# GENE-UP® *Salmonella* SLM

Qualitative test for the detection of *Salmonella* in food, pet food, and environmental samples. For microbiological control only

## SUMMARY

*Salmonella* has been recognized as a primary cause of foodborne illness worldwide.[1] This genus of bacteria is classified into two species: *S. enterica* and *S. bongori*, the former containing the vast majority of serotypes associated with human disease. *Salmonella* can contaminate a wide range of foods, including poultry, meat, eggs, dairy, fruit and vegetables, as well as pet food.[2]

In most cases, particularly in the United States, *Salmonella* infection is characterized by acute gastroenteritis. Symptoms include diarrhea, fever, abdominal cramps and vomiting lasting 4-7 days in most people.[3] Worldwide, especially in developing countries, salmonellosis or enteric fever (typhoid), is a common, more serious bacterial invasion of the bloodstream.[4] Typhoid symptoms include high fever, weakness, abdominal cramps, headache, loss of appetite and sometimes a rash. According to the World Health Organization, 16 million people contract typhoid annually, of which 600,000 die.[5]

GENE-UP® *Salmonella* (SLM) is a real-time Polymerase Chain Reaction (PCR) assay for detection of *Salmonella* in food, pet food, and environmental samples.

## PRINCIPLE AND EXPLANATION

The GENE-UP *Salmonella* kit is to be used with compatible PCR strip tubes (see equipment and consumables lists) in the GENE-UP Thermocycler. Each reaction vial in the GENE-UP *Salmonella* kit contains all of the necessary components for PCR, including sample-specific primers and probes and an internal amplification control.

The GENE-UP Thermocycler detects fluorescence at several wavelengths (channels) to allow for multi-target detection in the same reaction vessel. The fluorescent signal from a sample is recorded in channel 640, while the fluorescent signal for an internal amplification control is recorded in channel 705. The software automatically interprets the results for the internal amplification control and determines the sample result based on the outcome of the control.

Both the assay for the sample and the internal amplification control utilize dual Fluorescence Resonance Energy Transfer (FRET) hybridization probes. These probes consist of two different short oligonucleotides that hybridize to an internal sequence of the amplified fragment during the annealing phase of the reaction cycle. The first probe for the sample assay is labeled at the 3' end with fluorescein; the second probe is labeled at the 5' end with LC Red 640. FRET occurs only after the two probes come in close proximity from hybridizing to the template DNA.

The resulting fluorescent signal from the FRET interaction, which forms a real-time amplification curve, is how the amplified target is detected by the GENE-UP Thermocycler. After the PCR cycling program finishes, the PCR product(s) are melted to determine the presence of the target DNA. The software uses both the real-time amplification curve and the melt peak to make a positive or negative call.

### Internal amplification control

The internal amplification control, contained in the freeze-dried pellets, validates that the reaction conditions are sustainable for PCR to take place, thus validating a negative outcome for the sample. The internal amplification control is amplified by the same primer set but uses a different set of hybridization FRET probes to allow detection in the 705 channel.

## 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® *Salmonella* kit contains:

| Contents | Component | Description |
|---|---|---|
| 6 pouches with 4 vials | REAG | **Reagent**: freeze-dried pellets (1 vial = 8 PCR reactions; 192 reactions total) |
| 1 pouch with: | | |
| 2 vials | RecBUF | **Reconstitution buffer**: 2 x 600 µL reconstitution buffer |
| 1 vial | -BUF | **Negative-control buffer**: 850 µL |

The kit also includes two bags of Eppendorf MasterClear™ strip caps (12 x 8 each) and strip tubes (12 x 8 each).

Instructions for Use are provided in the kit or downloadable from www.biomerieux.com/techlib.

