



MicroBiologics®

EZ-COMP™ Samples

Lyophilized microorganism preparations for personnel competency assessment, analyst proficiency programs and internal proficiency testing.

Documentation (LIT.023A) is provided in the yellow envelope that lists the identification codes for the EZ-COMP™ samples. The individual conducting the competency or proficiency evaluation should file this document for reference.

INTENDED USE

EZ-COMP™ Samples are lyophilized preparations of mixed reference stock culture populations. Each sample contains a “target” microorganism and a microbiota or “mixed” population of microorganisms.

SUMMARY AND PRINCIPLE

Quality assurance programs in microbiology laboratories can be mandated by regulatory agencies, required by accrediting agencies, or simply support test results of known and defensible quality. Included in quality assurance programs is a system to assess and document the competency or proficiency of personnel to perform and interpret laboratory test procedures. Also, internal proficiency testing is employed to assess or evaluate the reliability and reproducibility of a test method to detect a target microorganism(s).

EZ-COMP™ Samples are a reliable source of materials for competency and proficiency testing.

PRINCIPLE

EZ-COMP™ Samples incorporate a lyophilization method reported by Obara et.al. which uses a suspending medium consisting of gelatin, skim milk, ascorbic acid, dextrose, and charcoal. The gelatin serves as a carrier for the microorganism. Skim milk, ascorbic acid, and dextrose protect the microorganism by preserving the integrity of the cell wall during freeze-drying and storage. The charcoal is included to neutralize any toxic substances formed during the lyophilization process.

FORMULA COMPONENTS

The lyophilized preparation consists of:

- Microorganism populations
- Gelatin
- Skim milk
- Ascorbic acid
- Dextrose
- Charcoal

SPECIFICATIONS AND PERFORMANCE

Each **EZ-COMP™ Sample** package includes:

- Two (2) latex free KWIK-STIK™ units of a mixed lyophilized microorganism population; a reservoir of hydrating fluid and a Dacron inoculating swab. Each device is sealed within a laminated pouch that contains a desiccator to prevent adverse moisture accumulation.
- Detailed instructions.

These lyophilized microorganism preparations result in a mixed population of microorganisms which are four (4) passages from reference culture and are traceable to the American Type Culture Collection (ATCC®) or other authentic reference culture collection.

PRECAUTIONS AND LIMITATIONS

- These products are for in-vitro use only.
- These devices, and subsequent growth of these microorganisms on culture media, are considered to be biohazard material.
- These devices contain viable microorganisms that may, under certain circumstances, produce disease. Proper techniques must be employed to avoid contact with any microorganism growth.
- The microbiology laboratory must be equipped, and have the facilities to receive, process, maintain, store and dispose of biohazard material.
- The microbiology laboratory personnel using these devices must be trained, experienced and demonstrate proficiency in processing, maintaining, storing and disposing of biohazard material.



- Agencies and statutes do regulate the disposal of all biohazard materials. Each laboratory must be aware of, and comply with, the proper disposal of biohazard materials.

STORAGE AND EXPIRATION

Store the **EZ-COMP™ Samples** at 2°C to 8°C in the original, sealed pouch containing the desiccator.

Stored as directed, the lyophilized microorganism preparation will retain, until the expiration date stated on the device label, its specifications and performance within the stated limits.

The **EZ-COMP™ Samples** should not be used if:

- The laminated pouch has been damaged, torn or punctured
- Stored improperly
- There is evidence of excessive exposure to heat or moisture
- The expiration date has passed

MATERIALS REQUIRED BUT NOT PROVIDED

Each **EZ-COMP™ Sample** simulates a clinical or a food sample. Each individual laboratory must provide all the equipment, materials, and methods required by its standard laboratory protocol to perform each specific laboratory test procedure.

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:
 - the procedures employed in the laboratory are contrary to printed and illustrated directions and instructions; or,
 - the products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature.

INSTRUCTIONS FOR USE**A. Sample Hydration**

1. The individual whose competency or proficiency is being assessed, or the individual responsible for performing internal proficiency challenge, must be provided with the following important information:
 - The source of the sample
 - The laboratory test procedure requested
 - Pertinent information to complete the assessment or challenge

Given this information, the individual will be able to process the **EZ-COMP™ Sample** as follows:

2. Remove the **EZ-COMP™ Sample** from 2°C to 8°C storage and allow the unopened pouch to equilibrate to room temperature.
3. Open the pouch and remove the KWIK-STIK™ unit.
4. Tear off the pull-tab from the KWIK-STIK™ unit. This label carries a code that identifies the microorganism(s) in the sample. Record the code or attach the label to the competency assessment checklist.
5. Take note of the position of the pellet in the bottom part of the device and the reservoir of hydrating fluid in the top (cap) part of the device. The fluid can be seen clearly if the device is held up to the light.
DO NOT DISASSEMBLE THE DEVICE DURING HYDRATION
6. Release the hydrating fluid by pinching the ampoule in the cap just below the fluid meniscus. Allow the hydrating fluid to flow through the swab shaft and into the bottom portion of the unit containing the gelatin pellet.
7. Hold the device vertically, with the cap up, and tap the bottom of the device on the counter to further facilitate the flow of the fluid.
8. Using a pinching action on the bottom portion of the unit, crush, and mix the pellet in the fluid until the pellet particles are uniform in size and the suspension is homogenous in appearance.

