# Instructions for Use

| | | |
|---|---|---|
| **Product:** | **ViRNAEx™** CE IVD | |
| **Cat. No:** | ViRNAEx 10 mL: MC-025-2020<br>ViRNAEx 50 mL: MC-026-2020 | MetaCell |
| **Manufacturer:** | **MetaCell s.r.o.,** Videňská 1083, 142 00 Prague Czech Republic<br>+420 732 792 355, info@virnaex.com | |
| **Package:** | ViRNAEx 10 mL<br>ViRNAEx 50 mL | |

## Storage

**ViRNAEx™** solution should be stored at room temperature (15 – 25 °C), after opening at the temperature 4- 8°C. When stored under these conditions, the solution will retain full activity until the expiration date indicated on the kit label.

## Intended use

**ViRNAEx™ -Viral Extraction** solution is designed for rapid (15min) isolation of viral RNAand DNA (nucleic acids - NA) from nasopharyngeal swabs, buccal swabs, sputum and saliva using specially developed technology to remove inhibitors. The isolation is designed for use on low nucleic acid samples. Isolated NA are suitable for amplification techniques such as RT-PCR of viral NA in clinical samples.



## Method Principle

The principle of isolation is based on the lysis of viral particles with the aid of detergents. Isolated NA is ready for direct use in RT-PCR, RT-qPCR and other applications.

## Introduction

The SARS-CoV-2 viral RNA extraction solution **ViRNAEx™** allows rapid extraction of viral RNA intended for the qualitative detection of nucleic acid from SARS-CoV-2 virus in nasopharyngeal swab and / or nasopharyngeal lavage / aspirate samples. Samples are taken from individuals suspected of being infected with COVID -19 by their healthcare provider in a viral transmission medium (VTM). SARS-CoV-2 RNA is generally detectable in nasopharyngeal swab specimens and / or nasal lavage / aspirate specimens during the acute phase of infection.

Testing of samples using **ViRNAEx™** for the SARS-CoV-2 test run is intended for qualified personnel in certified laboratories. Positive results indicate active SARS-CoV-2 infection; clinical correlation with the patient's medical history and other diagnostic information is necessary to determine the patient's infection status.

Positive results for the presence of SARS-CoV-2 RNA do not rule out bacterial infections or co-infections with other viruses. The detected agent may not be the definitive cause of the disease. Laboratories are obliged to report all positive results to the relevant public health authorities.

Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or other treatment decisions for the patient. Negative results must be combined with clinical observation, patient history, and epidemiological information.

Testing with **ViRNAEx™** is intended for use by trained personnel who are experienced in performing assays using qPCR or other gene expression detection systems.

**India Contact:**
**Life Technologies (India) Pvt. Ltd.**
306, Aggarwal City Mall, Opposite M2K Pitampura, Delhi – 110034 (INDIA). Ph: +91-11-42208000, 42208111, 42208222, Mobile: +91-9810521400, Fax: +91-11-42208444
Email: customerservice@lifetechindia.com Website: www.lifetechindia.com

## Required material not included:

- 100 x 1.5 ml tubes with lid for lysis and sample handling.
- 100 x microtubes with lid for extracted NA storage

## Required equipment

Thermoblock
Vortex
Tubes holder
Pipettes: 100 – 1000 µl

## Package contents

ViRNAEx 10 mL (100 isolations) or
ViRNAEx 50 mL (500 isolations)

## Precautions

Please wear gloves when using this product. It is recommended to work in a laminar hood (BIO hazard Class II). Avoid all skin contact with kit reagents. In case of contact, wash thoroughly with water. Do not ingest. See Safety Data Sheets for emergency procedures in case of accidental ingestion or contact, safety data sheets are available on www.virnaex.com.

## Primary sample collection, handling and storage

Collect the indicated samples according to a standard protocol in sampling tubes. Recommended swabs: Darcon swap - immerse swabs in transport medium for MicroTest ™ M4RT or MicroTest ™ M6 viruses (Termo Scientific), FLOQSwabs (Copan) – tampons immerse in UTM - (Universal Transport Medium, Copan). Other sampling kits based on polymeric materials with a transport medium for viruses.



**Do not use cotton swabs due to possible inhibition of the PCR reaction. The transport medium dilutes viruses and at low virus concentrations this dilution may cause false negative results.**
Samples should be transported to the laboratory at 4 °C. They are stable for at least 72 hours after sampling at 4 °C. If you are not able to transport swabs to the laboratory at 4 °C, it is possible to transport samples at room temperature within six hours.
For sample storage longer than 72 hours, freeze the sample at -20 ° C.

