



## 1. Reagents and Materials Provided

Table 1 Kit Content

| Component             | Amount               |                        |
|-----------------------|----------------------|------------------------|
|                       | 50 mL<br>(500 preps) | 100 mL<br>(1000 preps) |
| BioeXsen vNAT® Buffer | 1 x 50 mL            | 1 x 100 mL             |

Table 2 Storage Requirements and Shelf Life

| Component             | Transport Conditions | Storage Conditions | Shelf Life |
|-----------------------|----------------------|--------------------|------------|
| BioeXsen vNAT® Buffer | +2 - +60 °C          | +2 - +60 °C        | 12 months  |

Each reagent stored at storage temperature, can be used until the expiration date indicated on the tube/bottle. The expiration date of the kit is determined by the expiration date of the reagents.

## 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><li>6. Swabs for nasopharyngeal, oropharyngeal, and nasal swab samples</li></ol> <p><b>Extra components recommended to use:</b></p> <ol style="list-style-type: none"><li>7. PPE (Personal Protective Equipment)</li></ol> |

## 3. Intended Use and Test Principle

**BioeXsen vNAT® Buffer** is designed for the rapid preparation of viral nucleic acids (e.g., SARS-CoV-2, Influenza, HMPV, RSV etc.) from respiratory samples such as nasopharyngeal aspirate and lavage, bronchoalveolar lavage, saliva, nasopharyngeal swab, oropharyngeal swab, liquefied sputum and nasal washes. The prepared nucleic acids are suitable for applications like RT-PCR or any kind of enzymatic reaction. The detection limit for certain viruses depends on the individual procedures. We highly recommend using internal (low copy) standards as well as positive and negative controls to monitor the extraction, amplification, and detection processes.

The **BioeXsen vNAT® Buffer** is a buffer 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® Buffer** lyse envelope and nucleocapsid of viruses and release the genome. NP, guanidinium thiocyanate and NaN<sub>3</sub> in **BioeXsen vNAT® Buffer** preserve the integrity of the released genomes. **BioeXsen vNAT® Buffer** 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 a sterile transport tube containing 2-3 mL of viral transport medium (VTM) (Preparation of viral transport medium, Centers for Disease Control and Prevention, SOP#: DSR-052-01). Other sample types should be transferred into sterile containers containing VTM. 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® Buffer** 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® Buffer** 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 **BioeXsen vNAT® Buffer**, 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

**Samples in liquid form:** Swab samples in VTM / Nasopharyngeal aspirate or lavage / Bronchoalveolar lavage / Saliva

- Liquid respiratory sample is vortexed at the highest speed for 15 seconds.
- Transfer 100 µL of **BioXsen vNAT® Buffer** into a clean microcentrifuge tube.
- Add 100 µL liquid respiratory sample to the tube containing 100 µL **BioXsen vNAT® Buffer**.
- Vortex the tube at the highest speed for 15 seconds.
- Incubate the tube for 5 minutes at room temperature.
- The 200 µL mixture is ready to use in RT-qPCR.
- Store the mixture at +2 - +8 °C for maximum 3 months. For longer storage period, store at -70 °C or lower by avoiding repeated freezing and thawing of the mixture.

**Samples to be liquefied:** Sputum / Dry swab samples (dry swab samples should be analyzed within a maximum of 1 hour after the sampling; otherwise, these samples should not be accepted by the laboratory)

- Transfer the sample to 500 µL nuclease-free water or VTM.
  - Mix equal amounts of sputum and nuclease-free water (or VTM) and homogenize.
  - Transfer the dry swab sample to 500 µL nuclease-free water or VTM.
- Vortex the sample tube at the highest speed for 15 seconds.
- Transfer 100 µL of **BioXsen vNAT® Buffer** into a clean microcentrifuge tube.
- Add 100 µL liquefied sample to the tube containing 100 µL **BioXsen vNAT® Buffer**.
- Vortex the tube at the highest speed for 15 seconds.
- Incubate the tube for 5 minutes at room temperature.
- The 200 µL mixture is ready to use in RT-qPCR.
- Store the mixture at +2 - +8 °C for maximum 3 months. For longer storage period, store at -70 °C or lower by avoiding repeated freezing and thawing of the mixture.

## 7. Manufacturer and Technical Support



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| Symbol | Meaning                            | Symbol | Meaning                                  |
|--------|------------------------------------|--------|------------------------------------------|
|        | European Conformity                |        | Temperature limit<br>(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             |