DO NOT INCUBATE**B. Clinical Simulated Samples**

1. IMMEDIATELY, saturate the swab with the hydrated material and transfer the material to the culture media dictated by the laboratory protocol. On agar media, with slight pressure, rotate the swab, and inoculate one third of the agar medium. Using a sterile loop, streak through the inoculated area and then continue to streak the remainder of the agar surface for isolation.



2. IMMEDIATELY, incubate the inoculated media at temperature and environmental conditions dictated by laboratory protocol.
3. Following incubation, select representative well-isolated colonies for subsequent testing and indicated transfers, as dictated by laboratory protocol.

C. Food Simulated Samples

1. IMMEDIATELY, saturate the swab with the hydrated material and transfer the material to enrichment broth as dictated by laboratory protocol for qualitative analysis.
2. IMMEDIATELY, incubate the enrichment broth as dictated by laboratory protocol.
3. Proceed with subsequent testing steps as dictated by laboratory protocol.

IMPORTANT CONSIDERATIONS

1. Discard any remaining hydrated material in accordance with the laboratory protocol for disposal of biohazard materials.
2. The composition of the **EZ-COMP™ Sample** precludes its use as a reliable source of material for direct microscopic examinations.
3. The composition of the **EZ-COMP™ Sample** and the different technologies utilized in direct test methods (e.g. Direct Group A Streptococcus Tests) may preclude its use as a reliable source of material for direct tests.
4. Of equal importance to obtaining correct test results, is the ability of laboratory personnel to follow specific directives outlined in the Laboratory Procedure Manual or Laboratory S.O.P. Examples of these considerations include ALL the steps from sample receipt to issuing the final report.

BIOHAZARD CLEANUP

Should accidental leakage or spilling of the device or subsequent growth of the microorganism on agar media occur, the following information outlines materials and procedures which will safely facilitate the clean up of biohazard material.

1. **Material Safety Data Sheet (MSDS)**
 - A file must be maintained of all MSDS documents for biohazard material.
 - The MSDS file must be available to all employees.
 - All employees must be made aware of the location of the MSDS files.
2. **Biohazard Spill Kit**

Biohazard Spill Kits are available from commercial sources or can be made with the following materials.

 - One liter bottle of an aqueous germicidal solution
 - One pair of disposable latex and/or latex free gloves
 - One tweezers
 - One Biohazard Bag with Closure
 - One stack or roll of paper towels
3. **Procedure**
 - Notify **ALL** people working in the immediate area of the incident.
 - Do **NOT** leave the area unattended (unless you are the only individual in the area). Designate another employee to watch the incident area and divert traffic away from the incident area.
 - After notifying all employees in the immediate area, collect the Biohazard Spill Kit and **IMMEDIATELY** return to the area.
 - Put on the disposable gloves.
 - With the tweezers, pick up as much material as possible and carefully place the materials into the Biohazard Bag.
 - Saturate the spill area with germicidal solution.
 - Keep the spill area moist with the germicidal solution for the appropriate amount of time as indicated on the germicidal solution used.
 - Wipe up the area with the paper towels.
 - Place all used paper towels in the Biohazard Bag.
 - Following the cleanup, carefully remove the gloves and place into the Biohazard Bag.
 - Seal the Biohazard Bag.
 - Dispose of the Biohazard Bag in compliance with regulatory requirements.

**QUALITY CONTROL**

This product is developed, manufactured, and distributed:

- In compliance with the mandates of FDA: Quality System Regulation (QSR), 21CFR Part 820
- In conformance with the elements of ISO 9001:2000

Quality control functions may include, but are not limited to:

- Purity and growth characteristics
- Morphological features
- Biochemical activity
- The identity and traceability of the microorganism preparation to a reference culture
- The number of passages the microorganism preparation has been removed from the reference culture

The decision to perform additional quality control is the responsibility of each individual laboratory.

REFERENCES

The following reference cites the basis for the lyophilization method employed on these microorganism preparations.

1. Y. Obara, S. Yamai, T. Nikkawa, Y. Shimoda, and Y. Miyamoto. 1981. J. Clin. Microbiol. 14:61-66.

KEY OF SYMBOLS

Batch Code (Lot)



Biological Hazards
Biological Risks



Catalog Number



Caution consult accompanying documents
Attention, see instructions for use



Manufacturer



Temperature Limitation



Use By

WEB SITE

Visit our web site for current technical information and product availability.

www.microbiologics.com

ACKNOWLEDGEMENTS

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