INSTRUCTIONS FOR USE

CE IVD

Lab-Elite™ Certified Reference Material

INTENDED USE

Lab-Elite™ Certified Reference Material (CRM) is a pure, homogenous, stable, preparation of lyophilized microorganism with well-characterized microscopic, macroscopic, phenotypic and genotypic characteristics.

A Certificate of Analysis, provided with the CRM, lists the phenotypic properties of the strain as well as the American Type Culture Collection (ATCC®) or other authentic reference culture number.

These microorganism preparations are intended to be used for quality control of culture media, educational/instructional programs, method validation and other industrial quality control applications.

SUMMARY AND HISTORY

Microbiologics became ISO Guide 34 accredited in 2009 as a qualified reference material producer. ISO Guide 34 defines reference material as material that is "sufficiently homogeneous and stable with respect to one or more properties, which has been established to be fit for its intended use in a measurement process. Properties can be quantitative or qualitative (e.g. identity of substances or species)".

Homogeneity of CRM is ensured by testing a statistically valid number of samples from each new lot for purity, viability and morphological characteristics. In order for the new lot of CRM to be released for sale, all samples must be pure, grow satisfactorily, and demonstrate morphological characteristics typical for the strain. Stability is monitored by testing the viability of each CRM lot at the end of its shelf life.

Lab-Elite™ Certified Reference Material is a lyophilized microorganism preparation. The use of this lyophilized material provides equivalent results to traditional methods used in preparing, storing and maintaining reference stock culture collections.

LAB-ELITE™

Microbiologics®

A safer, healthier world.

PRINCIPLE

Lab-Elite™ Certified Reference Material incorporates a lyophilization method, proposed 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

Microorganism population	Skim milk	Dextrose
Gelatin	Ascorbic acid	Charcoal

PRODUCT DESCRIPTION

Lab-Elite™ Certified Reference Material is packaged inside a unit called a KWIK-STIK™. Each KWIK-STIK™ unit contains a lyophilized pellet of a single microorganism strain, a reservoir of hydrating fluid and an inoculating swab. The unit is sealed within a laminated pouch that contains a desiccant to prevent adverse moisture accumulation.

Lab-Elite™ Certified Reference Material is shipped in a canister containing one KWIK-STIK™ unit, a Certificate of Analysis, and the instructions for use.

- Certificate of Analysis: Lists the microorganism name, catalog number, ATCC® or other authentic reference culture number, purity, recovery, expiration date, release information, macroscopic and microscopic features and phenotypic test results.

No mercury or latex is contained in the lyophilized preparation or KWIK-STIK unit.

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 exposure and 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 laboratories personnel using these devices must be trained and able to 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 Lab-Elite™ Certified Reference Material at 2°C to 8°C in the original, sealed pouch containing the desiccator. Stored as directed, the lyophilized microorganism preparation will retain its specifications and performance within the stated limits until the expiration date stated on the device label. The product should not be used if:

- Stored improperly;
- There is evidence of excessive exposure to heat or moisture; or,
- The expiration date has passed.

INSTRUCTIONS FOR USE

1. Allow the unopened Lab-Elite™ (KWIK-STIK™) pouch to equilibrate to room temperature. Tear open pouch at notch and remove the KWIK-STIK™ unit.
2. Tear off Pull-Tab portion on the label and attach it to the primary culture plate or QC record. Do not disassemble the device during hydration.
3. Pinch (once only) the ampoule at the top of the KWIK-STIK™ (just below the fluid meniscus of the ampoule) found in the cap to release the hydrating fluid.
4. Hold vertically and tap on a hard surface to facilitate flow of fluid through shaft into bottom of unit containing pellet. Allow the hydrating fluid to flow through the swab shaft and into the bottom portion of the unit containing the pellet.
5. Using a pinching action on the bottom portion of the unit, crush the pellet in the fluid until the pellet suspension is homogenous.
6. IMMEDIATELY heavily saturate the swab with the hydrated material and transfer to agar medium.
7. Inoculate the primary culture plate(s) by gently rolling the swab over one-third of the plate.
8. Using a sterile loop, streak to facilitate colony isolation.
9. Using proper biohazard disposal, discard the KWIK-STIK™.
10. IMMEDIATELY incubate the inoculated primary culture plate(s) at temperature and conditions appropriate to the microorganism.

