MB582M HiPurA® Viral Nucleic Acid Purification Kit (Magnetic Bead Based)

Kit Contents

Product Code	Reagents provided	MB582M
		100 preps
DS0010	Lysis Solution (C1)	52 ml
DS1267	Prewash solution diluted (PWD)	65 ml
DS1019	Wash solution diluted (WSD)	65 ml
DS0040	Elution Buffer (ET) [10 mM Tris-Cl, pH 8.5]	5.25 ml
DS0013	Proteinase K	2 ml
DS1005A	Magnetic Beads	2 ml
DS0192	Carrier RNA	0.5 mg
DS0042	Elution Solution (RNase- Free Water)	0.55 ml

Intended Use

Recommended for isolation of HIV, HBV, HCV and other viral nucleic acid.

Introduction

HiPurA® Viral Nucleic Acid Purification Kit (Magnetic Bead Based) provides the fastest and easiest way to purify viral Nucleic acid for reliable use in amplification technologies. HiPurA® Viral Nucleic acid Purification Kit (Magnetic Bead Based) can be used for isolation of viral nucleic acid from a wide variety of viruses, but the performance may vary depending on the virus type.

HiPurA® Viral Nucleic Acid Purification Kit (Magnetic Bead Based)

This kit carries out efficient extraction of viral Nucleic acid from wide range of viral strains. Sample is first lysed under the highly denaturing conditions provided by Lysis Solution (C1) to inactivate RNases and to ensure isolation of intact viral Nucleic acid. When Carrier RNA is added to Elution Solution (RNase-free Water), it improves the binding of viral Nucleic acid to the magnetic beads especially in the case of low-titer samples, and limits possible degradation of the viral nucleic acid due to any residual RNase activity. This kit can be used for automated and manual extractions, but for the best results we recommend using on automated instruments.

Elution

The yield of Viral Nucleic acid depends on the sample type and the Viral load in the sample. A single elution with 50µl Elution Solution will provide sufficient Viral Nucleic acid to carry out multiple amplification reactions.

NOTE: For more concentrated Nucleic acid lower elution volume (30-40 µl) can be used. Larger elution volumes can also be used but may result in dilution of viral Nucleic acid sample.

ISO 9001-2015 CERTIFIED
WHO GMP CERTIFIED
ISO 13485-2016 CERTIFIED
CE

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Addition of internal control:

The internal control allows the user to check both the Nucleic acid purification procedure and possible PCR inhibition.

Purification control:

For this application, internal control should be added in a ratio of 0.1µl per 1µl of elution volume. For example, the nucleic acid is eluted in 50µl Elution Solution (RNase free water). Hence, 5µl of the internal control should be added.

For Insta NX® Mag32 and Insta NX® Mag16 (Plate)

1. If internal control is added in lysis solution i.e. in column 1 & 7 of filled plate for Viral Nucleic acid. Add 5µl of IC in column 1 & 7 of filled plate for Viral nucleic acid.

For Insta NX® Mag96

1. If internal control is added in lysis solution i.e. in Plate 2 of filled plate for Viral Nucleic acid. Add 5µl of IC in plate 2 of filled plate for Viral nucleic acid.

For Insta NX® Mag16 (Cartridge)

1. If internal control is added in lysis solution i.e. in Well 1 of filled cartridge for Viral Nucleic acid. Add 5µl of IC in well 1 of filled cartridge for Viral nucleic acid.

Refer manufacturer's instructions to determine the optimal concentration of Internal control to be used in purification process. Using a concentration other than that of recommended may reduce amplification efficiency.

Storage

HiPurA® Viral Nucleic Acid Purification Kit (Magnetic Bead Based) can be stored at room temperature (15-25°C) for up to 1 year without showing any reduction in performance. Store the DS0192- Carrier RNA in -20°C temperature on receipt. We recommend storing the reconstituted Carrier RNA at -20°C in aliquots to avoid repeated freeze and thaw.