## ADDITIONAL MATERIALS AND CONSUMABLES REQUIRED

The items below are NOT included with the reagent kits and are necessary for use of the GENE-UP *Salmonella* kit.

| Equipment | Consumables |
|---|---|
| GENE-UP® Thermocycler (REF 414056) | GENE-UP® Lysis Kit (REF 414057) |
| **Sample Manipulation:** | **Sample Manipulation:** |
| Blender with paddles<br>• AES Chemunex Smasher® (REF AESAP1064)<br>• easyMIX™ paddle blender (REF AESAP1068) | BPW broth<br>• 6 x 225 mL (bioMérieux REF 42043)<br>• 6 x 90 mL (bioMérieux REF 42042)<br>• 3x3 liters (bioMérieux REF 42629)<br>• 4x3 liters (REF AEB910303/4) |
| Vortex-Genie® Pulse | Sterile filter blender bags<br>• AES400P/50G Type P filter bag<br>• 415180 SMASHER® XL Bag 2L (400) |
| **Pipettes:** | **Confirmation:** |
| Adjustable, variable volume pipette:<br>• 0.5 –10 µL (single or multichannel pipette)<br>• Compatible with 5 µL, 20 µL and 45 µL | Plates<br>• SALSA™ Agar (REF AEB125980/AEB526760)<br>• XLD Agar (REF 43563)<br>• ASAP™ Agar (REF AEB520089/AEB520090<br>• SX2 Broth (REF 42121)<br>Confirmation:<br>• API® 20E (REF 20100)<br>• *Salmonella* spp Latex kit (REF MGNF42)<br>• VIDAS® SPT (REF 30707)<br>• VIDAS® SLM (REF30702) |
| Repeater pipette (optional) | |
| **Centrifugation:** | **Pipette Tips:** |
| Plate Centrifuge<br>• MPS1000™ Mini PCR Plate Spinner 110V (REF 419196) or<br>• MPS1000™ Mini PCR Plate Spinner 230V (REF 414555) | Compatible sterile, filter pipette tips for 20 µL and 45 µL |

| | |
|---|---|
| Mini Tube Centrifuge (VWR REF 93000-196) or equivalent | 10 µL Biotix filter pipette tip (REF 419194) |
| **GENE-UP Accessories:** | **PCR Consumables*:** |
| GENE-UP® PCR Tube Holder (REF 414573) | 12 x 8 Eppendorf MasterClear™ strip caps (REF 89094-210) |
| GENE-UP® Lysis Tube Remover (REF 414469) | 12 x 8 Eppendorf MasterClear™ strip tubes (REF 89094-212) |
| GENE-UP® Lysis Rack Adaptor (REF 414570) | |
| GENE-UP® Heavy Rack Holder (REF 414571) | |
| GENE-UP® Lysis Tube Holder (REF 414572) | |

* All required strip tubes and caps are included in the kit; additional strips and tubes must be purchased separately. It is not possible to use the 96-wells plates with the GENE-UP Thermocycler.

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

## WARNINGS AND PRECAUTIONS

For microbiological control only

1. The GENE-UP *Salmonella* kit must be used with the GENE-UP Lysis kit (REF 414057).
2. For professional use only.
3. Place the instrument in a room designed for microbiological analysis.
4. Comply with Good Laboratory Practice (e.g., standard ISO 7218).[6]
5. This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (do not ingest or inhale).
6. Do not use reagents after the expiration date indicated on the label.
7. Visually inspect vials before testing. Do not use vials with evidence of damage, leakage, or deterioration.
8. Do not mix reagents (or disposables) from different lots.
9. Powder-free latex or nitrile gloves are recommended for all PCR steps.
10. 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.
11. The equipment and accessories should be regularly cleaned and decontaminated.
12. **NEVER** remove the caps from the lysis tubes.
13. Do not try to remove the strip tube caps once they have been sealed to the PCR strip tubes

*Salmonella* is a Gram-negative facultative rod-shaped bacterium organism. Care must be taken when handling samples that may contain *Salmonella*.

