

# INSTRUCTIONS FOR USE



- **8206 Rifampicin-Resistant Mycobacterium tuberculosis Positive Control Panel (Inactivated Pellet)**
- **8238 Rifampicin-Resistant Mycobacterium tuberculosis Negative Control (Inactivated Pellet)**

## INTENDED USE

The Rifampicin-Resistant Mycobacterium tuberculosis Positive Control Panel (Inactivated Pellet) and Negative Control (Inactivated Pellet) are 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. These products have no qualitative or quantitative assigned values. These control materials are nonautomated and not intended to be used for screening, monitoring, or diagnosis. These controls are not intended for any specific patient population or specimen.

## SUMMARY AND PRINCIPLES

The Rifampicin-Resistant Mycobacterium tuberculosis Positive Control Panel (Inactivated Pellet) and Negative Control (Inactivated Pellet) 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 monitor test variation, lot-to-lot test kit performance, operator performance, and aid in identifying random or systemic error.

## COMPOSITION

The Rifampicin-Resistant Mycobacterium tuberculosis Positive Control Panel (Inactivated Pellet) consists of 3 positive controls with 6 individually packaged lyophilized pellets of each control. The Rifampicin-Resistant Mycobacterium tuberculosis Negative Control (Inactivated Pellet) consists of 6 individually packaged lyophilized pellets. The analytes in Table 1 have been inactivated using thermal treatments.

The Rifampicin-Resistant Mycobacterium tuberculosis Positive Control Panel (Inactivated Pellet) and Negative Control (Inactivated Pellet) are 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 Rifampicin-Resistant Mycobacterium tuberculosis Positive Control Panel (Inactivated Pellet) and Negative Control (Inactivated Pellet)

<b>Rifampicin-Resistant Mycobacterium tuberculosis Positive Control Panel (Inactivated Pellet) Analytes*</b>
<b>Positive Control 1</b>
<i>Mycobacterium bovis</i> (MTB) (BCG)
<b>Positive Control 2</b>
<i>Mycobacterium tuberculosis</i> (MTB/RIF) surrogate (rpoB: L511P, H526Y, S531L)
<b>Positive Control 3</b>
<i>Mycobacterium tuberculosis</i> (MTB/RIF) surrogate (rpoB: D516V, S522L)
<b>Rifampicin-Resistant Mycobacterium tuberculosis Negative Control (Inactivated Pellet) Analytes*</b>
<i>Mycobacterium gordonae</i>


\*All analytes are added at a target concentration of  $10^3$  -  $10^4$  copies per pellet. These are input concentrations and are not representative of recoverable concentrations or expected values.



## 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 these products have been inactivated, there is no known test or inactivation method that can assure that it will not transmit infection. These products must be treated as a potential biohazard. 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](http://www.microbiologics.com) or by contacting Customer Service at [info@microbiologics.com](mailto:info@microbiologics.com)
- These products do 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 Rifampicin-Resistant Mycobacterium tuberculosis Positive Control Panel (Inactivated Pellet) and Negative Control (Inactivated Pellet) 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 Rifampicin-Resistant Mycobacterium tuberculosis Positive Control Panel (Inactivated Pellet) and Negative Control (Inactivated Pellet) 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

- Nucleic acid extraction kit and assay
- Instrumentation for detection
- Rehydration fluid/buffer such as molecular water and sample reagent 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/tube of molecular water and sample reagent.
  - a. Minimum hydration volume of 2000 µl (500 µl molecular water, 1500 µl sample reagent) is recommended.
    - i. For known extrinsic factors and interfering substances, please refer to Table 2 below.
4. Recap the vial/tube and vortex for 10 seconds at full speed to mix.
5. If a centrifuge is not available, tap the capped vial/tube on a rigid surface to collect material at the bottom of the vial/tube.
  - a. Alternatively, centrifuge briefly to collect any droplets clinging to the cap or upper walls of the vial/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 Fluid/Buffer	Minimum Hydration Volume	Mix Format/Time	Known Extrinsic Factors and interfering Substances
Molecular Water and Sample Reagent	2000 µl (500 µl water, 1500 µl Sample Reagent)	Vortex for 10 seconds	N/A























## LIMITATIONS

- These products are unassayed control material. They 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.

