INSTRUCTIONS FOR USE

IVD UK CA CE 2797

8180 Gram-Positive Blood Culture Control Panel (Inactivated Pellet)

8181 Gram-Negative Blood Culture Control Panel (Inactivated Pellet)

INTENDED USE

The Gram-Positive and Gram-Negative Blood Culture Control Panels (Inactivated Pellet) are intended for use as non-viable, external, positive 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 Gram-Positive and Gram-Negative Blood Culture Control Panels (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 Gram-Positive and Gram-Negative Blood Culture Control Panels (Inactivated Pellet) both consist of 3 positive controls with 5 individually packaged lyophilized pellets of each control. The analytes in Table 1 have been inactivated using thermal treatments.

The Gram-Positive and Gram-Negative Blood Culture Control Panels (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.

HELIX|ELITE™ MOLECULAR STANDARDS

Microbiologics® QC SETS AND PANELS

Table 1: Contents of the Gram-Positive and Gram-Negative Blood Culture Control Panels (Inactivated Pellet)

Gram-Positive Blood Culture Control Panel (Inactivated Pellet) Analytes*
Positive Control 1
Enterococcus faecium (vanA)
Listeria monocytogenes
Staphylococcus epidermidis
Staphylococcus lugdunensis
Positive Control 2
Streptococcus agalactiae
Streptococcus anginosus
Streptococcus pyogenes
Positive Control 3
Staphylococcus aureus (mecA)
Enterococcus faecalis (vanB)
Streptococcus pneumoniae
Gram-Negative Blood Culture Control Panel (Inactivated Pellet) Analytes*
Positive Control 1
Acinetobacter baumannii
Pseudomonas aeruginosa
Enterobacter cloacae (CTX-M)
Positive Control 2
Klebsiella pneumoniae (KPC)
Citrobacter freundii
Escherichia coli (IMP)
Klebsiella pneumoniae (CTX-M, NDM)
Klebsiella pneumoniae (VIM)
Positive Control 3
Klebsiella oxytoca
Klebsiella pneumoniae (OXA)
Proteus vulgaris

*All analytes are added at a target concentration of 10^6 - 10^8 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 or by contacting Customer Service at 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 Gram-Positive and Gram-Negative Blood Culture Control Panels (Inactivated Pellet) at 2°C-8°C in the original packaging up to the indicated expiration date. After opening the foil pouch, rehydrate and use immediately.

The Gram-Positive and Gram-Negative Blood Culture Control Panels (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
- 1.5-ml microcentrifuge tubes
- For Gram-Positive Blood Culture Control Panel (Inactivated Pellet) a rehydration fluid/buffer such as sterile DI water or pH 7.2 phosphate buffer as required by assay to be performed
- For Gram-Negative Blood Culture Control Panel (Inactivated Pellet) a rehydration fluid/buffer such as sterile 0.85% saline or pH 7.2 phosphate buffer 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 hydration fluid/buffer recommended by the assay manufacturer.
   a. If not using a provided hydration fluid/buffer from the assay manufacturer, please refer to Table 2 below for sample volume and known extrinsic factors and interfering substances.
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
8180 Gram-Positive Blood Culture Control Panel (Inactivated Pellet)			
Sterile DI Water	500 µl	Vortex for 10 seconds	Sodium Chloride (NaCl) and substances containing NaCl (e.g. saline) and other salts
pH 7.2 Phosphate Buffer	500 µl	Vortex for 10 seconds	Sodium Chloride (NaCl) and substances containing NaCl (e.g. saline) and other salts
8181 Gram-Negative Blood Culture Control Panel (Inactivated Pellet)			
Sterile 0.85% Saline	1000 µl	Vortex for 10 seconds	N/A
pH 7.2 Phosphate Buffer	1000 µl	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

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

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WEBSITE

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

BIBLIOGRAPHY

- Claeys KC, Heil EL, Hitchcock S, Johnson JK, Leekha S. Management of Gram-Negative Bloodstream Infections in the Era of Rapid Diagnostic Testing: Impact With and Without Antibiotic Stewardship. Open Forum Infect Dis. 2020;7(10):ofaa427. Published 2020 Sep 12. doi:10.1093/ofid/ofaa427
- Mestas J, Polanco CM, Felsenstein S, Dien Bard J. Performance of the Verigene Gram-positive blood culture assay for direct detection of Gram-positive organisms and resistance markers in a pediatric hospital. J Clin Microbiol. 2014;52(1):283-287. doi:10.1128/JCM.02322-13

ASSISTANCE

Microbiologics, Inc.
200 Cooper Avenue North
St. Cloud, MN 56303 USA
www.microbiologics.com

Customer Service
Tel: +1.320.253.7400
U.S. Toll Free: +1.800.599.2847
Email: info@microbiologics.com

Technical Support
Tel: +1.320.229.7045
U.S. Toll Free: +1.866.286.6691
Email: techsupport@microbiologics.com

EU REP **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

UK REP **International Associates Limited**
Centrum House, 38 Queen Street,
Glasgow, Lanarkshire, G1 3DX, UK
UKRP@ia-uk.com

CH REP **Decomplix AG**
Freiburgstrasse 3, 3010
Bern, Switzerland

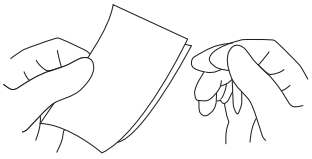
Additional copies of this product insert may be obtained at **www.microbiologics.com** or by emailing info@microbiologics.com

ILLUSTRATED INSTRUCTIONS

Each kit consists of 3 positive controls with 5 individually packaged lyophilized pellets of each control.

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.

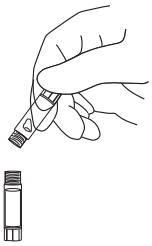


2

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 hydration fluid/buffer recommended by the assay manufacturer.

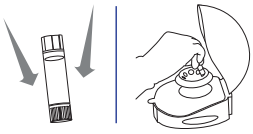


If not using a provided hydration fluid/buffer from the assay manufacturer, please refer to Table 2 for sample volume and known extrinsic factors and interfering substances.

4

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

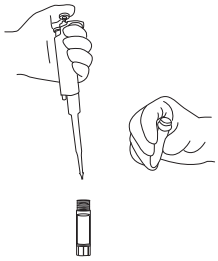
5



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.



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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	2025-07	Added Bibliography section, updated MediMark® Address and replaced EC rep Symbol with EU Rep.