



ONBOARDTM kit

PRODUCT INFORMATION SHEET

Product Name: ONBOARDTMFLOQ[®] Respiratory Ag Swab Kit (RUO)

Catalogue Number: VP-SK-RESPAG-02

Lot#: SKRESPAG020001

Storage: Store this preparation at 2 °C to 30 °C.

Description: This product consists of swabs containing desiccated SARS-CoV-2 nucleocapsid antigen, Influenza A and Influenza B on Copan FLOQSwabs[®].

Amount:

5x PROCEED TM FLOQ [®] SARS-CoV-2 Ag Swabs Positive Samples	(Cat# VP-S-19-02*)
5x PROCEED TM FLOQ [®] Influenza A Swabs Positive Samples	(Cat# VP-S-13-01)
5x PROCEED TM FLOQ [®] Influenza B Swabs Positive Samples	(Cat# VP-S-14-01)
5x PROCEED TM Negative Swab Samples	(Cat# VP-S-99-01)

***Product in advanced development.**

Intended Use: The products are to be used as positive test swab samples in nucleoprotein-based immunoassay tests for SARS-CoV-2, Influenza A and Influenza B. They are to be used on immunoassay 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 SARS-CoV-2 Ag, Influenza A and Influenza B Swab Positive Samples as well as the Negative sample in a test run, the exact same procedure for unknown specimens collected on a swab must be used. Refer to the manufacturer supplied instructions for use provided with the test kit. Elute the swab by referring to the preferred technique described in the assay instructions for use (usually 0.25-0.5 mL). Use 100-200 µL from the eluted swab sample for the detection step.

Expected Results: Testing SARS-CoV-2 Ag Swab Positive Sample using immunological assays for detection of SARS-CoV-2 nucleocapsid protein should result in a positive finding.
Testing Influenza A Swab Positive Sample using immunological assays for detection of Influenza A nucleocapsid protein should result in a positive finding.
Testing Influenza B Swab Positive Sample using immunological assays for detection of Influenza B nucleocapsid protein should result in a positive finding.
Testing Respiratory Negative Swab Positive Sample using immunological assays for detection of SARS-CoV-2, Influenza A and Influenza B nucleocapsid proteins should result in a negative finding.

Strain/Target:

SARS-CoV-2 Ag Swab Positive Sample: SARS-CoV-2 nucleocapsid protein
Influenza A Swab Positive Sample: Influenza A/ H1N1 Subtype
Influenza B Swab Positive Sample: Influenza B/ Hong Kong/5/72. ICTV 00.046.0.04.001

Hazards: We are aware of no specific biological hazards associated with this product. The preparation (influenza A and Influenza B) 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 coating buffer 0.02% sodium azide (CAS No. 26628-22-8) as a preservative.

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™ FLOQ® SARS-CoV-2 Ag Swab Positive Sample

Product Code: VP-S-19-02

Lot# 19S20002A

Test Kit	Target	Result
QUIDEL SOFIA SARS/FLU	SARS-CoV-2	Positive
	Influenza A	Negative
	Influenza B	Negative

Product Name: PROCEEDx™ FLOQ® Influenza A Swab Positive Sample

Product Code: VP-S-13-01

Lot# 13010005A

Test Kit	Target	Result
QUIDEL SOFIA SARS/FLU	Influenza A	Positive
	Influenza B	Negative
	SARS-CoV-2	Negative

Product Name: PROCEEDx™ FLOQ® Influenza B Positive Sample

Product Code: VP-S-14-01

Lot# 14010007A

Test Kit	Target	Result
QUIDEL SOFIA SARS/FLU	Influenza B	Positive
	Influenza A	Negative
	SARS-CoV-2	Negative

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

Product Code: VP-S-99-01

Lot# 99010008A

Test Kit	Target	Result
QUIDEL SOFIA SARS/FLU	SARS-CoV-2	Negative
	Influenza B	Negative
	Influenza A	Negative

Inactivation: SARS-CoV-2 Ag related Products are non-infectious. Influenza A and Influenza B related products are inactivated

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

Date of Manufacture: 2020-10-05

Expiry date: 2021-10-05

Quality Assurance Signature: 

Date: 28 October, 2020



Explanation of symbols used in Microbix product labelling:



Research use only



Caution, consult accompanying documents



Instructions for use



Use By



Temperature limitation



Manufacturer



Single use only



Contains sufficient for 'n' tests



Catalogue number



Lot number



Date of Manufacturing

FLOQ® is a trademark of Copan Italia Spa