according to local safety regulations. MP Biomedicals does not warrant that samples treated with Lysis Buffer or boiling are completely inactivated or non-infectious. After sample processing, remove and autoclave all the disposable plastics.
- Do not eat, drink or smoke in the laboratory working area.
- Wear disposable gloves, laboratory coats and goggles when handling samples and kit reagents.
- Do not use sharp or pointed objects when handling the reagent cartridges. This will prevent damage of the sealing foil and loss of reagent.
- Do not contaminate the reagents with bacteria, virus, or ribonuclease. Use disposable pipettes and RNase-free pipette tips only to remove aliquots from reagent bottles.
- Wash hands thoroughly after handling samples and test reagents.

#### Waste Handling

- Discard unused reagents and waste according to country, federal, state and local regulations.

#### STORAGE

Store at room temperature (15-25°C). Do not freeze the reagent cartridges. The kits are stable for 18 months under the condition.

After dissolving the RNA carrier, store it at 4°C (short-term, up to 1 month) or -20°C (long-term). Do not freeze-thaw the frozen RNA carrier more than 3 times.

Store the purified nucleic acid at 4°C (up to 24 hours) or at -20°C for longer storage. Repeated freeze-thawing is not allowed.

#### STARTING MATERIAL

Sample Type	Target Nucleic Acid	Sample Volume (Amount of starting material)	Elution Volume
Serum	Total bacterial/ Viral Nucleic Acids (DNA + RNA)	100-400 µl (virus) 100-200 µl (virus/bacteria)	50-300 µl
Plasma			
CSF			
Pretreated Urine			
Cell-free body fluids			
Controls/	Add controls /internal control in the		

Internal Control*	extraction procedure if the downstream analysis needed
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- This kit is designed for extraction of viral and bacterial nucleic acids from plasma or serum, or from a pool of such cell-free body fluids.
- After extraction, store the nucleic acid at 4°C (up to 24 hours) or -20°C for longer storage. Repeated freeze-thawing is not allowed.

#### SPECIMEN PREPARATION

- The purification procedure is optimized for use with 100-400 µl serum, plasma\*, CSF, pretreated urine or other cell-free body fluid samples. (\*Blood samples treated with EDTA or citrate as an anticoagulant can be used for plasma preparation).
- Samples can be either fresh or frozen, provided that they have not been refrozen after thawing.
- RNA Carrier serves two purposes during the purification procedure.
  - It enhances binding of viral nucleic acids to the silica surface of the magnetic particles, especially when the sample contains very few target molecules.
  - Addition of large amounts of RNA Carrier reduces the chances of RNA degradation in the rare event that RNases are not denatured by the chaotropic salts and detergent in the lysis buffer. If RNA carrier is not added to the reaction, recovery of DNA or RNA may be reduced.
- After collection and centrifugation, plasma, serum, or CSF can be stored at 2-8°C for up to 6 hours. For longer storage, we recommend freezing aliquots at -20°C or -80°C. Thaw samples at room temperature (15-25°C), and process the samples immediately when they have equilibrated to room temperature. Do not refreeze the aliquots after thawing. Repeated freeze-thawing leads to denaturation and precipitation of proteins, resulting in reduced viral titers and therefore reduced yields of nucleic acids. If cryo-precipitates are visible in the samples, centrifuge at 6800 x g for 3 minutes, transfer the supernatants to fresh tubes without disturbing the pellets, and start the purification procedure immediately.

#### RNA CARRIER

Add 1.0 ml RNase-free water to lyophilize the RNA Carrier (provided in the kit) and vortex to mix.

Store the RNA Carrier at 4°C (short-term, up to 1 month) or -20°C (long-term). Do not freeze-thaw the frozen RNA Carrier more than 3 times. It is recommended to divide it into conveniently sized aliquots.

