

INSTRUCTIONS FOR USE



■ Parasite Suspensions in Formalin

INTENDED USE

Microbiologics Parasite Suspensions support quality assurance programs by serving as quality control challenges containing specific parasitic populations of known characteristics. These samples support formal quality assurance programs by serving as quality control challenges, to document personnel's proficiency when performing procedures and to properly interpret microscopic test results. Microbiologics Parasite Suspensions may also be used for teaching purposes in an educational setting.

SUMMARY AND EXPLANATION

These types of samples are typically used for educational purposes, or for testing the proficiency of personnel in identifying and testing for particular organisms.

PRINCIPLES

This product is intended to be used in one or more of the following techniques depending on the characteristics of the organism:

- Immunoassay for the detection of antigens
- Wet mount microscopy to observe morphological characteristics of the organism
- Acid-Fast staining to observe staining and morphological characteristics of the organism

COMPOSITION

- Parasites (See catalog or website, www.microbiologics.com, for specific details about each parasite)
- Fecal material
- Formalin solution, neutral buffered, 10%

WARNINGS AND PRECAUTIONS

DANGER. Toxic if swallowed. Toxic if inhaled. Potential cancer hazard.

- For in vitro diagnostic use only.
- For professional use only.
- See the Safety Data Sheet, located on the Microbiologics website, www.microbiologics.com, for complete precautions and safety instructions.
- Do not handle until all safety precautions have been read and understood.
- Use personal protective equipment as required. Wear protective gloves/protective clothing/eye protection/face protection.
- IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth.
- If exposed or concerned: Get medical advice/attention.
- Causes skin irritation. Wash hands thoroughly after handling.
- May cause an allergic skin reaction.
- May cause damage to organs.
- Contaminated work clothing should not be allowed out of the workplace.
- Causes serious eye irritation. IF IN EYES: Rinse cautiously with water for several minutes. Remove contacts, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
- May cause respiratory irritation. Avoid breathing dust/fume/gas/mist/vapours/spray. Use only in a well-ventilated area.
- Do not eat, drink or smoke when using this product.
- Though these suspensions contain fixed, non-viable organisms, for the safety of all personnel they should be handled as if they contain biohazard material.
- The laboratory must be equipped to, and have the facilities to receive, process, maintain, store, and dispose of biohazard material.
- All Microbiologics products and packaging are latex free.

PARASITE
SUSPENSIONS

INSTRUCTIONS FOR MIXING _____

The sample shall be mixed by vigorous shaking by hand, or by vortexing.

STORAGE AND EXPIRATION _____

The Parasite Suspensions should be stored at 15°C - 30°C.

Store in a well-ventilated place. Keep container tightly closed. Store locked up. The expiration date of these products is two years from the date of manufacture. The Parasite Suspensions should not be used if:

- They are stored improperly
- There is evidence of exposure to excessive heat or damage to the containers
- The expiration date has passed

Comply with state and local regulations for disposal of this product.

INSTRUCTIONS FOR USE _____

These samples can be used for wet mounts, antigen detection, and Acid-Fast staining.

For all procedures:

1. Thoroughly mix the suspension by vigorously shaking or vortexing.
2. Allow the suspension to settle for 5-10 minutes before use in any testing procedure.
3. Carefully insert a pipette into the bottom of the vial and remove a single drop for testing. Consult laboratory SOPs, or stain, or kit manufacturer instructions for testing procedures.

MATERIAL AND EQUIPMENT REQUIRED BUT NOT PROVIDED _____

- Timer
- Transfer pipettes
- Any other materials specified by the SOP or kit being used

QUALITY CONTROL _____

Consult laboratory SOP or manufacturer instructions for quality control needs.

LIMITATIONS _____

This product may not be suitable for use with all kits and procedures. Please see kit manufacturer instructions for sample details. For professional use only.

MICROBIOLOGICAL STATE _____

This sample contains fixed, non-viable organisms.

KEY OF SYMBOLS



Batch Code (Lot)



Health Hazard



Catalog Number



Attention, see Instructions for Use



Refer to Instructions for Use



In Vitro Diagnostic Medical Device



Manufacturer



Temperature Limitation



Use By



Acute toxicity



CE Mark



Authorized Representative in the European Community

PRODUCT WARRANTY

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

1. The procedures employed in the laboratory are contrary to printed and illustrated directions and instructions.
2. The products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature.

REFERENCES

1. Ash, L.R., and Orihel, T.C. Atlas of Human Parasitology- 2nd Ed. (American Society of Clinical Pathologists, 1984)
2. Garcia, L.S. A Practical Guide to Diagnostic Parasitology (ASM Press, 2009)

WEBSITE

Visit our website for current technical information and product availability.

www.microbiologics.com

ACKNOWLEDGEMENTS



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MediMark® Europe

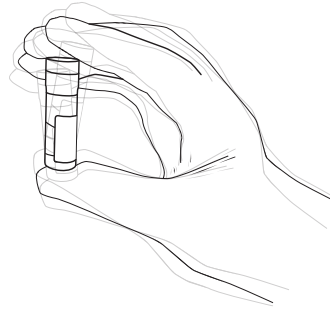
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PARASITE SUSPENSIONS

ILLUSTRATED INSTRUCTIONS

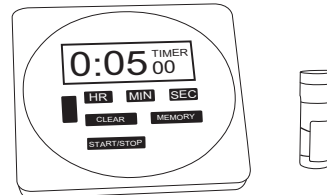
1

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