

INSTRUCTIONS FOR USE

IVD

■ 8244 Pneumonia (33 Targets) Control Panel

INTENDED USE

The Pneumonia (33 Targets) Control Panel is intended for use as an external positive and negative quality control to monitor the performance of nucleic acid testing procedures for the detection of all pneumonia pathogens and/or targets 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 Pneumonia (33 Targets) Control Panel can be used to monitor the extraction, amplification and detection process of molecular testing assays that include the pneumonia pathogens and/or targets listed 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 Pneumonia (33 Targets) Control Panel product consists of 6 individually packaged positive control 1 pellets, 6 individually packaged positive control 2 pellets, and 6 individually packaged negative control pellets. The pneumonia pathogens have been inactivated using irradiation, chemical, and/or thermal treatments. The positive controls contain pneumonia pathogens listed in Table 1. The negative control is a blank pellet and does not contain microorganisms. It is composed of a proprietary preservation matrix.

The Pneumonia (33 Targets) Control Panel is lyophilized in a PCR compatible patient-relevant 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 Pneumonia (33 Targets) Control Panel

Positive Control 1 - Semi-Quantitative Bacteria	Positive Control 2 - Viruses and Atypical Bacteria
<i>Acinetobacter baumannii</i>	<i>Chlamydomphila pneumoniae</i>
<i>Enterobacter cloacae</i> (CTX-M)	<i>Legionella pneumophila</i>
<i>Escherichia coli</i> (IMP)	<i>Mycoplasma pneumoniae</i>
<i>Haemophilus influenzae</i>	Adenovirus Type 6
<i>Klebsiella aerogenes</i>	Coronavirus 229E
<i>Klebsiella oxytoca</i>	Human Metapneumovirus surrogate*
<i>Moraxella catarrhalis</i>	Rhinovirus 1B
<i>Proteus vulgaris</i>	Influenza A Subtype H1-2009
<i>Pseudomonas aeruginosa</i>	Influenza B
<i>Serratia marcescens</i>	Parainfluenza Virus 1
<i>Staphylococcus aureus</i> (mecA/C, MREJ)	Respiratory Syncytial Virus
<i>Streptococcus agalactiae</i> (B)	
<i>Streptococcus pneumoniae</i>	
<i>Streptococcus pyogenes</i> (A)	
<i>Escherichia coli</i> (NDM)	
<i>Klebsiella pneumoniae</i> (OXA-48)	
<i>Klebsiella pneumoniae</i> (VIM-1)	
<i>Klebsiella pneumoniae</i> (KPC)	

*See limitations on page 2.


HELIX|ELITE™
MOLECULAR STANDARDS


Microbiologics
QC SETS AND PANELS

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use.
- For professional use only. To be used by personnel trained in the use of the assay.
- Do not open foil pouch until ready to rehydrate and use.
- This product must be treated as a viable specimen and handled in accordance with Biosafety Level 1 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical laboratories or other equivalent guidelines. Although this product has been inactivated, there is no known test or inactivation method that can assure that this product will not transmit infection.
- Possible eye and skin irritant.
- Wear proper personal protective equipment.
- 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 320.229.7045 or U.S. Toll Free 1.866.286.6691.
- This product does not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- This product is not made with natural rubber latex.

MATERIALS REQUIRED BUT NOT PROVIDED

- Nucleic acid extraction kit, for assays that are not sample to result
- Instrumentation for detection
- Molecular grade water
- Pipettors capable of delivering 0.2-1000µl volumes
- Nuclease-free aerosol barrier pipette tips
- 1.5-ml microcentrifuge tubes
- 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 grade water.
 - a. Minimum hydration volume of 200 µl is recommended.
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: Each pellet is intended as a single use test. Dilutions may be performed and used immediately. Storage of the rehydrated or diluted material for future use is not recommended.

STORAGE AND EXPIRATION

Store the Pneumonia (33 Targets) Control Panel at 2°C-25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, rehydrate and use immediately.

Pneumonia (33 Targets) Control Panel should not be used if:

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

LIMITATIONS

















E.coli is used as the host microorganism for Human Metapneumovirus in Positive Control 2 and may occasionally be detected as a target. To control for cross contamination we recommend to run Positive Control 1, the Negative Control, and lastly Positive Control 2. This will help ensure the *E.coli* call in Positive Control 2 is because it is the host for the recombinant Human Metapneumovirus.

This product may not be suitable for use with all kits and procedures. 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).

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

 LOT	Batch Code (Lot)		Consult Instructions for Use
 REF	Catalog Number		Temperature Limitation
	Caution, Consult Accompanying Documents		Use By
	Contains sufficient for <n> tests		Telephone Number
 IVD	In Vitro Diagnostic Medical Device	 QTY	Quantity
	Manufacturer		Health Hazard
 CONTROL+	Positive Control		Do not use if package is damaged and consult instructions for use.
 CONTROL-	Negative Control		Do not re-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.
- If the resuscitated culture 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.

ACKNOWLEDGEMENTS



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ILLUSTRATED INSTRUCTIONS

Each kit consists of 6 individually packaged positive control 1 pellets, 6 individually packaged positive control 2 pellets, and 6 individually packaged 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 grade water.

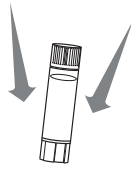
Minimum hydration volume of 200 μ l is recommended.

4



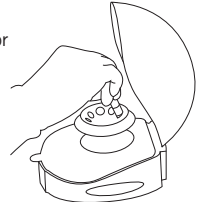
Recap the vial and vortex for 10 seconds at full speed to mix.

5



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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

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