MATERIALS REQUIRED BUT NOT PROVIDED

The Technical Information Bulletin (TIB.081) “Recommended Growth Requirements” lists the recommended media and incubation requirements. This bulletin is available from our web site at www.microbiologics.com.

- Lab-Elite™ Certified Reference Material requires non-selective, nutrient or enriched agar media to optimize growth and recovery.
- Lab-Elite™ Certified Reference Material requires specific incubation times and conditions to optimize growth and recovery.

KEY OF SYMBOLS

Authorized Representative in the European Community

Batch Code (Lot)


Biological Hazards Biological Risk


CE Mark

Catalog Number


Caution consult accompanying documents Attention, see instructions for use

In Vitro Diagnostic Medical Device


Manufacturer


Temperature Limitation


Use By

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 CE Mark requirements
- In conformance with ISO Guide 34

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

PRODUCT WARRANTY

These products are covered under warranty 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
- The products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature.

REFERENCES

1. ISO Guide 34:2009. International Organization for Standardization. 3rd Edition, 2009. Prepared by the ISO Reference Materials Committee

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

The selection of reference stock cultures is only one integral part of the overall scheme for QC challenge procedures and techniques. Reference to guidelines for each laboratory's applications is essential. Examples might include:

1. Clinical Microbiology Procedures Handbook. ASM. Washington, D.C.

2. FDA Bacteriological Analytical Manual.

3. Manual of Clinical Microbiology, ASM, Washington, D.C.

4. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically. CLSI.

5. Official Methods of Analysis of the Association of Official Analytical Chemists.

6. Performance Standards for Antimicrobial Disk Susceptibility Tests. CLSI.

7. Quality Assurance for Commercially Prepared Microbiological Culture Media. CLSI.

8. Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria. CLSI.

9. Standard Methods for the Examination of Dairy Products. American Public Health Association.

10. Standard Methods for the Examination of Water and Wastewater. American Water Works Association.

11. US Pharmacopeia and National Formulary

ACKNOWLEDGEMENTS

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WEBSITE

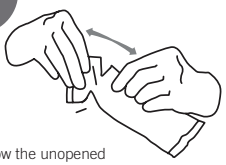
Visit our website for current technical information and product availability.

www.microbiologics.com

ILLUSTRATED INSTRUCTIONS

One self contained device including a lyophilized microorganism pellet, reservoir of hydrating fluid and inoculating swab (KWIK-STIK™ format).

1



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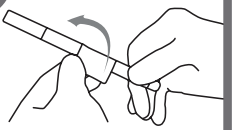
2



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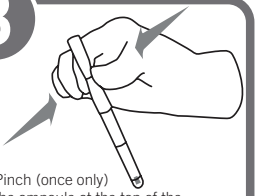
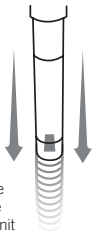
3



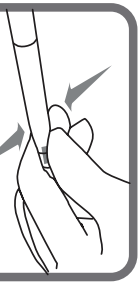
Pinch (once only) the ampoule at the top of the KWIK-STIK™ (just below the fluid meniscus of the ampoule) found in the cap to release the hydrating fluid.

4



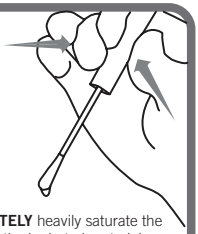
Hold vertically and tap on a hard surface to facilitate flow of fluid through shaft into bottom of unit containing pellet. Allow the hydrating fluid to flow through the swab shaft and into the bottom portion of the unit containing the pellet.

5



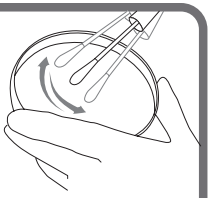
Using a pinching action on the bottom portion of the unit, crush the pellet in the fluid until the pellet suspension is homogenous.

6



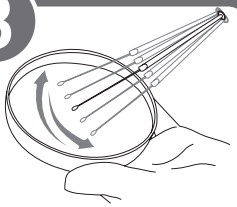
IMMEDIATELY heavily saturate the swab with the hydrated material and transfer to agar medium.

7



Inoculate the primary culture plate(s) by gently rolling the swab over one-third of the plate.

8



Using a sterile loop, streak to facilitate colony isolation.

9

Using proper biohazard disposal, discard the KWIK-STIK™.

10

IMMEDIATELY incubate the inoculated primary culture plate(s) at temperature and conditions appropriate to the microorganism.

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