

Instructions For Use

8268 Rapid SARS-CoV-2 Control Panel

Intended Use

The Rapid SARS-CoV-2 Control Panel is intended for use as non-viable, external, positive, and negative control material to evaluate the performance of nucleic acid amplification testing (NAAT) procedures that detect SARS-CoV-2 in direct specimens. This product has no qualitative or quantitative assigned values. It is nonautomated and not intended to be used for screening, monitoring, or diagnosis. This product is not intended for any specific patient population or specimen.

Summary And Principles

The Rapid SARS-CoV-2 Control Panel can be used to monitor the extraction, amplification and detection process of molecular testing assays that detect SARS-CoV-2. Routine use of quality controls monitors test variation, lot-to-lot test kit performance, operator performance, and aid in identifying random or systemic error.

Composition

The Rapid SARS-CoV-2 Control Panel consists of 6 individually packaged lyophilized positive control swabs, and 6 individually packaged lyophilized negative control swabs. The SARS-CoV-2 virus has been inactivated using chemical treatments.

Both the positive and negative controls are lyophilized in a PCR-compatible matrix prepared with materials of plant and animal origin, preservatives, and stabilizers, and formulated into ready-to-use foam swabs.

Table 1: Contents of the Control Panel

Analytes*
Rapid SARS-CoV-2 Positive Control
SARS-CoV-2 Virus
Negative Blank Control
Blank control

* The analyte is added at a target concentration of 10⁶ copies per swab. The input concentration is not representative of recoverable concentrations or expected values.

Warnings And Precautions

- For In Vitro Diagnostic use only.
- To be used by personnel trained in the use of the assay and in disposal of biohazardous materials.
- The inactivated lyophilized swabs are single-use only. If hydrated, do not freeze for reuse. If reused, the inactivated lyophilized swabs may not perform as expected, including but not limited to, degradation or over-dilution of material resulting in false negatives, contamination resulting in false positive results or positive detection of organisms not on the swab, and environmental contamination.
- Do not open foil pouch until ready to use.
- Although this product has been inactivated, there is no known test or inactivation method that can assure that it will not transmit infection. This product must be treated as a potential biohazard and be handled using universal laboratory precautions. Wear appropriate personal protective equipment. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled. Disinfect any spills and dispose of all materials in accordance with national and local regulations.
- This product does not contain any hazardous substances listed in 1272/2008/EC.
- Report any serious incident that has occurred in relation to the device to Microbiologics and the local regulatory officials in which the user and/or the patient is established.

Storage And Expiration



Store the Rapid SARS-CoV-2 Control Panel at 2°C-25°C in the original packaging up to the indicated expiration date. After opening, rehydrate and use the swab immediately. Do not use swab more than 1 hour after the pouch has been opened, and do not exceed 25°C after pouch has been opened.

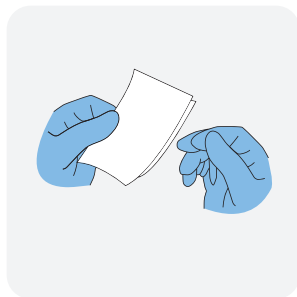
The Rapid SARS-CoV-2 Control Panel should not be used if:

- Stored improperly
- There is evidence of excessive exposure to heat or moisture
- The expiration date has passed
- Packaging is damaged

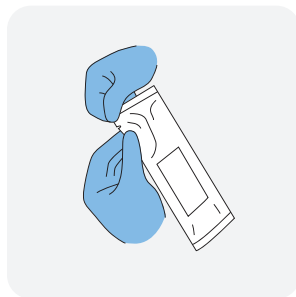
Materials Required But Not Provided

- Assay for detection including required instrumentation and consumables.
- Rehydration buffer such as a sample reagent or saline as required by assay to be performed.
- Pipettors capable of delivering 0.5-1000 µL volumes (if applicable).
- Nuclease-free aerosol barrier pipette tips (if applicable).

