

INSTRUCTIONS FOR USE



■ 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 EXPLANATION _____

Microbiologics is an accredited reference and certified reference material producer under ISO 17034. This standard defines a reference material as “material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.” ISO 17034 also defines a certified reference material (CRM) as “material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.” Each lot of Lab Elite™ CRM microorganisms is tested using Microbiologics’ metrologically valid procedures. The results from these procedures, including statements of the specified value and associated uncertainty, are listed on the Certificate of Analysis and are unique to the stated lot.

COMPOSITION _____

Lab-Elite™ Certified Reference Material (CRM) pellets contain a pure population of microorganisms and excipients for the purpose of structure and/or stability including gelatin, skim milk, ascorbic acid, carbohydrate, and charcoal.

PRODUCT DESCRIPTION _____

Each Lab-Elite™ unit contains a lyophilized pellet of a single microorganism strain, a reservoir of hydration fluid and an inoculating swab. The unit is sealed within a laminated pouch that contains a desiccant to prevent adverse moisture accumulation. The Lab Elite™ CRM is one passage from the reference culture.

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

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

No mercury or latex is contained in the lyophilized preparation or Lab-Elite™ unit.



CERTIFIED REFERENCE MATERIAL
Lab-Elite™

PRECAUTIONS AND LIMITATIONS

- Not intended for clinical use.
- This product may not be suitable for use with all kits and procedures.
- Not intended for human, animal or pet consumption.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located on our website at www.microbiologics.com or by contacting Technical Support at 1.320.229.7045 or U.S. Toll Free 1.866.286.6691.
- The hydration fluid in the Lab-Elite™ unit may cause serious eye irritation. If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation persists, get medical advice/attention.
- Wear protective gloves/protective clothing/eye protection/face protection. Wash hands thoroughly after handling.
- These devices contain viable microorganisms that may 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.
- Only trained laboratory personnel should use these devices.
- Agencies and statutes regulate the disposal of all biohazard materials. Each laboratory must be aware of and comply with the proper disposal of biohazard materials.
- Lab-Elite™ unit microorganisms are not made with natural rubber latex.

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 website 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.

INSTRUCTIONS FOR USE

1. Allow the unopened Lab-Elite™ pouch to equilibrate to room temperature. Tear open pouch at notch and remove the Lab-Elite™ 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. Over the edge of the work bench or counter, crack the ampoule at the top of the Lab-Elite™ unit (just below the fluid meniscus) to release the hydration fluid. Crack the ampoule only once. Cracking the ampoule multiple times may cause glass shards to puncture the plastic housing, creating a risk for injury.
4. Hold vertically and tap on a hard surface to facilitate flow of the fluid through the shaft into the bottom of the unit where the pellet is contained. Do not shake the Lab-Elite™ unit and do not cover the small vent hole on the top of the Lab-Elite™ unit.
5. Using a pinching action on the bottom portion of the unit, crush the pellet in the fluid until the pellet has dissolved.
6. Immediately heavily saturate the swab with the hydrated material and transfer to the appropriate agar medium or use according to the laboratory's SOP. Use immediately upon hydration.
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 Lab-Elite™ unit.
10. Immediately incubate the inverted inoculated primary culture plate(s) at temperature and conditions appropriate to the microorganism. *Culture method can be found on the product's page at www.microbiologics.com.*

TECHNICAL NOTES

Certified Value


- The certified value of the Lab-Elite™ Certified Reference Material product is the identification of the microorganism by its qualitative properties. There is no evaluation or traceability to a quantitative value. The identification of the strain has been tested using methods and procedures included in our ISO 17025 scope.

STORAGE AND EXPIRATION

Store Lab-Elite™ Certified Reference Material at 2°C to 8°C in the original, sealed pouch containing the desiccant. When 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.
- The expiration date has passed.

KEY OF SYMBOLS

| | | | |
|---|---|---|------------------------------|
|  LOT | Batch code (lot) |  | Consult instructions for use |
|  | Biological risks |  | Manufacturer |
|  REF | Catalog number |  | Temperature limitation |
|  | Caution, consult accompanying documents |  | Use-by date |

Please refer to product labels for applicable symbols.

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.
- The rehydrated material is frozen, Microbiologics cannot guarantee the stated characteristics of the product.

WEBSITE

Visit our website, www.microbiologics.com, for current technical information, product availability, biohazard cleanup, growth requirements and Certificate of Analysis.

ACKNOWLEDGMENTS



Microbiologics, Inc.

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

Technical Support

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

Customer Service

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

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



*Look for the ATCC Licensed Derivative® Emblem for all products derived from ATCC® cultures. The ATCC Licensed Derivative Emblem, the ATCC Licenses Derivative Word Mark, and the ATCC Catalog Marks are trademarks of ATCC. Microbiologics, Inc. is licensed to use these trademarks and to sell products derived from ATCC® cultures.

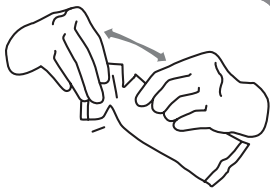
Lab-Elite™

CERTIFIED REFERENCE MATERIAL

ILLUSTRATED INSTRUCTIONS

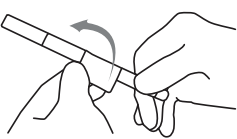
One self contained device including a lyophilized microorganism pellet, reservoir of hydration fluid and inoculating swab (Lab-Elite™ format).

1



Allow the unopened Lab-Elite™ pouch to equilibrate to room temperature. Tear open pouch at notch and remove the Lab-Elite™ unit.

2

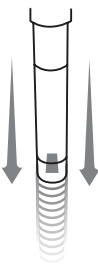


Tear off pull-tab portion on the label and attach it to the primary culture plate or QC record. Do not disassemble the device during hydration.

3

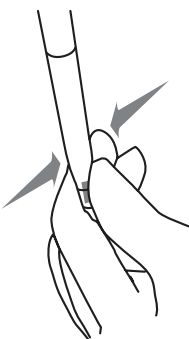
Over the edge of the work bench or counter, crack the ampoule at the top of the Lab-Elite™ unit (just below the fluid meniscus) to release the hydration fluid. Crack the ampoule only once. Cracking the ampoule multiple times may cause glass shards to puncture the plastic housing, creating a risk for injury.

4



Hold vertically and tap on a hard surface to facilitate flow of the fluid through the shaft into the bottom of the unit where the pellet is contained. Do not shake the Lab-Elite™ unit and do not cover the small vent hole on the top of the Lab-Elite™ unit.

5



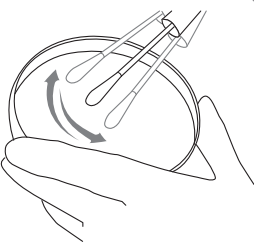
Using a pinching action on the bottom portion of the unit, crush the pellet in the fluid until the pellet has dissolved.

6



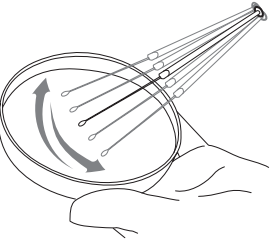
Immediately heavily saturate the swab with the hydrated material and transfer to the appropriate agar medium or use according to the laboratory's SOP. Use immediately upon hydration.

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 Lab-Elite™ unit. 

10

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

Culture method can be found on the product's page at microbiologics.com