Strict compliance with BSL-2 practices, containment equipment, and facilities are recommended for all activities utilizing known or potentially infectious clinical materials or cultures.[7] While BSL-2 containment is suitable for all other salmonellae, BSL-3 practices and equipment are recommended for activities likely to produce significant aerosols or for activities involving production quantities of this particular organism.

Laboratory personnel must be adequately trained to handle pathogens before being permitted to analyze samples for *Salmonella*. Follow appropriate safety guidelines when handling potentially contaminated samples. Waste should be disposed of in compliance with local and national legislation.

*S. enterica* serovar Typhi (*Salmonella* Typhi) is the causative agent of typhoid fever and is a documented hazard to laboratory personnel as *Salmonella* may be present in feces, blood and urine. Laboratory-acquired *Salmonella* Typhi infections usually present with symptoms of septicemia, headache, abdominal pain and high fever, and it causes death more than other salmonellae. The infectious dose is low (<103 organisms), and the incubation period may vary from one to six weeks, depending upon the dose of the organism.

Vaccines for *Salmonella* Typhi are available and should be considered for personnel regularly working with potentially infectious materials.[7]

## STORAGE CONDITIONS

1. Store the GENE-UP kit at room temperature (15-25°C).
2. DO NOT REFRIGERATE.
3. Do not use the reagents beyond the expiration date printed on the kit box and/or label.
4. After opening the kit, check that the pouches are correctly sealed and undamaged. If not, do not use them.
5. If stored according to the recommended conditions, all components are stable until the expiration date indicated on the label.
6. Only remove the required number of vials from the pouch.
7. Once pouches are opened, freeze-dried pellets should be reconstituted and used within 30 days. Freeze-dried pellets should be stored in original sealed pouch (with lab adhesive or bag clip).
8. Once freeze-dried pellets are reconstituted, testing on the GENE-UP Thermocycler should be initiated as soon as possible. Storage conditions for vials are presented in the following table:

| Storage Condition | Time |
|---|---|
| Ambient temperature | 2 hours |
| +2-8°C | 2 days |
| -20°C | 8 days |

## SAMPLE PREPARATION

For short enrichment protocols and for pooling portion, allow the enrichment broth to reach 42°C ± 1°C before use. For a portion of 25 g to be analyzed, enrich for 18-24 hours; allow the enrichment broths to reach room temperature (15-25°C) before use.

Frozen samples must be thawed before use.[8]

### AOAC RI approved protocols (No. 061504)

### 25 g of Human Food Products and Pet Food - General Procedure

1. In a blender bag with filter, aseptically place the following:
   - 25 g of sample
   - 225 mL of buffered peptone water (BPW) broth

   **NOTE:** For certain matrices, it is recommended to follow the specific preparation techniques described in the appropriate standards.[6,8,9]
2. Mix using a paddle blender.
3. Incubate at 41.5-42°C for 18-24 hours.
4. After incubation, manually mix the contents of the blender bag. Optionally, a sterile technique can be used to remove 1 mL of enriched sample and to place it in a pre-labeled microcentrifuge tube.
5. For PCR testing, continue to the Lysis section.
6. For confirmation of positive results, follow guidelines for continued enrichment steps in the Confirmation of Positive Results section.

**NOTE:** Do not discard the individual enriched samples until the analysis is complete and it has been confirmed that further testing is not required.

### 25 g of Raw Meat Samples (Not Poultry) – Short Enrichment Protocol

1. In a blender bag with filter, aseptically place the following:
   - 25 g of sample
   - 225 mL of pre-warmed (42°C) BPW broth
2. Mix using a paddle blender.
3. Incubate at 41.5-42°C 8-24 hours.
4. After incubation, manually mix the contents of the blender bag. Optionally, a sterile technique can be used to remove 1 mL of enriched sample and to place it in a pre-labeled microcentrifuge tube.
5. For PCR testing, continue to the Lysis section.
6. For confirmation of positive results, follow guidelines for continued enrichment steps in the Confirmation of Positive Results section.