Materials needed but not provided

- RNase- free pipette tips (aerosol barrier recommended)- For Insta NX® Mag32, Insta NX® Mag96, Insta NX® Mag16 Extraction
- Collection Tube, Polypropylene (2.0 ml) (PW1139)- For Insta NX® Mag32, Insta NX® Mag96, Insta NX® Mag16 Extraction
- Insta NX® Mag32 (LA1096)
- Insta NX® Mag96 (LA1097)
- Insta NX® Mag16 (LA1118)
- 96 Deep Well Plate for Insta NX® Mag96 - For Insta NX® Mag96 Extraction (LA1097B)
- Cartridges- For Insta NX® Mag16 Extraction
- Cartridge Holder (LA1118CH)- For Insta NX® Mag16 Extraction
- 96 Deep Well Plate for Insta NX® Mag32- For Insta NX® Mag32 Extraction (LA1096B)
- 96 Elution Plate for Insta NX® Mag96- For Insta NX® Mag96 Extraction (LA1097C)
- Magnetic rod's tip for Insta NX® Mag32- For Insta NX® Mag32, Insta NX® Mag16 Extraction (LA1096A)
- Magnetic tip comb for Insta NX® Mag96- For Insta NX® Mag96 Extraction (LA1097A)
- Vortex
- Polypropylene sealing film (PR21) Vortex

Precautions to be taken while handling RNA

Ribonucleases (RNases) are very stable and active enzymes that generally do not require cofactors to function. Since RNases are difficult to inactivate and even minute amounts are sufficient to destroy RNA, do not use any plasticware or glassware without first eliminating possible RNase contamination. Great care should be taken to avoid inadvertently introducing RNases into the RNA sample during or after the isolation procedure. In order to create and maintain an RNase-free environment, the following precautions must be taken during pretreatment and use of disposable and non- disposable vessels and solutions while working with RNA.

1. Always wear latex or vinyl gloves while handling reagents and RNA samples to prevent RNase contamination from surface of the skin or from dusty laboratory equipment. Change gloves frequently and keep tubes closed whenever possible.
2. Use sterile, disposable plasticware and autoclavable pipettes reserved for RNA work to prevent cross-contamination with RNases from shared equipment.
3. Non-disposable plasticware should be treated before use to ensure that it is RNase-free. Plasticware should be thoroughly rinsed with 0.1M NaOH, 1mM EDTA followed by RNase-free water. Alternatively, chloroform-resistant plasticware can be rinsed with chloroform to inactivate RNases.
4. Glassware used for RNA work should be cleaned with a detergent, thoroughly rinsed, and oven baked at 240°C for four or more hours before use. Alternatively, glassware can be treated with DEPC (Diethyl pyro carbonate). Fill glassware with 0.1% DEPC (0.1% in water), allow to stand overnight at 37°C, and then autoclave or heat to 100°C for 15 min to eliminate residual DEPC.
5. Solutions (water and other solutions) should be treated with 0.1% DEPC

General Preparation Instructions

1. **Thoroughly mix reagents**

   Examine the reagents for precipitation. If any kit reagent forms a precipitate (other than enzymes), warm at 55-65°C until the precipitate dissolves and allow cooling to room temperature (15-25°C) before use.

2. Ensure that clean & dry Nuclease-free tubes and tips are used for the procedure.
3. Vortex magnetic beads before the use.
4. **Reconstitute Carrier RNA**

Number of Preps	Carrier RNA	Elution Buffer (RNase free water)
100	0.5 mg	0.5 ml

Dissolve Carrier RNA thoroughly by pipetting. We recommend storing the reconstituted Carrier RNA at -20°C in aliquots to avoid repeated freeze and thaw.

Specimen Handling and Collection

Collect EDTA blood, plasma, serum or other body fluids in a sterile container. Thaw the samples on ice before use. Repeated freeze- thaw of samples should be avoided.

NOTE: Plasma to be collected in EDTA tubes only.

Types of Specimen

Clinical samples: Blood, Plasma, serum, nasopharyngeal swab, oropharyngeal swab in Viral Transport Medium.

Instructions before use

- Vortex Magnetic Beads (DS1005A) before use to ensure they are homogenous. Avoid creating bubbles during pipetting.