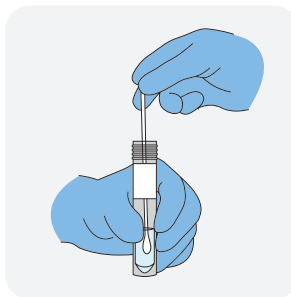
Instructions For Use



1. Read package insert, instructions for use or lab protocol for the applicable assay. Some instruments and assays are equipped with special QC settings. In these instances, it may be necessary to use the special setting when using QC Sets and Panels.

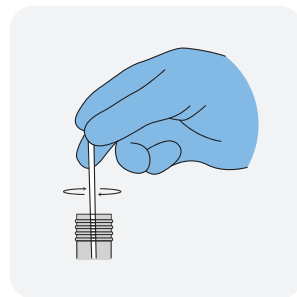


2. Tear open pouch at notch and remove swab from pouch.



3. Place swab into the provided hydration fluid/buffer from the assay manufacturer.

If hydration fluid/buffer is not provided by the assay manufacturer, 0.85% Saline may be used. A minimum volume of 200 µl is needed to hydrate the swab. It is not recommended to exceed 3,000 µl to avoid over diluting the product.



4. Swirl swab 5 times in hydration fluid/buffer.

5. Remove swab if indicated by assay manufacturer instructions.

6. Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.

Limitations

- There are no known extrinsic factors or interfering substances specific to this product. Please consult assay instructions for any extrinsic factors or interfering substances.
- This product is unassayed control material. It may not be suitable for use with all kits and procedures as not all instruments and assays are compatible with multi-target controls. Customer is responsible for verifying the performance of this product with their chosen instrumentation and assay(s). As a third-party control manufacturer, Microbiologics provides quality controls that deliver an independent, unbiased assessment of performance with any instrument or method. While not intended to replace control materials provided by the assay/instrument supplier, third-party control materials should be considered.
- Target concentrations of each analyte are specific to Microbiologics' assay method and procedures. These organisms are intact, non-viable, and may be used with any PCR-based test or assay. Microbiologics guarantees each nucleic acid is present and can be amplified but does not guarantee specific analyte concentrations. Each laboratory should

























establish its own range of acceptable values on their assay system per their internal quality assurance procedure/ program. Nucleic acid reactivity, which may vary over time, is dependent on a laboratory's instrumentation, assay method, procedures, calibration, or technician. Microbiologics' molecular controls are not calibrators and should not be used for assay calibration or as an absolute reference material.

- The linear barcode found on the foil pouch labels may not be readable by all devices.

Microbiological State

This product was prepared using suitable inactivation methods. While the product has been tested for innocuity, universal laboratory precautions are recommended, and material should be treated as though it was a viable specimen.

Key Of Symbols

	Authorized Representative in the European Community / European Union		In vitro diagnostic medical device
	Batch code (Lot)		Manufacturer
	Biological risks		Negative control
	Catalog number		Positive control
	Caution		Quantity
	CE mark		Swiss Authorized Representative
	Consult instructions for use or consult electronic instructions for use		Telephone number
	Contains sufficient for <n> tests		Temperature limit
	Water; Fluid		UK Conformity Assessed mark
	Do not re-use		UK Responsible Person
	Do not use if package is damaged and consult instructions for use		Use-by-date
	Health hazard		EU Authorized Representative

Please refer to product labels for applicable symbols.

Notice To Purchasers

The purchase of this product allows the purchaser to use it for Research and Quality Control. No general patents or other license of any kind other than this specific right of use from purchase is granted hereby. No other rights are conveyed expressly, by implication or by estoppel to any other patents. Furthermore, no rights for resale are conferred with the purchase of this product.

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Website

Visit our website, www.microbiologics.com, for current technical information and product availability.

Bibliography

- Tsang NN, So HC, Ng KY, Cowling BJ, Leung GM, Ip DK. Diagnostic performance of different sampling approaches for SARS-COV-2 RT-PCR testing: A systematic review and meta-analysis. The Lancet Infectious Diseases. 2021;21(9):1233-1245. doi:10.1016/s1473-3099(21)00146-8

Assistance



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Revision History

Publication History		
Revision	Date	Description of Change
A	2023-07-06	Initial Release
B	2025-12	Added negative control to kit components; included note clarifying control nature; added analyte table; added bibliography; updated key of symbols