**NOTE:** Do not discard the individual enriched samples until the analysis is complete and it has been confirmed that further testing is not required.

### 375 g of Raw Meat Products (Not Poultry)

1. In a blender bag with filter, aseptically place the following:
   - 375 g of sample
   - 1125 mL of pre-warmed (42°C) BPW broth
2. Mix using a paddle blender.
3. Incubate at 41.5-42°C for 10–24 hours.
4. After incubation, manually mix the contents of the blender bag. Optionally, a sterile technique can be used to remove 1 mL of enriched sample and to place it in a pre-labeled microcentrifuge tube.
5. For PCR testing, continue to the Lysis section.
6. For confirmation of positive results, follow guidelines for continued enrichment steps in the Confirmation of Positive Results section.

**NOTE:** Do not discard the individual enriched samples until the analysis is complete and it has been confirmed that further testing is not required.

### Environmental Surface Sponges and Swabs

1. Into the sampling bag, place the appropriate amount of BPW enrichment broth: 90 mL for sponges, or 10x mL for x swabs (x≤15) .
2. Mix manually for 1 minute.
3. Incubate at 41.5-42°C for 18-24 hours.
4. After incubation, manually mix the contents of the blender bag. Optionally, a sterile technique can be used to remove 1 mL of enriched sample and to place it in a pre-labeled microcentrifuge tube.
5. For PCR testing, continue to the Lysis section.
6. For confirmation of positive results, follow guidelines for continued enrichment steps in the Confirmation of Positive Results section.

**NOTE:** Do not discard the individual enriched samples until the analysis is complete and it has been confirmed that further testing is not required.

## LYSIS

**NOTE:** Refer to GENE-UP Lysis Kit package insert (REF 414057) for general information about the kit.

1. Use the plate map created in the GENE-UP Routine software to determine the number of lysis tubes required from the GENE-UP Lysis Kit and place the correct number of lysis tubes in the GENE-UP Lysis Tube Holder. (If less than 8 tubes in a strip are required, the strips can be cut apart, and only the used tubes are placed in the GENE-UP Lysis Tube Holder.)

   **CAUTION: Never open the lysis tubes. If a lysis tube opens or leaks, this should be considered a contamination event.**
2. Place the GENE-UP Lysis Tube Holder on the GENE-UP Heavy Rack Holder.
3. Transfer 20 µL of sample into the lysis tube. Use the Plate Map from the GENE-UP Routine software to pipette each sample into the correct plate position.
4. Remove the GENE-UP Lysis Tube Holder from the GENE-UP Heavy Rack Holder.
5. Place the GENE-UP Lysis Tube Holder on the GENE-UP Lysis Rack Adaptor.
6. Run the bead beater at maximum speed for 5 minutes. The speed must be above 2000 rpm.
7. When lysis is complete, remove the GENE-UP Lysis Tube Holder from the GENE-UP Lysis Rack Adaptor.
8. Clip the GENE-UP Lysis Tube Holder into the GENE-UP Heavy Rack Holder, and proceed to Final Setup for PCR.

**NOTE:** Do not discard the individual enriched samples until the analysis is complete and further testing is not required. Enriched samples can be stored at 2-8°C for up to 72 hours. The lysate can be stored for up to 3 days at 2-8°C or -20°C for extended storage.

## FINAL SETUP FOR PCR

Before beginning the procedure, put on a clean pair of powder-free latex or nitrile gloves.

1. Determine the number of samples to be tested and open a Freeze-dried reagent pouch. A single freeze-dried vial contains enough reagent to prepare 8 samples.
2. To ensure that the reagent pellet or pellet fragments are at or near the bottom of each vial, tap the reagent vial on the bench or centrifuge for 3 seconds. Carefully remove the rubber cap from the reagent vial. Do not discard the rubber cap.
3. Add 45 µL of the reconstitution buffer (blue) to the reagent vial without touching the pellet. Mix using a vortex (after closing the vial) to rehydrate the pellet. Centrifuge the tube or tap it on the bench to ensure all the liquid is on the bottom of the vial.

