

INSTRUCTIONS FOR USE



■ 8254 Blood Culture Identification Control Panel (43 Targets)

INTENDED USE

The Blood Culture Identification Control Panel (43 Targets) is intended for use as non-viable, external, positive, and negative control materials to evaluate the performance of nucleic acid amplification testing (NAAT) procedures that detect the analytes in Table 1. This product has no qualitative or quantitative assigned value. This control material is nonautomated and not intended to be used for screening, monitoring, or diagnosis. This control is not intended for any specific patient population or specimen.

SUMMARY AND PRINCIPLES

The Blood Culture Identification Control Panel (43 Targets) can be used to monitor the extraction, amplification and detection process of molecular testing assays that include the analytes in Table 1. 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 Blood Culture Identification Control Panel (43 Targets) consists of 6 individually packaged lyophilized positive control 1 pellets, 6 individually packaged lyophilized positive control 2 pellets, and 6 individually packaged lyophilized negative control pellets. The analytes in Table 1 have been inactivated using thermal treatments.

The Blood Culture Identification Control Panel (43 Targets) is lyophilized in a PCR compatible matrix. The organisms are prepared in a buffered solution with materials of plant and animal origin, preservatives, and stabilizers. The solution is lyophilized into a ready-to-use pellet.

Table 1: Contents of the Blood Culture Identification Control Panel (43 Targets).

Analytes*	
Positive Control 1	
<i>Bacteroides fragilis</i>	<i>Candida auris</i>
<i>Klebsiella aerogenes</i>	<i>Cryptococcus neoformans</i>
<i>Salmonella Typhimurium</i>	<i>Klebsiella pneumoniae</i> (OXA-48)
<i>Stenotrophomonas maltophilia</i>	<i>Escherichia coli</i> (NDM, CTX-M)
<i>Enterococcus faecium</i> (vanA/B)	<i>Klebsiella pneumoniae</i> (VIM-1)
<i>Staphylococcus lugdunensis</i>	<i>Escherichia coli</i> (mcr-1, ESBL)
Positive Control 2	
<i>Candida albicans</i>	<i>Enterococcus faecalis</i> (vanB)
<i>Candida krusei</i>	<i>Escherichia coli</i> (IMP)
<i>Neisseria meningitidis</i>	<i>Klebsiella oxytoca</i>
<i>Pseudomonas aeruginosa</i>	<i>Listeria monocytogenes</i>
<i>Staphylococcus aureus</i> (MRSA)	<i>Staphylococcus epidermidis</i>
<i>Streptococcus agalactiae</i> (Group B)	<i>Candida parapsilosis</i>
<i>Streptococcus pyogenes</i>	<i>Haemophilus influenzae</i>
<i>Acinetobacter baumannii</i>	<i>Klebsiella pneumoniae</i> (KPC)
<i>Candida glabrata</i>	<i>Proteus vulgaris</i>
<i>Candida tropicalis</i>	<i>Serratia marcescens</i>
<i>Enterobacter cloacae</i> (CTX-M)	<i>Streptococcus pneumoniae</i>
Negative Control	
Blank pellet	

*All analytes are added at a concentration of 10^4 - 10^7

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- For professional use only. To be used by personnel trained in the use of the assay.
- The inactivated lyophilized pellets are single-use only. Once hydrated, do not freeze for reuse.
- 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.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located on the Microbiologics website at www.microbiologics.com or by contacting Technical Support at 1.320.229.7045 or U.S. Toll Free 1.866.286.6691.
- This product does not contain any hazardous substances listed in 1272/2008/EC.
- This product is not made with natural rubber latex.
- 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.

