Huwel Automated and MagRack Nucleic Acid Extraction (Version 2.0)

HL-ANX-96 : 96 Ext **PI/HLANX-01**

Introduction

Huwel Automated and MagRack Nucleic Acid Extraction systems are fast, economical and easy isolation or purification methods for extraction of high purity viral RNA/DNA from Nasopharyngeal or Throat swabs in VTM/MTM, Plasma and Body Fluids. The buffer system provided in the extraction system allows efficient lysis followed by selective binding of Nucleic acid to the Magnetic bead to recover good yield.

Intended Use

Huwel Automated and MagRack Nucleic Acid Extraction or Purification system is intended for the extraction, enrichment, purification or other processing of nucleic acid, which could be used for clinical *In vitro* testing.

Principle

The clinical samples containing cells or virus particles will be lysed to release nucleic acids. Subsequently, the nucleic acid of high purity is obtained in the process of washing and elution.

No. of pre filled plates provided for 96 Extractions:

Component	Quantity for 96 Extractions	Storage
Sample Extraction Plate	6 no	RT

***Poly-A is provided in a separate reagent vial (Storage temperature -20°C)**

List of Plates provided:

1. 96 deep well plate with pre filled Lysis buffer
2. 96 deep well plate with pre filled Magnetic beads
3. 96 deep well plate with pre filled Wash buffer-1
4. 96 deep well plate with pre filled Wash buffer-2
5. 96 deep well plate with pre filled Elution buffer
6. 96 deep well Empty plate with 96 well comb

Sample Type

- Swab, tissue homogenate, freshly collected whole blood, serum, plasma, and alveolar lavage fluid, etc.
- Sampling: The sample is collected as per regular sampling procedure.
- Sample storage and transportation: The sample shall be handled as soon as it is collected. The sample shall be transported in the sealed kettle or foam canister with ice.

Extraction Protocol

Take out the pre packaged deep well plate, gently shake it to make liquid gather at the bottom of plate. The plate seal shall be removed carefully prior to use to prevent liquid spill.

Nucleic Acid Automatic Extraction System Preprocess:

1. Add 200 µL of sample and 5 µL of Poly A to the Pre filled Lysis buffer 96 deep well plate as per the number of samples being processed
   (**Note**: Reconstitute Poly A with 500 µL of Huwel elution buffer and store at -20°C)
2. Place the 96 deep well plate in the instrument.

3. Implement the extraction procedure as per Instrument user manual (Nexor 96 fully automated nucleic acid extractor)
4. Finally, transfer the Eluent from Elution plate in to fresh 1.5 mL centrifuge tubes and store at -20°C until further use.

Program Run

S. No	Slot	Step Name	Wait (Sec)	Mix (Sec)	Attract (Sec)	Mixing Speed	Volume(µL)	Temp°C
1	1	Lysis	0	180	0	H	600	80
2	2	Transfer Beads	0	30	20	H	200	Off
3	1	Binding	0	180	60	H	600	Off
4	3	Wash-1	0	60	30	H	700	Off
5	4	Wash-2	0	60	30	H	700	Off
6	5	Elution	90 Sec	120	40	H	100	80

Validated Instrument:

- Nexor 96 fully automated nucleic acid extractor

Materials required but not supplied

1. Biosafety Cabinet
2. Calibrated variable micropipettes
3. Sterile pipette filter tips (aerosol free)
4. Vortex mixer
5. Sterile Nitrile gloves
6. Facemask
7. Head cap
8. Lab coat
9. Nucleic acid automatic extraction system

Usage Limitations

1. The product is to be used by personnel specially trained in the *In vitro* diagnostics procedures only.
2. Follow the product insert strictly for optimal results.
3. Do not use the kit beyond the expiry date mentioned on the box.
4. Follow the guidelines provided in product insert for sample collection, storage and transport.
5. For ideal performance, store the kit under recommended conditions only.

Safety Precautions

1. All patient specimens should be considered as potentially infectious and handled in a BSL2 biosafety hood with BSL3 practices.
2. Wear personal protective equipment, including gloves, head cap, face mask, shoe cover and lab coats when handling kit reagents/sample extraction. Wash hands thoroughly using detergents before and after performing the test.
3. Do not smoke, drink or eat in areas where kit reagents and/or human specimens are being used.
4. Dispose of unused kit reagents and human specimens as per regulatory guidelines.

Storage Conditions and Product Stability

1. This kit shall be used within its shelf life. Avoid freezing
2. Kit reagents are stable through the end of the expiration date indicated on the box when stored at specified temperature/s.
3. Only use the protocol provided in this kit insert. Alterations to the protocol and deviations from the times and temperatures specified may lead to erroneous results.

Symbols

Symbol	Meaning
	Catalog number
	In Vitro Diagnostic Medical Device
	Manufacture
	Date of manufacture
	Contents sufficient for <n>tests
	Temperature limitations
	Use by date
	Batch number
	Consult Instructions for Use
	Important Note
	Biological risk (handle carefully)

Ordering Information

 **HL-ANX-96 : 96 Ext**

 **PI/HLANX-01**

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