Procedure for Insta NX® Mag32

Accessories for Insta NX® Mag32

LA1096A

Magnetic Rods Tip for Insta NX® Mag32

LA1096B

96 Deep Well Plate for Insta NX® Mag32

Instructions before use

- Vortex Mag Beads (DS1005A) before use to ensure they are homogenous.
- The total volume of each well should not exceed more than 1000µl or it may overflow.
- Place a new clean Magnetic rod's tip for Insta NX® Mag32 (LA1096A) in the instrument.

  NOTE: Always replace the Magnetic rod's tip for Insta NX® Mag32 with a new one or it will cause cross contamination of the sample.
- Place the 96 Deep Well Plate for Insta NX® Mag32 (LA1096B) containing the sample and reagents into the instrument corresponding to the magnetic rod.

Set up processing plates as follows:

1. Switch on the UV light for 10 minutes prior to use.
2. Open the door of Insta NX® Mag32 machine.
3. Add reagents to the 96 Deep Well Plate for Insta NX® Mag32 (LA1096B) according to the below table.

Column no.	Sample/ Reagents	Volume (µl)	NOTE
Column 1	Sample	140µL of sample	
	Lysis Solution (C1) (DS0010)	500	
	Carrier RNA	5	Reconstitute Carrier RNA (Refer General Preparation Instructions)
	Proteinase K (DS0013)	20	
	Internal Control	5	**OPTIONAL**
	Magnetic Beads (DS1005A)	20	
Column 2	Blank	Blank	-
Column 3	Wash solution diluted (DS1019)	600	
Column 4	Prewash solution diluted (DS1267)	600	
Column 5	Blank	Blank	
Column 6	Elution Buffer (ET) [10 mM Tris-Cl, pH 8.5] (DS0040)	50	
Column 7	Sample	140µL of sample	
	Lysis Solution (C1) (DS0010)	500	
	Carrier RNA	5	Reconstitute Carrier RNA (Refer General Preparation Instructions)
	Proteinase K (DS0013)	20	
	Internal Control	5	**OPTIONAL**
	Magnetic Beads (DS1005A)	20	
Column 8	Blank	Blank	
Column 9	Wash solution diluted (DS1019)	600	
Column 10	Prewash solution diluted (DS1267)	600	
Column 11	Blank	Blank	
Column 12	Elution Buffer (ET) [10 mM Tris-Cl, pH 8.5] (DS0040)	50	

4. Fix a new clean Magnetic rod's tip for Insta NX® Mag32 (LA1096A) in the instrument.

   NOTE: Always replace the Magnetic rod's tip for Insta NX® Mag32 (LA1096A) with a new one, or it will cause cross- contamination of the sample.

5. Place the filled 96 Deep Well Plate for Insta NX® Mag32 (LA1096B) onto the machine.

6. Execute the procedure for MB582M32.

7. After the run is complete, slide the platform of the machine. Remove the 96 Deep Well Plate for Insta NX® Mag32 (LA1096B) from the position. Slide the platform back to its position and discard the Magnetic rod's tip for Insta NX® Mag32 (LA1096A). Dispense the eluted Nucleic acid to a new Collection Tube, Polypropylene (2.0 ml) (PW1139) (not provided). The eluate contains pure Nucleic acid.

NOTE: A small amount of magnetic beads may be observed in the final eluate at the bottom of the tube. Avoid transferring these magnetic beads into a new Collection Tube, Polypropylene (2.0 ml) (PW1139) (not provided).

Storage of the eluate with purified DNA: The eluate contains pure Viral DNA. For short-term storage (24-48 hrs) of the DNA, 2-8°C is recommended. For long-term storage, -20°C or lower temperature (-80°C) is recommended. Avoid repeated freezing and thawing of the sample which may cause denaturing of DNA. The Elution Buffer will help to stabilize the DNA at these temperatures.

Storage of the eluate with purified RNA: The recommended storage temperature for the eluted RNA is -80°C. Avoid repeated freezing and thawing of the sample which may cause denaturing of RNA.

