

# GENE-UP® Lysis Kit

For lysing samples for use in GENE-UP reagent kits

## SUMMARY

The GENE-UP® Lysis Kit has been designed for use with the GENE-UP reagent kits.

Detection of microbial DNA in food samples by Polymerase Chain Reaction (PCR) requires an extraction method that efficiently lyses cells of all possible target microorganisms. The lysis technique employed by this kit is bead beating, a commonly used physical disruption method used to release DNA from cells.

## PRINCIPLE AND EXPLANATION

The GENE-UP Lysis kit uses a bead beating technique to physically disrupt the cells of the target microorganism in a food sample. Once the DNA is extracted in this step, the sample is ready for PCR as per the associated GENE-UP reagent kit instructions.

## COLOR DYES

Color dyes have been added to each reaction component. The sample lysis buffer is red in color, and the reagent PCR master mix is blue in color when rehydrated. When these two components are mixed in a given well on a PCR plate or strip, they form a purple color.

## CONTENTS OF THE KIT

The GENE-UP Lysis kit contains the following:

- 2 pouches each with 1 rack of 96 lysis tubes

Instructions for Use are provided in the kit or downloadable from [www.biomerieux.com/techlib](http://www.biomerieux.com/techlib).

## ADDITIONAL MATERIALS AND CONSUMABLES REQUIRED

The items below are NOT included with the GENE-UP Lysis kit and are necessary for use of the kit.

Equipment & Consumables	
Sample Manipulation:	Pipettes & Pipette Tips:
Vortex-Genie® Pulse	Adjustable, variable volume pipette:
GENE-UP® Lysis Tube Holder (REF 414572)	<ul style="list-style-type: none"> <li>• 0.5 –10 µL (single or multichannel pipette)</li> <li>• Compatible with 5 µL, 20 µL and 45 µL</li> </ul>
GENE-UP® Heavy Rack Holder (REF 414571)	
GENE-UP® Lysis Rack Adaptor (REF 414570)	10 µL Biotix filter pipette tip (REF 419194)
GENE-UP® Lysis Tube Remover (REF 414469)	

**Note:** Refer to the associated reagent kit instructions for use for additional items required for the sample preparation procedure.

Standard supplies and equipment commonly found in a microbiology laboratory are not provided.

## WARNINGS AND PRECAUTIONS

1. Must be used with GENE-UP kits.
2. For professional use only.
3. Perform the lysis steps in a room designed for microbiological analysis.
4. Comply with Good Laboratory Practice (e.g., standard ISO 7218).
5. Powder-free latex or nitrile gloves are recommended for use with kit.
6. Spills should be wiped up thoroughly after treatment with bleach or a nucleic acid degradation solution. See the GENE-UP user manual for information on cleaning spills on or in the instrument. Do not autoclave solutions containing bleach.
7. The equipment and accessories should be regularly cleaned and decontaminated.
8. Care must be taken when handling samples that may contain the target microorganisms. Laboratory personnel must be adequately trained to handle pathogens before being permitted to analyze food samples. Follow appropriate safety guidelines when handling potentially contaminated samples. Waste should be disposed of in compliance with local and national legislation.
9. Do not discard the individual enriched samples until the analysis is complete and it has been confirmed that further testing is not required. The lysate can be stored for up to 3 days at 2-8°C.

## STORAGE CONDITIONS

1. Store the Lysis kit (including the lysis tubes) at 2-8°C until the expiration date.

**NOTE:** The kit can be stored for 3 months at 15-25°C, at which time it should be discarded.

2. Do not use the lysis tubes beyond the expiration date printed on the kit box.
3. After opening the kit, check that the tubes are correctly sealed and undamaged. If damaged, do not use.
4. If stored according to the recommended conditions, all components are stable until the expiration date indicated on the label.
5. Only pull the needed number of tubes for inoculation. Remaining tubes should be resealed in their original bag and stored according to your institution's guidelines.

## INSTRUCTIONS FOR USE

Refer to the associated reagent instructions for use for directions on using these samples to complete testing:

Product	REF
GENE-UP® <i>Salmonella</i>	414150
GENE-UP® <i>Listeria</i> (spp.)	414059
GENE-UP® <i>E. coli</i> O157:H7	414152
GENE-UP® <i>Listeria monocytogenes</i>	414058

## LIMITATIONS OF THE PROCEDURE

The GENE-UP Lysis Kit is to be used with the associated PCR reagent kits only.

**WASTE DISPOSAL**

Dispose of used lysis tubes as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products. It is the responsibility of each laboratory to handle waste and effluents produced according to their type and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

**USE / VALIDATION STATEMENT**

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**REVISION TABLE**

This section contains a summary of changes made to the GENE-UP Lysis Kit Instructions for Use.

Revision Date	Revision Number	Change Type	Change Summary
2016-04	43-04323 B	Content Change	<b>Storage Conditions:</b> Clarification of storage temperature. <b>Color Dyes:</b> Addition of section.
2015-10	43-04323 A	N/A	Creation of new document.

**NOTE: Minor typographical, grammar, and formatting changes are not included in the revision history.**

**Change Type categories:**

- **Correction** = Correction of documentation anomalies.
- **Content Change** = Implementation of new and modified (updated) intended use and performance characteristics.
- **Administrative** = Implementation of non-technical changes noticeable to the user.

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**REFERENCES**

1. International Organization for Standardization 2007. Microbiology of Food and Animal Feeding Stuffs - General Requirements and Guidance for Microbiological Examinations ISO 7218, 3rd ed., 2007-08-15, International Organization for Standardization, Geneva, Switzerland.

**AVAILABILITY**

For technical assistance, contact your local bioMérieux representative.

**INDEX OF SYMBOLS**

Symbol	Meaning
	Catalogue number
	Manufacturer
	Date of Manufacture
	Temperature limit
	Use by date
	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Keep away from sunlight
	Do not use if package is damaged



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