



INSTRUCTION FOR USE

Marina Ex NAT Tube

For Research Use Only



100



MBLNAT001



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1. INTENDED USE

For Research Use Only (RUO). Not for use in diagnostic procedures. No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of disease. Furthermore, this sample collection tube is not intended for the diagnosis of infectious diseases in animals.

The **Marina Ex NAT Tube** contains 1 mL of viral nucleic acid extraction and preservation liquid. This tube is used to transfer sample, including nasopharyngeal swabs, oropharyngeal swabs, anterior nasal swabs, and mid-turbinate nasal swabs, suspected of containing respiratory tract pathogens. The liquid inside the tube can be used directly in Real-Time Reverse Transcription Polymerase Chain Reaction (RT-qPCR) reactions.

2. PRINCIPLE of the PROCEDURE

The **Marina Ex NAT Tube** contains a lysis buffer designed to extract and preserve nucleic acids from respiratory tract samples. This lysis buffer allows for the direct initiation of RT-qPCR after just 5 minutes of sample collection, streamlining the testing process and improving workflow efficiency.

The formulation of the **Marina Ex NAT Tube** works together to lyse the pathogens, releasing the genome. Once the genome is released, the reagent preserves the integrity of the nucleic acids.

By maintaining the stability of the genetic material, the **Marina Ex NAT Tube** ensures reliable results while also inactivating pathogens, providing an additional layer of safety when handling samples suspected of containing respiratory pathogens.

3. TUBE COMPONENTS

Table 1. Tube components.

Component	Description	Quantity x Volume
		100 rxn MBLNAT001
Marina Ex NAT Tube	Nucleic acid extractive and preservative liquid	100 tubes each containing 1 mL of reagent

4. EQUIPMENT and MATERIALS REQUIRED but NOT PROVIDED

- 2-8°C Refrigerator
- $\leq -20^{\circ}\text{C}$ Freezer
- $\leq -70^{\circ}\text{C}$ Freezer (Optional)
- Vortex mixer
- Biological Safety Cabinet (BSC)
- PCR cabinet for PCR Setup
- Adjustable Micropipettes: 1-10, 10-100, 100-1000 μL
- Sterile DNase/RNase free micropipettes tips - Compatible with the micropipettes
- Disposable, powder-free, nitrile gloves
- Disposable (preferably) laboratory coat
- Surface decontaminants - Freshly diluted 10% bleach solution (0.5% NaClO)

5. WARNING and PRECAUTIONS

- The **Marina Ex NAT Tube** is intended for research use only and should be used by professionally trained, qualified personnel. All procedures should be performed in accordance with Good Laboratory Practices (GLP).
- Biological material used for nucleic acid extraction should be handled as potentially infectious. Appropriate safety precautions are recommended when handling biological material (e.g., do not pipet by mouth; wear disposable gloves; disinfect hands after completing the test).
- Biological material should be inactivated before disposal (e.g., autoclaving). Disposable items should be autoclaved or incinerated after use.
- In the event of a spill involving potentially infectious materials, the spill should be immediately absorbed with paper tissue, and the affected area should be disinfected using a suitable standard disinfectant or 70% alcohol. Materials used for cleaning spills, including gloves, should be inactivated before disposal (e.g., autoclaving).
- Disposal of all samples, unused reagents and waste should be in accordance with country, federal, state, and local regulations.
- To avoid microbial contamination of reagents during aliquoting, it is recommended to use sterile, single-use pipettes and tips. Reagents that appear cloudy or show signs of microbial contamination should not be used.
- The tubes should be stored away from nucleic acid sources and PCR amplicons to prevent contamination.
- Always check the expiration date on the tubes. Do not use expired or improperly stored tubes.

6. HANDLING, STORAGE, and STABILITY

- When stored under the specified conditions, the tubes remain stable until the expiration date printed on the package. The expiration date is 24 months from the date of manufacture.
- Do not use expired or improperly stored components.

7. TEST PROCEDURE

7.1. Sample Preparation

Nasopharyngeal swabs, oropharyngeal swabs, combined nasopharyngeal/oropharyngeal swabs, anterior nasal swabs, and mid-turbinate nasal swabs should be collected by a healthcare provider following the appropriate guidelines.

The swab samples must be placed immediately into the **Marina Ex NAT Tube**, and it will be ready for PCR reactions thereafter.

7.2. PCR Reaction Preparation and Processing

Perform the reaction with the appropriate PCR protocol according to the recommendations of the PCR kit manufacturer.

8. ASSAY LIMITATIONS

- The **Marina Ex NAT Tube** is intended for use only by professionally trained and qualified staff.
- Nasopharyngeal swabs, oropharyngeal swabs, combined nasopharyngeal/oropharyngeal swabs, anterior nasal swabs, and mid-turbinate nasal swabs should be collected by a healthcare provider following the appropriate guidelines. A false negative result may occur if the specimen is improperly collected, transported, or handled.
- False negatives can also occur if amplification inhibitors are present in the specimen or if insufficient numbers of organisms are present.
- There is a risk of false positive results due to cross-contamination by target viruses and/or bacteria, their nucleic acids or amplified products, or from non-specific signals in the assay. Proper handling of consumables, as outlined in the Warnings and Precautions section, is crucial to minimize this risk.
- The use of cotton or calcium alginate swabs, or swabs with wooden shafts, may result in false negative outcomes due to the presence of substances that can inactivate certain pathogens and inhibit PCR. Flocked (polyester) or dacron swabs are recommended for the collection of swab samples.
- Mutations within the target regions of the assays used with the **Marina Ex NAT Tube** may affect primer and/or probe binding, potentially leading to failure in detecting the virus.

9. PERFORMANCE CHARACTERISTICS

9.1. Performance of the Marina Ex NAT Tube on the Inactivation

Inactivation performance of the **Marina Ex NAT Tube** was tested on 9 different pathogens, as listed in the table below.

The concentration of organisms tested (in triplicate) was at least 1.0E+06 CFU/mL for bacteria, fungi, and parasites, and at least 1.0E+05 units/mL for viruses. The organisms listed below were pipetted into the **Marina Ex NAT Tube**, and after a 5-minute period, samples taken from these tubes were cultured. In this study, no growth was observed in any of the cultured samples.

Table 2. Pathogens used for the inactivation study.

Analyte	Isolate ID/Source
SARS-CoV-2	ATCC VR-1986HK
Influenza A	ATCC VT-1469
Human Bocavirus	ATCC VR-3251SD
<i>Haemophilus influenzae</i>	ATCC 33391
<i>Staphylococcus aureus</i>	ATCC 12600
<i>Klebsiella pneumoniae</i>	ATCC 13883
<i>Candida albicans</i>	ATCC 10231
<i>Candida glabrata</i>	ATCC 90030
<i>Candida parapsilosis</i>	ATCC 22019

10. EXPLANATION of SYMBOLS

Symbol	Title of Symbol	Symbol	Title of Symbol
	Research Use Only		Use-by date
	Manufacturer		Batch code
	Negative control		Non-sterile
	Positive control		Consult instructions for use or consult electronic instructions for use
	Control		Caution
	Temperature limit		Catalogue number
	Keep away from sunlight		Do not use if package is damaged and consult instructions for use
	Keep dry		Keep upright
	Contains sufficient for <n> tests		Protect from heat and radioactive sources

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