MATERIALS REQUIRED BUT NOT PROVIDED

- Nucleic acid extraction kit, for assays that are not sample to result
- Instrumentation for detection
- 1.5-ml microcentrifuge tubes
- Rehydration buffer such as molecular water as required by assay to be performed
- Pipettors capable of delivering 0.5-1000 µl volumes
- Nuclease-free aerosol barrier pipette tips
- Vortex
- Microcentrifuge (optional)

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. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.
3. Hydrate the lyophilized pellet into a vial of molecular water.
 - a. Minimum hydration volume of 200 µl is recommended.
 - i. For known extrinsic factors and interfering substances, please refer to Table 2 below
4. Recap the vial and vortex for 10 seconds at full speed to mix.
5. If a centrifuge is not available, tap the capped vial on a rigid surface to collect material at the bottom of the vial.
 - a. Alternatively, centrifuge briefly to collect any droplets clinging to the cap or upper walls of the tube.
6. Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.
7. Note: Dilutions may be performed and used immediately. Storage of diluted material for future use is not recommended.

Table 2: Sample Volume

Hydration Buffer	Minimum Hydration Volume	Mix Format/Time	Known Extrinsic Factors and interfering Substances
Molecular Water	200 µl	Vortex for 10 seconds	N/A

STORAGE AND EXPIRATION



Store the Blood Culture Identification Control Panel (43 Targets) at 2°C-25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, rehydrate and use immediately. In-use stability of the rehydrated pellet at room temperature (25°C) is 6 hours.

The Blood Culture Identification Control Panel (43 Targets) 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

PERFORMANCE CHARACTERISTICS

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.




















LIMITATIONS

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.

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		Health hazard
	Batch code (lot)		In vitro diagnostic medical device
	Biological risks		Manufacturer
	Catalogue number		Negative control
	Caution		Positive control
	CE Mark		Quantity
	Consult instructions for use or consult electronic instructions for use		Telephone number
	Contains sufficient for <n> tests		Temperature limit
	Do not re-use		Use-by date
	Do not use if package is damaged and consult instructions for use		

Please refer to product labels for applicable symbols.

PRODUCT WARRANTY

These products are covered under warranty to meet the specifications and performance printed and illustrated in product inserts, instructions and supportive literature. The warranty, expressed or implied, is limited when:

- The procedures employed in the laboratory are contrary to printed and illustrated directions and instructions.
- The products are employed for applications other than the intended use cited in product inserts, instructions and supportive literature.
- The rehydrated material is frozen, Microbiologics cannot guarantee the stated characteristics of the product.

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.

ASSISTANCE ---



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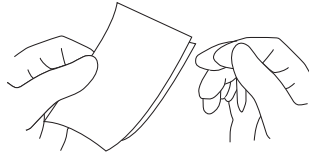
Additional copies of this product insert may be obtained at www.microbiologics.com or by emailing info@microbiologics.com.

ILLUSTRATED INSTRUCTIONS

Each kit consists of 6 individually packaged lyophilized positive control 1 pellets, 6 individually packaged lyophilized positive control 2 pellets, and 6 individually packaged lyophilized negative control pellets.

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



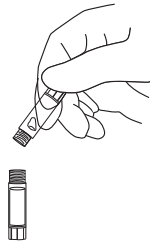
Tear open pouch at notch. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.

3

Hydrate the lyophilized pellet into a vial of molecular water.

Minimum hydration volume of 200 μ l is recommended.

For known extrinsic factors and interfering substances, please refer to Table 2.

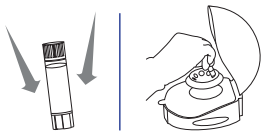


4



Recap the vial and vortex for 10 seconds at full speed to mix.

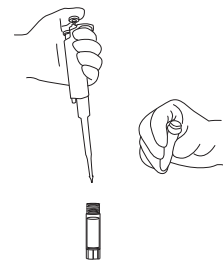
5



If a centrifuge is not available, tap the capped vial on a rigid surface to collect material at the bottom of the vial. Alternatively, centrifuge briefly to collect any droplets clinging to the cap or upper walls of the tube.

6

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



7

Note: Dilutions may be performed and used immediately. Storage of diluted material for future use is not recommended.

REVISION HISTORY ---

Publication History		
Revision	Date	Description of Change
A	10.JAN.2022	Initial release
B	16.JUN.2022	Added CE-symbol to page 1, added EU hazardous statement to the Warnings and Precautions section, added EU contact information to Assistance section, added temperature range symbol.