   **NOTE**: If using a vortex, it also is necessary to centrifuge.
4. Place empty strip tubes onto the GENE-UP PCR Tube Holder following the plate map from the GENE-UP Routine software.
5. Pipette 5 µL of the blue rehydrated solution into a PCR strip tube in the GENE-UP PCR Tube Holder.
6. Using a 10 µL Biotix filter pipette tip, transfer 5 µL of lysed sample (red) in the appropriate PCR tube containing 5 µL of the blue rehydrated solution. To determine the appropriate plate position for each sample, refer to the Plate Map from the GENE-UP Routine software. When the sample is added to the PCR reagent, the solution will turn purple in color.

   **NOTE:** Do NOT force the pipette tip into the lysis tube. Do NOT agitate the lysate before aspirating the sample. The solid material must stay at the bottom of the tube.

   **NOTE:** Avoid pipetting beads and bubbles.

   **NOTE:** For dark samples, red coloration of the lysate may not be visible; there may also be no purple coloration of the final PCR solution.

   **If using a multichannel pipette, perform the following steps:**

   a. Ensure that the pipette is level when aspirating and dispensing
   b. Remove tips slowly in order to avoid pulling the caps off of the lysis tubes
   c. Visually check for the presence of lysate in the tips
   d. Visually check to confirm the absence of beads in the tips.

7. Place a strip cap on each strip tube.
8. Seal the strip caps onto each strip tube using the top piece (any of the four curved edges) of the GENE-UP Lysis Tube Remover Tool.
9. Place the GENE-UP PCR Tube Holder containing the PCR tubes in the plate centrifuge. Balance the centrifuge. Spin for 10 seconds.
10. The plate is now ready to be processed in the GENE-UP instrument and must be started within 15 minutes.

**NOTE:** The lysis tubes can be removed from the GENE-UP Lysis Tube Holder using the GENE-UP Lysis Tube Remover Tool. The GENE-UP Lysis Tube Holder is reusable, but the used lysis tubes should be disposed of in accordingly (see Waste Disposal section).

**NOTE:** Unused rehydrated PCR reagent should be stored according to the guidelines in the Storage Condition section. Reconstitution buffer can be saved to rehydrate the remaining reactions if fewer than 96 reactions were utilized.

## NEGATIVE CONTROL PROCEDURE

Follow the same procedure in the Final Setup for PCR section, using 5 µL of negative control buffer instead of lysed sample (step 6).

## START THE RUN AND VIEW THE RESULTS

Please refer to the appropriate GENE-UP user manual for instructions on how to start a run, view results, and use the GENE-UP Routine software.

## RESULTS INTERPRETATION

Results are automatically interpreted once the PCR run is completed. The Routine software interprets data of both amplification and melting curves for each sample and gives a positive, negative, or invalid result as indicated in the following table.

| ***Salmonella* spp. (640 nm)** | **Internal amplification control (705 nm)** | **Result** |
|---|---|---|
| + | + | + |
| + | - | + |
| - | + | - |
| - | - | Invalid |

In case of an invalid result, proceed to the protocol in the "PCR Inhibition Protocol" section to remove inhibitions.

## PCR INHIBITION PROTOCOL

In case of an invalid result, dilute the lysate to 1:3 in the negative control buffer :

1. Transfer 10 µL of negative control buffer in an adapted microtube and add 5 µL of lysate.
2. Follow the same procedure in the "Final Setup for PCR" section, using 5 µL of this dilution of lysate.

**NOTE**: It is recommended to retest in parallel the lysate without dilution.

## CONFIRMATION OF POSITIVE RESULTS

### Confirmation of positive results obtained using the AOAC RI approved protocols

All positive results must be confirmed according to the BAM[8] or MLG[9], or according to the following bioMérieux GENE-UP confirmation protocol. Confirmation must be performed using the enrichment broth (stored at 2-8°C for up to 72 hours).