### Sputum and saliva:

Collect the indicated samples according to a standard protocol in sampling tubes. In the laboratory, dilute 1:1 sputum or saliva with PBS or physiological saline solution. In case of high viscosity, you can add another portion of PBS or physiological saline solution. Then vortex the sample thoroughly. Sputum and saliva samples should be transported to the laboratory at 4 °C. For sample storage longer than 48 hours, freeze the sample at -20 °C.

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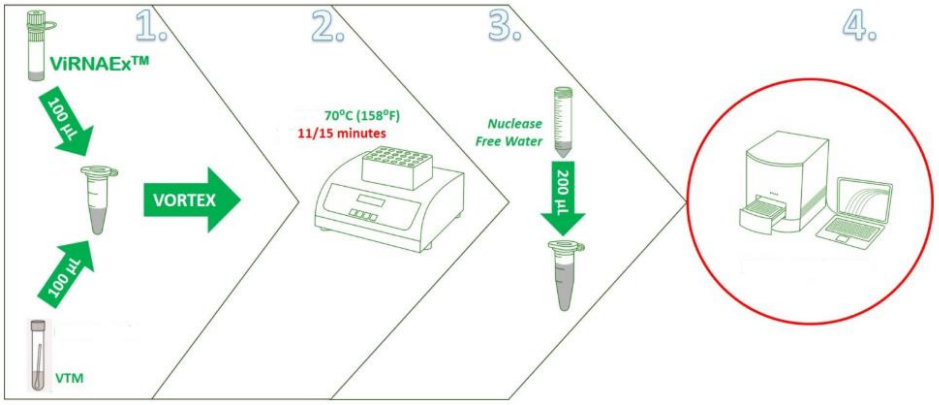
## Extraction protocol

**Please wear gloves while working with ViRNAEx™**




1. Pipette 100 µl of sample (**transport medium or diluted sputum or saliva**) into 1.5 ml tubes (not included in kit). Add 100 µl **ViRNAEx™** solution into the sample tubes (100 µl). Close the lid and vortex for 10 sec.

**ViRNAEx™ solution has to be mixed before the use**

*Note: You may add internal isolation control in this step, follow the instructions of the detection kit used, if applicable.*

2. Heat the sample at 70 °C for 11 or 15 min. The incubation time is dependent on the type of the virus transfer media. If a new VTM is used, try both time variants at the beginning

3. Add 200 µl Nuclease Free Water into the preheated tube and vortex for 10 sec.

4. Diluted sample is ready to be used for qPCR, pipette the volume needed for qRT-PCR reaction.



## Performance characteristics

The kit was tested for the isolation of viral nucleic acids of coronavirus SARS-CoV-2 from clinical specimens such as buccal swabs, nasopharyngeal swabs, saliva and sputum. Subsequent testing using Real-Time PCR analyses and comparison with other commercial methods verified a sufficient yield of viral NA from the samples.

**ViRNAEx™** showed 100% concordance in 120 clinical samples tested for RNA viru SARS-CoV-2 presence if compared to the standardly used RNA isolation method. Reproducibility of the results reached 100%.

## Warnings and general precautions

**This kit is intended for *in vitro* use only.**
**• As SARS-CoV-2 is a serious pathogen, please follow actual WHO recommendations for BSL2+or BSL3 laboratories!**
**• Lab safety gloves and respirators FFP3 are necessary for work with coronaviruses. Please work in appropriate biohazard boxes.**
Keep in mind that the RNA of some viruses can also cause infection.
• Handle and dispose of all biological samples as if they could transmit infective agents. Avoid direct contact with the biological samples. Avoid splashing or spraying.
• Use vortexes in the Biohazard box only to prevent aerosol contamination.
• Dispose of all used tools, tips and work materials and clothing as potentially infectious and dispose of them in accordance with applicable regulations and recommendations for the handling of highly infectious waste.

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• Keep in mind that all reagents and materials you work with may transmit infectious agents. Avoid direct contact with reagents. Waste must be disposed in accordance with adequate safety regulations. Consumables must be incinerated. Liquid wastes containing acids or bases must be neutralized before disposal.
• Wear suitable protective clothing and gloves and protect eyes/face.
• Never pipette solutions by mouth.
• Do not eat, drink, smoke or apply cosmetic products in the work areas.
• Wash hands carefully after handling samples and reagents.
• Work in standard mode of separate rooms: isolation, PCR set up, amplification, detection
• Dispose of leftover reagents and waste in compliance with adequate security measures.
• Read all the instructions provided with the kit before running the assay.
• Follow the instructions provided with the kit while running the assay.
• Do not use the kit after the expiry date.
• Only use the reagents provided and those recommended by the manufacturer.
• Do not change recommended protocol!