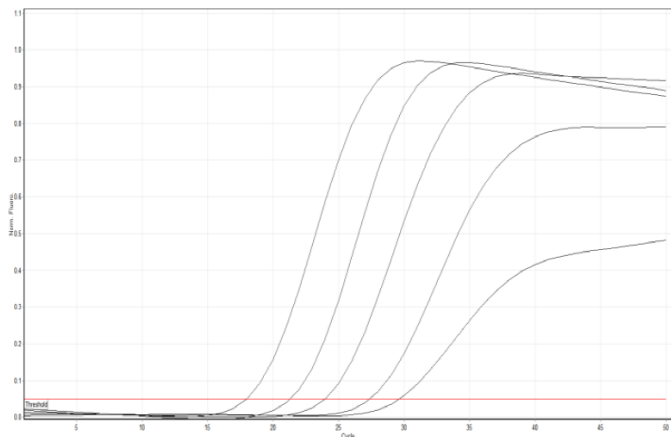
**Before nucleic acid extraction, it is recommended to add the RNA Carrier to the sample.** Add 5 µl Carrier RNA (for 100 µl sample), 10 µl (for 200 µl sample) or 20 µl (for 400 µl sample) into the Sample Tube.

## RESULTS

Nucleic acid yields depend on the sample type, number of nucleated cells in the sample, and the protocol used for purification of Nucleic acid.

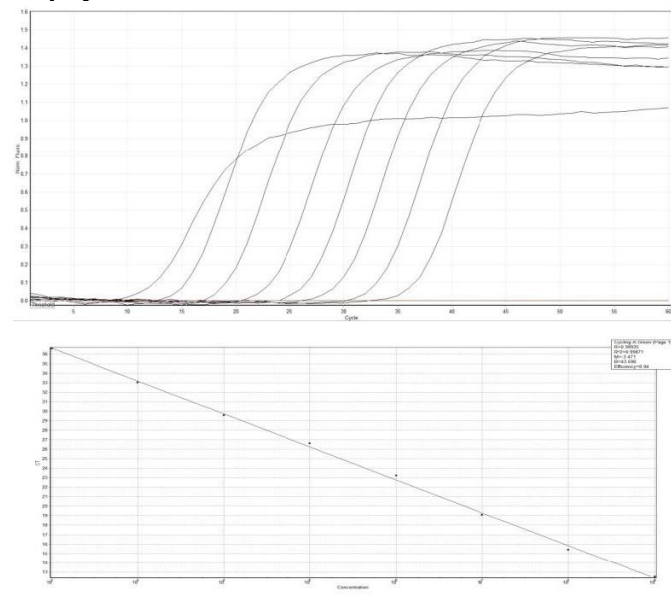
### Sensitivity

#### Hepatitis B virus (HBV)



Using serum spiked with serial-diluted Hepatitis B Virus (in range of 300000-30 IU/ml). 200 µl serum sample were extracted and eluted in 100ul. 30 µl eluate was used for real-time PCR reaction.

#### Staphylococcus aureus



Performing serial-dilution on Staphylococcus aureus (ATCC27154) in range of 109-101 copy/ml). As little of 20 copies (about 102 copy/ml bacteria in the sample) spiked-in (about 5 copy in PCR reaction) bacteria can be detected.

## CONTROLS / INTERNAL CONTROL

Using appropriate controls for downstream analysis:

Type	Description	Location
<b>Positive control</b>	Using sample which is positive for target	Placed in sample tube
<b>Negative control</b>	Using sample which is negative for target or water (NTC)	Placed in sample tube
<b>Internal control (IC)</b>	Using a defined quantity control	Placed in sample tube or the round well of the reaction chamber

## LIMITATION OF THE METHOD

The MPure Extraction Kits and the **MPure-12 aNAP System** are not intended for use as part of a specific *in vitro* diagnostic test. The user is responsible for establishing performance characteristics necessary for downstream diagnostic applications. Appropriate controls must be included in any downstream diagnostic applications using nucleic acid purified using the **MPure-12 aNAP System** and the MPure Extraction Kits.

## LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer makes no expressed warranty other than that the test kit will function as an *in vitro* diagnostic assay within the specifications and limitations described in the Product Instructions For Use when used in accordance with the instructions contained therein. The manufacturer disclaims any warranty, expressed or implied, including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer is limited to either replacement of the product or refund of the purchase price of the product. The manufacturer shall not be liable to the purchaser or third parties for any damage, injury or economic loss howsoever caused by the product in the use or in the application thereof.

## TECHNICAL PROBLEMS / COMPLAINTS

Should there be any technical problem / complaint, please do the following:

1. Note the kit lot number and the expiry date.
2. Retain the kits and the results that were obtained.
3. Contact the nearest MP Biomedicals office or your local distributor.



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