



ONBOARD™ kit

TECHNICAL INFORMATION SHEET

Product Name: SARS-CoV-2 ONBOARD™ kit

Catalogue Number: VP-K-CoV2-01

Storage: Store this preparation at 2 °C to 8 °C.

Description: This product contains twelve samples, four negative samples containing human fibroblast cells and eight positive samples containing whole SARS-CoV-2 cDNA genome and human fibroblasts in a preservative solution.

Volume: 12 x 0.5 mL PROCEEDx™ SARS-CoV Samples

Intended Use: The product is to be used as a positive and negative test sample in nucleic acid based tests for SARS-CoV-2. The product is to be used for nucleic acid test instrument (device) verification/validation, manufacturing QMS, educational and R&D purposes.

NOT FOR USE IN DIAGNOSTIC PROCEDURES. FOR RESEARCH USE ONLY

Handling: It is recommended that the product is tested according to kit Manufacturer's instructions for testing of clinical samples. Before use, the product should be thoroughly mixed by micropipette aspiration of 200 µL from the sample volume and vortex immediately prior use vortexing for approximately 30 seconds. In protocols for the assessment of samples collected by swab procedures, the amount of liquid should be used directly with the extraction step or transferred to the cartridge as per test manufacturers' instructions.

PROCEDURE: When including the PROCEEDx™ SARS-CoV-2 Positive and Negative Samples in a test run, the exact same procedure for unknown specimens collected in STM must be used. Refer to the manufacturer supplied instructions for use provided with the SARS-CoV-2 test kit.

- Skip the swab elution step (described in some assay instructions for use)
- Use 100-400 µL from the sample for the kit extraction step.
- Use the volume recommended in the assay instructions for use for testing the sample after the extraction step (usually 5-20 µL from the eluted purified nucleic acid volume).
- After extraction, proceed with RT-PCR by using the sample test volume specified in the assay instructions for use (usually 5-20 µL from the eluted purified nucleic acid volume).

Expected Results: Testing of the product in PCR-based assays for SARS-CoV-2 should result in a positive finding for HPV-45, including such assays where the presence of human DNA is required for the determination of a positive result.

Hazards: The reagent has been inactivated and should contain no infectious material: however, it should be handled as if potentially infectious, generally accepted good laboratory practices appropriate to biological reagents should be employed. The buffer solution contains methanol (CAS no. 67-56-1) as a preservative. Please refer to the Safety Data Sheet (SDS).

Strain/Cell line: SARS-CoV-2 NC_045512 and MRC2

Assistance: If you have any questions regarding the production, testing or use of this material, please send them together with any relevant data to Microbix Technical Services, at customer.service@microbix.com or fax 905-361-8911. Your complete satisfaction with the performance of this product is important to us.

Quality Control Information

Product Name: PROCEEDx™SARS-CoV-2 Positive Sample

Product Code: VP-19-01

| qPCR Test Kit | Target | Result |
|--|----------------|-----------------|
| CDC 2019-Novel Coronavirus (2019-nCoV) based RT-PCR test for detection of SARS-CoV-2 | SARS-CoV-2 | Positive |
| | Human DNA (RP) | Positive |

Inactivation: Product was inactivated by gamma irradiation.

Product Name: PROCEEDx™SARS-CoV-2 Negative Sample

Product Code: VP-99-M3

| qPCR Test Kit | Target | Result |
|--|----------------|-----------------|
| CDC 2019-Novel Coronavirus (2019-nCoV) based RT-PCR test for detection of SARS-CoV-2 | SARS-CoV-2 | Negative |
| | Human DNA (RP) | Positive |

Inactivation: Product was inactivated.



Explanation of symbols used in Microbix product labelling



Research use only



Toxic by inhalation, contact with skin and if swallowed



Highly Flammable



Caution, consult accompanying documents



Instructions for use



Manufacturer



Single use only



Contains sufficient for 'n' tests



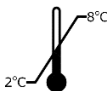
Catalogue number



Lot number



Use By



Temperature limitation