

ONBOAR kit

PRODUCT INFORMATION SHEET

Product Name: ONBOARDx™ Respiratory kit (RUO)

Lot Number: P530985

Catalogue Number: VP-K-RESP-01

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

Description: This product consists of liquid formulations containing native Influenza A, Influenza B, RSV and whole genome cDNA SARS-CoV-2 viruses.

Amount:

3x PROCEEDx™ SARS-CoV-2 Positive Samples	(Cat# VP-19-01)
3x PROCEEDx™ RSV Positive Samples	(Cat# VP-07-01)
3x PROCEEDx™ Influenza A Positive Samples	(Cat# VP-13-01)
3x PROCEEDx™ Influenza B Positive Samples	(Cat# VP-14-01)

Intended Use: The products are to be used as positive test swab samples in nucleic acid-based tests for SARS-CoV-2, Respiratory Syncytial Virus (RSV) and Influenza A&B (Flu A&B). They are to be used on nucleic acid test instruments (devices) for verification/validation, manufacturing QMS, educational and R&D purposes.

NOT FOR USE IN DIAGNOSTIC PROCEDURES. FOR RESEARCH USE ONLY.

Instructions for Use: When including the PROCEEDx™ Positive Samples in a test run, the exact same procedure for unknown specimens collected on a swab and eluted in the medium must be used. Refer to the manufacturer supplied instructions for use provided with the SARS-CoV-2, RSV and Flu A&B test kit.

- Use 100-400 μL from the sample solution for the extraction step.
- After extraction proceed with RT-PCR by using the sample test volume specified in the assay instruction for use (usually 5-20 µL from the eluted purified nucleic acid volume).

Expected Results:

Testing of the PROCEEDx™ SARS-CoV-2 Positive Sample in PCR-based assays for SARS-CoV-2 should result in a positive finding, including such assays where the presence of human DNA is required for the determination of a positive or negative result.

Testing of the PROCEEDx™ RSV Positive Sample in PCR-based assays for RSV should result in a positive finding. Testing of the PROCEEDx™ Influenza A Positive Sample in PCR-based assays for RSV should result in a positive finding.

Testing of the PROCEEDx™ Influenza B Positive Sample in PCR-based assays for RSV should result in a positive finding.

Hazards: The preparation 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) and 0.02% sodium azide (CAS No. 26628-22-8) as a preservative. Please refer to the Safety Data Sheet (SDS).

Strain/Cell line:

SARS-CoV-2 NC 045512 and MRC2

Influenza A/H1N1 Subtype

Influenza B/Hong Kong/5/72. ICTV 00.046.0.04.001

Human respiratory syncytial virus, Long strain. ICTV 01.048.2.01.001

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

Lot Number: 19010004D Product Code: VP-19-01

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

Product Name: PROCEEDx™ RSV Positive Sample

Lot Number: 07010004K Product Code: VP-07-01

qPCR Test Kit	Target	Result	
Cepheid Xpert Xpress Flu/RSV	RSV	Positive	The state of the s
	Influenza A	Negative	
	Influenza B	Negative	

Product Name: PROCEEDx™ Influenza A Positive Sample

Lot Number: 13010002N Product Code: VP-13-01

qPCR Test Kit	Target	Result	HEER
Cepheid Xpert Xpress Flu/RSV	Influenza A	Positive	
	RSV	Negative	
	Influenza B	Negative	

Product Name: PROCEEDx™ Influenza B Positive Sample

Lot Number: 14010008A3 Product Code: VP-14-01

qPCR Test Kit	Target	Result	
Cepheid Xpert Xpress Flu/RSV	Influenza B	Positive	
	Influenza A	Negative	
	RSV	Negative	

Inactivation: Products were inactivated.

Quality Control Summary: This lot meets specifications and is released for shipment.

Expiry date: 2021-04-06



Date: 04 January 2021



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

FLOQ® is a trademark of Copan Italia Spa