INSTRUCTIONS FOR USE

CE IVD

Parasite Suspensions in Formalin

INTENDED USE

Parasite Suspensions are intended for use as external non-viable control materials without a qualitative or quantitative assigned value for visually evaluating the morphological characteristics of the parasites in Table 1 using wet mount microscopy and/or traditional staining techniques. 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 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:

- 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 Table 1 for list of Parasite Suspensions)
- Fecal material
- Formalin solution, neutral buffered, 10%

Table 1: Parasite Suspensions

Catalog Number	Description
FP01	Parasite Suspensions Giardia lamblia
FP02	Parasite Suspensions Cryptosporidium species
FP03	Parasite Suspensions Diphyllobothrium latum
FP04	Parasite Suspensions Taenia species
FP05	Parasite Suspensions Ascaris lumbricoides
FP06	Parasite Suspensions Strongyloides stercoralis
FP08	Parasite Suspensions Trichuris trichiura
FP09	Parasite Suspensions Iodamoeba buetschlii
FP10	Parasite Suspensions Necator americanus
FP11	Parasite Suspensions Hymenolepis nana
FP12	Parasite Suspensions Endolimax nana
FP13	Parasite Suspensions Entamoeba coli

PARASITE SUSPENSIONS

Microbiologics

WARNINGS AND PRECAUTIONS

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

- For in vitro diagnostic use only.
- For professional use only. To be used by personnel trained in the use of the device.
- Each droplet of the provided suspension is single-use only. Do not reuse or freeze.
- Product contains formalin, which is a known interfering substance for polymerase chain reaction (PCR) experiments.
- All Microbiologics products and packaging are latex free.
- 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.
- 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.

MATERIAL AND EQUIPMENT REQUIRED BUT NOT PROVIDED

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

INSTRUCTIONS FOR USE

These samples can be used for wet mounts 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 droplet for testing. The droplet should be used immediately for traditional staining or wet mount microscopy. Consult laboratory SOPs, or stain, or kit manufacturer instructions for testing procedures.

STORAGE AND EXPIRATION

The Parasite Suspensions should be stored at 15°C - 30°C. Do not freeze, 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 stability of the suspension after opening the vial, when stored at these conditions, 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
- The package is damaged.

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

QUALITY CONTROL

Consult laboratory SOP or manufacturer instructions for quality control needs.

LIMITATIONS

Control materials are unassayed, have no assigned value, and may not be suitable for use with all kits and procedures. The customer is responsible for verifying the performance of this product with their chosen instrumentation and assay. Please see kit manufacturer instructions for sample details.

MICROBIOLOGICAL STATE

This sample contains fixed, non-viable organisms.

KEY OF SYMBOLS

	Exclamation Mark		Do not re-use
EC REP	Authorized Representative in the European Community		Do not use if package is damaged and consult instructions for use
LOT	Batch Code (Lot)		Health Hazard
	Biological Risks	IVD	In Vitro Diagnostic Medical Device
REF	Catalog Number		Manufacturer
	Caution		Temperature limit
CE	CE Mark		Use-By Date
	Consult instructions for use or consult electronic instructions for use	UK CA	UK Conformity Assessed mark
EU REP	EU Authorized Representative	UK REP	UK Responsible Person
CH REP	Swiss Authorized Representative		

Please refer to product labels for applicable symbols.

BIBLIOGRAPHY

- Ash, L. R., & Orihel, T. C. (1984). Atlas of human parasitology (2nd ed.). American Society of Clinical Pathologists.
- Garcia, L.S.(2009). A Practical Guide to Diagnostic Parasitology. American Society of Microbiology.

WEBSITE

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

ACKNOWLEDGEMENTS

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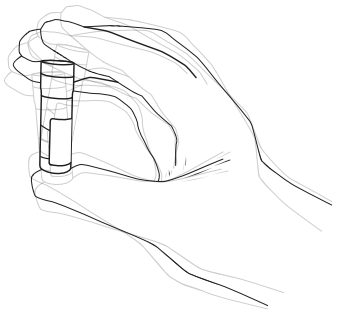
PARASITE
SUSPENSIONS

ILLUSTRATED INSTRUCTIONS

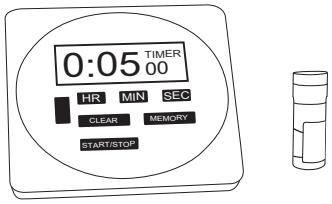
1

Thoroughly mix the suspension by vigorously shaking or vortexing.



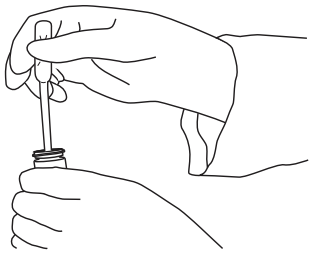
2

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.



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REVISION HISTORY

Publication History		
Revision	**Date**	**Description of Change**
H	2022-08-05	Revised intended use section verbiage, added EU warnings and precautions, added biological risks and do not use if package is damaged and consult instructions for use symbols to Key of Symbols, updated Key of Symbols symbol descriptions, alphabetized the key of symbols, added revision history table. Removed “Immunoassay for the detection of antigens” in Principles section. Added “To be used by personnel trained in the use of the device” in Warnings and Precautions section. Removed “These products do not contain any hazardous substances listed in 1272/2008/EC” in Warnings and Precautions section. Added “Do not freeze”, “The stability of the products after opening the vial, when stored at these conditions, is two years from the date of manufacture”, and “should not be used if the package is damaged” in Storage and Expiration section. Revised verbiage in Limitations section. Added statement about single-use only to Warning and Precautions section, removes Instructions for Mixing section, revised Storage and Expiration section, revised Instructions for Use section step #3, adjusted order/layout of sections, added "Do Not Re-Use" symbol to Key of Symbols.
I	2025-09	Updated Bibliography section, updated MediMark Address, replaced EC Rep Symbol with EU Rep, removed Warranty information, Updated GHS symbol, add UKCA symbol, UK Rep and CH Rep.