## MICROBIOLOGICAL STATE

These products were prepared using suitable inactivation methods. While these products have 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
	Device for near-patient testing		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		Water; Fluid
	EU Authorized Representative		

Please refer to product labels for applicable symbols.

## NOTICE TO PURCHASERS

The purchase of these products 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 these products.

The Microbiologics logo is a registered trademark of Microbiologics, Inc.

## WEBSITE

Visit our website, [www.microbiologics.com](http://www.microbiologics.com), for current technical information and product availability.

## BIBLIOGRAPHY

- Jamieson FB, Guthrie JL, Neemuchwala A, Lastovetska O, Melano RG, Mehaffy C. Profiling of rpoB mutations and MICs for rifampin and rifabutin in Mycobacterium tuberculosis. J Clin Microbiol. 2014;52(6):2157-2162. doi:10.1128/JCM.00691-14

## ASSISTANCE



### Microbiologics, Inc.

200 Cooper Avenue North  
St. Cloud, MN 56303 USA  
[www.microbiologics.com](http://www.microbiologics.com)

### Customer Service

Tel: +1.320.253.7400  
U.S. Toll Free: +1.800.599.2847  
Email: [info@microbiologics.com](mailto:info@microbiologics.com)

### Technical Support

Tel: +1.320.229.7045  
U.S. Toll Free: +1.866.286.6691  
Email: [techsupport@microbiologics.com](mailto:techsupport@microbiologics.com)



### MediMark® Europe

11 rue Emile Zola  
38100 Grenoble, France  
Tel: +33 (0)4 76 86 43 22  
Fax: +33 (0)4 76 17 19 82  
Email: [info@medimark-europe.com](mailto:info@medimark-europe.com)



### International Associates Limited

Centrum House, 38 Queen Street,  
Glasgow, Lanarkshire, G1 3DX, UK  
[UKRP@ia-uk.com](mailto:UKRP@ia-uk.com)



### Decomplic AG

Freiburgstrasse 3, 3010  
Bern, Switzerland

Additional copies of this product insert may be obtained at [www.microbiologics.com](http://www.microbiologics.com) or by emailing [info@microbiologics.com](mailto:info@microbiologics.com)

## ILLUSTRATED INSTRUCTIONS

The Rifampicin-Resistant Mycobacterium tuberculosis Positive Control Panel (Inactivated Pellet) consists of 3 positive controls with 6 individually packaged lyophilized pellets of each control. The Rifampicin-Resistant Mycobacterium tuberculosis Negative Control (Inactivated Pellet) consists of 6 individually packaged lyophilized 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**

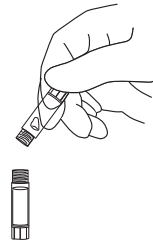


Tear open pouch at notch. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.

**3**

Hydrate the lyophilized pellet into a vial/tube of molecular water and sample reagent.

Minimum hydration volume of 2000  $\mu$ l (500  $\mu$ l molecular water, 1500  $\mu$ l sample reagent) is recommended.



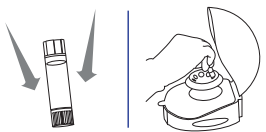
For known extrinsic factors and interfering substances, please refer to Table 2.

**4**



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

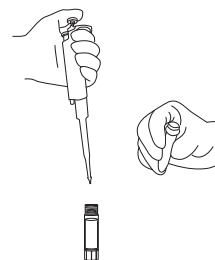
**5**



If a centrifuge is not available, tap the capped vial/tube on a rigid surface to collect material at the bottom of the vial/tube. Alternatively, centrifuge briefly to collect any droplets clinging to the cap or upper walls of the vial/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	2023-06-13	Initial Release to IVDR
B	2025-08	Added Bibliography section, updated MediMark® Address and replaced EC rep Symbol with EU Rep.