Procedure for Insta NX® Mag96

Accessories for Insta NX® Mag96

LA1097A	LA1097B	LA1097C
Magnetic Tip Comb for Insta NX® Mag96	96-DeepWell Plate for Insta NX® Mag96	96 Elution Plate for Insta NX® Mag96

Instructions before use

- Vortex Mag Beads (DS1005A) before use to ensure they are homogenous.
- The total volume of each well should not exceed more than 1000µl or it may overflow.
- Place a new clean Magnetic tip comb for Insta NX® Mag96 (LA1097A) in the instrument.

  NOTE: Always replace the Magnetic tip comb for Insta NX® Mag96 (LA1097A) with a new one or it will cause cross contamination of the sample.
- Place the 96 Deep Well Plate for Insta NX® Mag96 (LA1097B) and 96 Elution Plate for Insta NX® Mag96 (LA1097C) containing the sample and reagents into the instrument according to the plate position mentioned in the table below.

Set up processing plates as follows:

1. Switch on the UV light for 10 minutes prior to use.
2. Open the door of Insta NX® Mag96 machine.
3. Take five blocks of 96 Deep Well Plate for Insta NX® Mag96 (LA1097B) and one 96 Elution Plate for Insta NX® Mag96 (LA1097C). Add samples and reagents to the 96 well plates according to the below table.

Plate position	Sample/ Reagents	Volume (µl)	NOTE
2	Sample	140µL of sample	
	Lysis Solution (C1) (DS0010)	500	
	Carrier RNA	5	Reconstitute Carrier RNA (Refer General Preparation Instructions)
	Proteinase K (DS0013)	20	
	Internal Control	5	**OPTIONAL**
	Magnetic Beads (DS1005A)	20	
5	Wash solution diluted (DS1019)	600	
7	Prewash solution diluted (DS1267)	600	
	Magnetic rod's tip	-	
8 96 Elution Plate for Insta NX® Mag96 (LA1097C)	Elution Buffer (ET) [10 mM Tris-Cl, pH 8.5] (DS0040)	50	

4. Place a new clean Magnetic tip comb for Insta NX® Mag96 (LA1097A) in the 96 Deep Well Plate for Insta NX® Mag96 (LA1097B) (Plate position 7).

   NOTE: Always replace the Magnetic tip comb for Insta NX® Mag96 (LA1097A) with a new one, or it will cause cross- contamination of the sample.

5. Place the filled 96 Deep Well Plate for Insta NX® Mag96 (LA1097B) and 96 Elution Plate for Insta NX® Mag96 (LA1097C) onto the machine.
6. Execute the procedure for MB582M96.
7. After the run is complete, discard the Magnetic tip comb for Insta NX® Mag96 (LA1097A). Remove the 96 Deep Well Plate for Insta NX® Mag96 (LA1097B) and 96 Elution Plate for Insta NX® Mag96 from the position. The 96 Elution Plate for Insta NX® Mag96 contains pure eluted Nucleic acid. Seal the plate with sealing film (not provided).

   NOTE: A small number of magnetic beads may be observed in the final eluate at the bottom of the tube. Avoid transferring these magnetic beads into a new Collection Tube, Polypropylene (2.0 ml) (PW1139) (not provided).

Storage of the eluate with purified DNA: The eluate contains pure Viral DNA. For short-term storage (24-48 hrs) of the DNA, 2-8°C is recommended. For long-term storage, -20°C or lower temperature (-80°C) is recommended. Avoid repeated freezing and thawing of the sample which may cause denaturing of DNA. The Elution Buffer will help to stabilize the DNA at these temperatures.

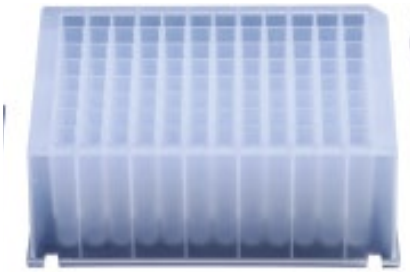
Storage of the eluate with purified RNA: The recommended storage temperature for the eluted RNA is -80°C. Avoid repeated freezing and thawing of the sample which may cause denaturing of RNA.

