

## 1. Reagents and Materials Provided

Table 1 Kit Content

Component	Amount	
	100 Pcs	200 Pcs
BioeXsen vNAT® Transfer Tube (screw caps)	100 tubes	200 tubes
vNAT® Specimen Collection Swab (Polyester flocked, breakable shaft, sterile)	100 swabs	200 swabs

Table 2 Storage Requirements and Shelf Life

Component	Transport Conditions	Storage Conditions	Shelf Life
BioeXsen vNAT® Transfer Tube	+15 - +50 °C	+15 - +50 °C	12 months

## 2. Materials Required but Not Provided

Table 3 Components required but not included with the test

Components required but not included with the test	
<ol style="list-style-type: none"> <li>1. Sample container and VTM</li> <li>2. Adjustable micropipettes and compatible tips</li> <li>3. Centrifuge</li> <li>4. Vortex machine</li> </ol>	<ol style="list-style-type: none"> <li>5. 1.5 or 2 mL microcentrifuge tubes, nuclease-free</li> </ol> <p><b>Extra components recommended to use:</b></p> <ol style="list-style-type: none"> <li>6. PPE (Personal Protective Equipment)</li> </ol>

## 3. Intended Use and Test Principle

**BioeXsen vNAT® Transfer Set** is designed for the rapid preparation of viral nucleic acids (e.g., SARS-CoV-2, Influenza, HMPV, RSV etc.) from respiratory swab samples such as nasopharyngeal (NP) swab, oropharyngeal (OP) swab, combined NP-OP swab, anterior nasal swab and mid-turbinate nasal swab samples. **BioeXsen vNAT® Transfer Set** contains viral nucleic acid extractive and preservative liquid. When clinical swab specimens suspected of respiratory tract viruses are transferred in this tube, the liquid inside the tube can be used directly in reverse-transcription and real-time PCR (RT-qPCR) reactions. The nucleic acid extractive and protective liquid inactivates viral pathogens in the sample, 5 minutes after contact with the clinical specimen.

The **BioeXsen vNAT® Transfer Set** contains vNAT® reagent that extracts and preserves viral nucleic acids in respiratory tract samples. It enables the initiation of the real-time RT-PCR within 5 minutes of introduction of the sample. Polyethyleneimine coated tetradecyl dimethyl benzyl ammonium chloride-based nanoparticles (NP) and Tween 20 in **BioeXsen vNAT® Transfer Set** lyse envelope and nucleocapsid of viruses and release the genome. NP, guanidinium thiocyanate and NaN<sub>3</sub> in **BioeXsen vNAT® Transfer Set** preserve the integrity of the released genomes. **BioeXsen vNAT® Transfer Set** also include BSA which is known as a PCR facilitator.

## 4. Collection, Storage and Shipment of Clinical Specimens

Swab samples should be collected by a healthcare provider in accordance with the updated version of CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. The swab samples should be placed immediately into the BioeXsen vNAT® Transfer Tube of the **BioeXsen vNAT® Transfer Set** after specimen collection. Specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation. Specimens can be stored at +2 - +8 °C for up to 3 days (72 h) after collection. If a delay in extraction is expected, store specimens at

-70 °C or lower in accordance with the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. Clinical specimens in **BioeXsen vNAT® Transfer Set** can be stored at +2 - +8 °C for 3 months. For long term storage extracted nucleic acid should be stored at -70 °C or lower. It is important to avoid repeated freezing and thawing of specimens.

## 5. Warnings

1. Do not mix the kit components with different lot numbers or chemicals of the same name but from different manufacturers.
2. Use separate micropipettes for pipetting qPCR mixes and template nucleic acids.
3. Regularly clean the wipeable surfaces of the rooms, benches, and devices where the test is performed with 10% NaOCl.
4. The BioeXsen vNAT® Transfer Tube of the **BioeXsen vNAT® Transfer Set** contains guanidinium thiocyanate. To avoid the danger of cyanide gas production, bleach or acidic solutions should not be added to sample collection tubes or containers.
5. Immediately clean up any spill containing potentially infectious material with 0.5-1% (w/v) sodium hypochlorite (10-20% (v/v); bleach). Dispose of cleaning materials in a biohazard waste stockpot. If the spill contains vNAT®, do not use bleach or acidic solutions. Due to the danger of cyanide gas formation, clean with a suitable laboratory detergent and water.

## 6. Application Protocol

5 minutes after the sampling, the samples in the BioeXsen **vNAT**<sup>®</sup> Transfer Tube of the **BioeXsen vNAT**<sup>®</sup> Transfer Set can directly be used in RT-qPCR. BioeXsen **vNAT**<sup>®</sup> Transfer Tube should be vortexed at the highest speed for 5 seconds before pipetting the sample. The sample volume added to each PCR reaction should not exceed 25% of the total RT-qPCR volume.

## 7. Manufacturer and Technical Support















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Symbol	Meaning	Symbol	Meaning
	European Conformity		Temperature limit (Store temperature)
	For <i>In vitro</i> Diagnostic Use		Keep away from light
	Catalog Number		Keep away from water/moisture
	Lot Number (Batch Code)		Non-Sterile
	Manufacturer		Keep it upright
	Use-by Date (Expiration Date)		Consult Instructions for Use