



ONBOARDTM kit

PRODUCT INFORMATION SHEET

Product Name: ONBOARDxTMFLOQ® SARS-CoV-2 Ag Swab Kit (RUO)

Catalogue Number: VP-SK-COV2AG-01

Lot#: P530307

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

Description: This product consists of swabs containing desiccated SARS-CoV-2 nucleocapsid antigen on Copan FLOQSwabs®.

Amount:

10x PROCEEDxTMFLOQ® SARS-CoV-2 Ag Swabs Positive Samples

(Cat# VP-S-19-02*)

2x PROCEEDxTM 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. 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 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 Respiratory Negative Swab Positive Sample using immunological assays for detection of SARS-CoV-2 nucleocapsid proteins should result in a negative finding.

Strain/Target:

SARS-CoV-2 Ag Swab Positive Sample: SARS-CoV-2 nucleocapsid protein

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# 19S20001A5

Test Kit	Target	Result
QUIDEL SOFIA SARS	SARS-CoV-2	Positive

Product Name: PROCEEDx™ FLOQ® SARS-CoV-2 Negative Sample
Product Code: VP-S-99-01

Lot# 99010006A

Test Kit	Target	Result
QUIDEL SOFIA SARS	SARS-CoV-2	Negative

Inactivation: SARS-CoV-2 Ag related Products are non-infectious.

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

Date of Manufacture: 2020-07-08

Expiry date: 2021-07-07

Quality Assurance Signature: 

Date: 10 November, 2020



Explanation of symbols used in Microbix product labelling:



Research use only



Caution, accompanying documents

consult



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