Procedure for Insta NX® Mag16

Accessories for Insta NX® Mag16

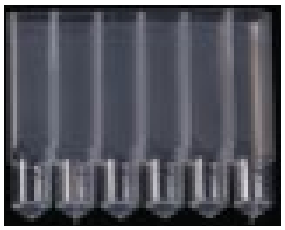
LA1096A

Magnetic Rods Tip for Insta NX® Mag32



LA1097B

96 Deep Well Plate for Insta NX® Mag96



Cartridge

Instructions before use

- Vortex Mag Beads (DS1005A) before use to ensure they are homogenous.
- The total volume of each well should not exceed more than 1000µl or it may overflow.
- Place a new clean Magnetic rod's tip for Insta NX® Mag32 (LA1096A) in the instrument.

  NOTE: Always replace the Magnetic rod's tip for Insta NX® Mag32 with a new one or it will cause cross contamination of the sample.
- Place the 96 Deep Well Plate for Insta NX® Mag96 (LA1097B)/ Cartridge containing the sample and reagents into the instrument corresponding to the magnetic rod.

Set up processing plates as follows:

1. Switch on the UV light for 10 minutes prior to use.
2. Add reagents to the 96 Deep Well Plate for Insta NX® Mag96 (LA1097B) according to the below table.

Column no.	Sample/ Reagents	Volume (µl)	NOTE
Column 1	Sample	140µL of sample	
	Lysis Solution (C1) (DS0010)	500	
	Carrier RNA	5	Reconstitute Carrier RNA (Refer General Preparation Instructions)
	Proteinase K (DS0013)	20	
	Internal Control	5	**OPTIONAL**
	Magnetic Beads (DS1005A)	20	
Column 2	Blank	Blank	-
Column 3	Wash solution diluted (DS1019)	600	
Column 4	Prewash solution diluted (DS1267)	600	
Column 5	Blank	Blank	
Column 6	Elution Buffer (ET) [10 mM Tris-Cl, pH 8.5] (DS0040)	50	
Column 7	Sample	140µL of sample	
	Lysis Solution (C1) (DS0010)	500	
	Carrier RNA	5	Reconstitute Carrier RNA (Refer General Preparation Instructions)
	Proteinase K (DS0013)	20	
	Internal Control	5	**OPTIONAL**
	Magnetic Beads (DS1005A)	20	
Column 8	Blank	Blank	
Column 9	Wash solution diluted (DS1019)	600	
Column 10	Prewash solution diluted (DS1267)	600	
Column 11	Blank	Blank	
Column 12	Elution Buffer (ET) [10 mM Tris-Cl, pH 8.5] (DS0040)	50	

3. Fix a new clean Magnetic rod's tip for Insta NX® Mag32 (LA1096A) in the instrument.

   NOTE: Always replace the Magnetic rod's tip for Insta NX® Mag32 (LA1096A) with a new one, or it will cause cross- contamination of the sample.

4. Place the filled 96 Deep Well Plate for Insta NX® Mag96 (LA1097B) onto the machine.

5. Execute the procedure for MB582M16.

6. After the run is complete, slide the platform of the machine. Remove the 96 Deep Well Plate for Insta NX® Mag96 (LA1097B) from the position. Slide the platform back to its position and discard the Magnetic rod's tip for Insta NX® Mag32 (LA1096A). Dispense the eluted Nucleic acid to a new Collection Tube, Polypropylene (2.0 ml) (PW1139) (not provided). The eluate contains pure Nucleic acid.

NOTE: A small amount of magnetic beads may be observed in the final eluate at the bottom of the tube. Avoid transferring these magnetic beads into a new Collection Tube, Polypropylene (2.0 ml) (PW1139) (not provided).

Set up processing cartridges as follows:

1. Switch on the UV light 10 mins prior to use.
2. Open the door of Insta NX® Mag16 machine.
3. Place the Cartridges into the Cartridge Holder (LA1118CH).
4. Add reagents to the cartridges according to the below table.