### GENE-UP CONFIRMATION PROTOCOL

1. Using enriched sample, mix samples thoroughly by hand.
2. Use a loop to isolate the sample directly from enrichment, and streak the sample on a SALSA™ agar plate or on ASAP™ and XLD agar plates; incubate at 35°±1°C for 24 ± 3 hours.
3. If a typical colony is obtained, test an isolated colony directly using a *Salmonella* spp. latex or API® 20E strip.

In the event of discordant results such as a positive result with the GENE-UP test, or no confirmation using on a plate (untypical colonies), the laboratory must take the necessary steps to ensure that the results obtained are accurate. The following steps are recommended:

1. Transfer 100 µL from the enrichment to 10 mL SX2 for a second enrichment. Incubate at 42°±1°C for 24 ± 3 hours.
2. Use a loop to isolate the sample directly from the second enrichment.
3. Streak the sample on SALSA, ASAP, or XLD agar plate. Incubate at 35°±1°C for 24 ± 3 hours. Alternatively, VIDAS® SLM (or SPT) can be performed with an input volume of 500 µL. If no typical Salmonella colony is identified, the result is considered negative.
4. If a typical colony is obtained, test an isolated colony directly using a *Salmonella* spp. latex or API 20E strip.

## QUALITY CONTROL

External quality control can be performed using one *Salmonella* strain. Add one isolated colony from a fresh and pure culture in 9 mL of BPW. Mix and incubate at 42°C for 18-24 hours. Dilute 1/100 the culture in BPW in order to obtain a suspension containing approximately $10^6$ cells/mL of the strain.

Follow the protocol from Lysis steps to Confirmation of Positive Results sections. Check that the results obtained correspond to the characteristics of the tested strains.

**NOTE:** It is the responsibility of the user to perform Quality Control in accordance with any applicable local regulations.

## LIMITATIONS OF THE PROCEDURE

The GENE-UP *Salmonella* kit has been evaluated on a large number of matrices. However, given the wide variety of products and manufacturing procedures, it is recommended to check that the composition of the matrices tested does not affect the reliability of GENE-UP results.

## WASTE DISPOSAL

Dispose of used or unused reagents 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.

***The GENE-UP Salmonella method has been validated and certified by the AOAC Research Institute as a Performance Tested Method (Certificate No. 061504) for the detection of Salmonella in a variety of foods.***

PERFORMANCE TESTED AOAC RESEARCH INSTITUTE LICENSE NUMBER 060903

**PERFORMANCE TESTED METHOD**
**Certified by AOAC Research Institute**
**www.aoac.org**

*The following matrices were included in the AOAC validation: Fresh Raw ground Beef (375g,25g), Fresh Raw chicken breast (25g) Fresh Raw fish (25g), Creamy peanut butter(25g), Vanilla ice cream (25g), Dry pet food (25g), Stainless steel (sponge).*

## USE / VALIDATION STATEMENT

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## AVAILABILITY

For technical assistance, contact your local bioMérieux representative.

## INDEX OF SYMBOLS

| Symbol | Meaning |
|---|---|
| REF | Catalogue number |
|  | Legal Manufacturer |
|  | Date of Manufacture |
|  | Temperature limitation |
|  | Use by date |
| LOT | Batch code |
|  | Consult Instructions for Use |
|  | Contains sufficient for <n> tests |
|  | Keep away from sunlight |
|  | Do not use if package is damaged |
| SLM | *Salmonella* |

## REVISION TABLE

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

| Revision Date | Revision Number | Change Type | Change Summary |
|---|---|---|---|
| 2016-04 | 43-04319 B | Content Change | **Final Setup for PCR:** Clarification of steps.<br>**Quality Control:** Clarification of process.<br>**Color Dyes**, **Results Interpretation, PCR Inhibition Protocol:** Addition of sections. |
| 2015-10 | 43-04319 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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