## Manufacturer:

**MetaCell s.r.o.,** Videnska 1083, 142 00 Prague, Czech Republic,



## Symbols

| | |
|---|---|
| LOT | Batch code |
| REF | Catalogue number |
| | Upper limit of temperature |
| | Keep away from sunlight |
| | Do not use if package damaged |
| | Number of tests |
| CE | Fulfilling the requirements of European Directive 98/79/EC for *in vitro* medical diagnostic device |
| IVD | *in vitro* diagnostic medical device |
| | Manufacturer |
| | Use-by-date |

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ViRNAEx™

# EC DECLARATION OF CONFORMITY

**Without the participation of a Notified body – diagnostic medical devices in vitro**

According to the Section 13 par.2 of the Act No 22/1997 Coll. On technical requirements for products and on changes and amendments to the other Acts, in the wording of later regulations (bellow only the "Act") and according to the Council and European Parliament Directive 98/79/EC dated October 27, 1998, on in vitro diagnostic medical devices (bellow only "Directive"), requirements of which were adopted in the Czech Government Regulation No.56/2015 Coll. establishing technical requirements for in vitro diagnostic medical devices, in the wording of later regulations.

Manufacturer **MetaCell s.r.o.,** Vídeňská 1083, 142 00 Praha, Czech Republic, hereby declares that following product:

## ViRNAEx

Complies with the basic requirements to the Directive and under normal use it is safe for this intended purpose. The manufactures have taken measures assuring compliance of all medical agents introduced into the market with their technical documentation and with the basic requirements.

The following directive, regulation and decision were used to demonstrate the compliance:

- Europe Parliament and Council Directive 98/97/ES
- Government Regulation No.56/2015 Coll.

Products: **ViRNAEx 10ml**
**ViRNAEx 50 ml**

Prague, August 3,2020

MetaCell s.r.o.
Vídeňská 1083
142 00 Praha 4
IČ: 29384699

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Ref. No.
sukl191284/2020

File No.
sukls181462/2020

Person in charge/e-mail
Ing. Jan Staněk
jan.stanek@sukl.cz

Date
3 August 2020

# RESOLUTION

The State Institute for Drug Control, based at Prague 10, Šrobárova 48 (hereinafter the "Institute"), as the administrative body competent pursuant to Section (§) 9, letter c) of the Act No. 268/2014 Coll., on medical devices and on changes in the Act No. 634/2004 Coll., on administrative fees, as amended later (hereinafter the "Act on Medical Devices"), decided in the administrative procedure, File No. sukls181462/2020, in agreement with the said Act and with Section (§) 67 of the Act 500/2004 Coll., Code of Administrative Procedure, as amended later (hereinafter the "Code of Administrative Procedure"),

as follows:

Pursuant to Section (§) 35, paragraph 1 of the Act on Medical Devices, the Institute hereby grants the application lodged by the person with the registration No. 062121, MetaCell s.r.o., based at Vídeňská 1083, 14200 Prague, Company Registration No.: 29384699, for notification of the medical device.

| Registration number | Name of the medical device | Manufacturer´s registration number | Manufacturer |
|---|---|---|---|
| 00894032 | ViRNAEx | 062121 | MetaCell s.r.o. |
| | Identification code of the variant | Name complement | Catalogue No. |
| | 0001 | ViRNAEx 10 ml | MC-025-2020 |
| | 0002 | ViRNAEx 50 ml | MC-026-2020 |

Validity of the notification of the above listed medical devices shall be five years after this resolution comes into legal force.

Grounds of the resolution

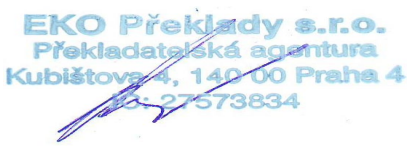
Pursuant to Section (§) 68, paragraph 4 of the Administrative Code, no substantiation of the resolution is required if the administrative authority of the first instance has satisfied requests of all the parties involved in the full scope.

Instruction

No appeal is possible against this resolution in agreement with Section (§) 35, paragraph 1 of the Act on Medical Devices.

OFFICIAL SEAL IMPRINT

Ing. Petr Vykypěl
Head of Department of Registrations and Notifications
Section of Medical Devices



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