Well no.	Sample/ Reagents	Volume (µl)	NOTE
Well 1	Sample	140µL of sample	
	Lysis Solution (C1) (DS0010)	500	
	Carrier RNA	5	Reconstitute Carrier RNA (Refer General Preparation Instructions)
	Proteinase K (DS0013)	20	
	Internal Control	5	**OPTIONAL**
	Magnetic Beads (DS1005A)	20	
Well 2	Blank	Blank	
Well 3	Wash solution diluted (DS1019)	600	
Well 4	Prewash solution diluted (DS1267)	600	
Well 5	Blank	Blank	
Well 6	Elution Buffer (ET) [10 mM Tris-Cl, pH 8.5] (DS0040)	50	

5. Fix a new clean Magnetic rod's tip for Insta NX® Mag32 (LA1096A) in the instrument.

   NOTE: Always replace the Magnetic rod's tip for Insta NX® Mag32 (LA1096A) with a new one, or it will cause cross- contamination of the sample.

6. Place the filled Cartridge along with cartridge holder into the machine.
7. Execute the procedure for MB582M16.

8. After the run is complete, slide the platform of the machine. Remove the Cartridge holder from its position. Slide the platform back to its position and discard the Magnetic rod's tip for Insta NX® Mag32 (LA1096A). Dispense the eluted Nucleic acid to a new Collection Tube, Polypropylene (2.0 ml) (PW1139) (not provided). The eluate contains pure Nucleic acid.

NOTE: A small amount of magnetic beads may be observed in the final eluate at the bottom of the tube. Avoid transferring these magnetic beads into a new Collection Tube, Polypropylene (2.0 ml) (PW1139) (not provided).

Storage of the eluate with purified DNA: The eluate contains pure Viral DNA. For short-term storage (24-48 hrs) of the DNA, 2-8°C is recommended. For long-term storage, -20°C or lower temperature (-80°C) is recommended. Avoid repeated freezing and thawing of the sample which may cause denaturing of DNA. The Elution Buffer will help to stabilize the DNA at these temperatures.

Storage of the eluate with purified RNA: The recommended storage temperature for the eluted RNA is -80°C. Avoid repeated freezing and thawing of the sample which may cause denaturing of RNA.

Warning

Certified for *in vitro* Diagnostic Use (IVD). Not for Medicinal Use. Read the procedure carefully before beginning the protocol. Wear protective gloves/protective clothing/eye protection/face protection. Follow good clinical laboratory practices while handling clinical samples. Standard precautions should be followed as per established guidelines. Safety guidelines may be referred in safety data sheets of the product.

Limitations

The yield of Nucleic acid depends upon the type and the volume of starting material used.

Performance and Evaluation

The yield and efficiency of purification is determined by performing Real- Time PCR. Yield of viral Nucleic acid isolated from biological samples is usually very less (approx. <1 µg). As a result it is difficult to measure the yield spectrophotometrically. Another point to keep in mind that the carrier RNA will account for most of the Nucleic acid present. The yield and efficiency of purification is determined by performing Quantitative RT-PCR. All the QC passed batches have at least 90% recovery of the viral Nucleic acid.

Quality Control

Each lot of HiMedia's HiPurA® Viral Nucleic acid Purification Kit (Magnetic Bead Based) is tested against predetermined specifications to ensure consistent product quality.

Safety Information

The HiPurA® Viral Nucleic acid Purification Kit (Magnetic Bead Based) is for laboratory use only, not for drug, household or other uses. Take appropriate laboratory safety measures and wear gloves when handling. Not compatible with disinfecting agents containing bleach. Please refer the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

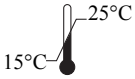
Please refer disclaimer Overleaf.

Disposal

User must ensure safe disposal by autoclaving and/ or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed off in accordance with current laboratory techniques.

Technical Assistance

At HiMedia, we pride ourselves on the quality and availability of our technical support. For any kind of technical assistance mail to mb@himedialabs.com.

IVD	In vitro diagnostic medical device
CE	CE Marking
	Storage temperature
	Do not use if package is damaged
	HiMedia Laboratories Private Limited, Reg. Off: Plot No. C-40, Road No. 21Y, MIDC, Wagle Industrial Area, Thane, (West) 400604, Maharashtra, INDIA. Web: www.himedialabs.com
EC REP	CE Partner 4U ,Esdoornlaan 13, 3951 DB Maarn The Netherlands, www.cepartner 4u.eu
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Disclaimer :

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