



RapidChek®
Listeria monocytogenes

**Part #: 10001180, 10001435,
10001734, 10001436, 10001409,
10001410, 10001363, 10001368**

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RapidChek® *Listeria monocytogenes*



Intended Use

The RapidChek® *Listeria monocytogenes* Test System is designed to detect *Listeria monocytogenes* on selected environmental surfaces, frozen cooked breaded chicken, hot dog, cured ham, frozen cooked shrimp, and ice cream. The validated surfaces include stainless steel and plastic. The test kit permits the presumptive detection and identification of the target pathogen in a minimum of 44 hours for environmental surfaces and food types when *Listeria monocytogenes* is present at low levels. The kit is intended for use by qualified, properly-trained personnel in commercial, academic, and governmental organizations involved in the processing of food products and/or monitoring the safety of such products.



The test kit permits the presumptive detection and identification of the target pathogen in a minimum of 44 hours for environmental surfaces and food types when *Listeria monocytogenes* is present at low levels. The kit is intended for use by qualified, properly-trained personnel in commercial, academic, and governmental organizations involved in the processing of food products and/or monitoring the safety of such products.

Principle of the Assay

This immunoassay test uses a double antibody sandwich format. An antibody specific to *Listeria monocytogenes* is sprayed and immobilized in a line on the surface of a membrane comprising a “test line”. A second antibody reagent, also recognizing *Listeria monocytogenes* and labeled with colloidal gold, is contained within a reagent pad upstream from the test line on the membrane. As the enriched sample moves by capillary action from the filter pad into the antibody–gold pad, the antibody–gold reagent specifically binds *Listeria monocytogenes* and moves with the liquid sample into the test membrane. The sample passes through the test line where the immobilized *Listeria monocytogenes* antibody captures the *Listeria monocytogenes* –antibody–gold complex, causing the formation of an antibody–*Listeria monocytogenes* “sandwich” and development of red color at the test line. Antibody–*Listeria monocytogenes* sandwiches are not formed in the absence of *Listeria monocytogenes*, resulting in no red color development at the test line. Reagents immobilized at the control line capture excess gold reagent passing through the test line. The presence of red color at the control line indicates that the test strip flowed correctly. Therefore, the presence of only one line (control line) on the membrane indicates a negative sample and the presence of two lines indicates a positive sample.



RapidChek®

Listeria monocytogenes



Contents of Kit

10001435

<u>Description</u>	<u>Quantity</u>
RapidChek® <i>L. mono</i> Test Strips (10001180)	50
Transfer pipettes (400 µL)	50
Plastic tubes (12 x 75 mm)	50
Package Insert	1

10001734

<u>Description</u>	<u>Quantity</u>
RapidChek® <i>L. mono</i> Test Strips (10001180)	5
Transfer pipettes (400 µL)	5
Plastic tubes (12 x 75 mm)	5
Package Insert	1
RapidChek® <i>Listeria</i> NextDay™ Media	4 x 14 g

10001436

<u>Description</u>	<u>Quantity</u>
RapidChek® <i>L. mono</i> Test Strips	500

10001409

<u>Description</u>	<u>Quantity</u>
RapidChek® <i>Listeria</i> NextDay™ Media	500 g

10001410

<u>Description</u>	<u>Quantity</u>
RapidChek® <i>Listeria</i> NextDay™ Media	5 kg

10001363

<u>Description</u>	<u>Quantity</u>
RapidChek® <i>Listeria</i> Media Supplement	10 g

10001368

<u>Description</u>	<u>Quantity</u>
RapidChek® <i>Listeria</i> Media Supplement	100 g



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Storage of Reagents

The RapidChek® *Listeria monocytogenes* Test Kit (media and strips) should be stored at room temperature (15 – 30 °C). The RapidChek® *L. monocytogenes* test strips used in this kit must be kept in the canister with the humidity indicating card. The humidity indicating card should be blue in color. After opening the canister, care should be taken to re-seal the closure to protect the strips from moisture. The RapidChek® *Listeria* Media Supplement must be stored refrigerated (2 – 8 °C).

Materials Required but Not Supplied

Environmental sampling sponge or swab
Dey-Engley neutralizing broth
Sample bags
Mechanical homogenizer (optional)
Plastic test tube rack (Fisher Scientific, dimensions 20 x 10 cm, holds 75 x 12 mm tubes)
Incubator capable of maintaining 30 ± 2 °C
Balance with an accuracy of ± 0.1 gram

Media Preparation and Sample Enrichment

A. Media Preparation, Autoclaved

1. Add 46.2 ± 0.2 g of RapidChek® *Listeria* NextDay™ Media to 1 liter of room temperature DI water. Shake until completely dissolved.
2. Autoclave at 121 °C for 15 minutes.
3. For frozen cooked shrimp, just prior to use, add 0.5 g per Liter of RapidChek® *Listeria* supplement. Shake vigorously until the media is completely mixed.

Note: The media can be stored at 2 – 30 °C for up to four weeks. After refrigeration, media should be equilibrated to 20 – 30 °C before use.



RapidChek®
Listeria monocytogenes



B. Sample Enrichment, Sponge Samples (Stainless Steel)

1. Pre-moisten a 7.5 x 4 cm cellulose, non-bactericidal sampling sponge with 10 mL of DE broth.
2. Sample a 4 x 4 inch square surface by wiping the sponge on the surface in a backward and forward motion for 30 seconds.

Place the sponge into a sterile bag for either transportation to the lab or sample enrichment.

3. Add 60 mL of prepared RapidChek® *Listeria* NextDay™ Media. Make sure to completely cover the sponge with media.
4. Place the sample bag into a mechanical homogenizer and homogenize for 30 seconds or hand massage the bottom of the bag.
5. Close the bag loosely and incubate for 44 to 48 hours at 30 ± 2 °C.
6. Proceed to the RapidChek detection procedure.

C. Sample Enrichment, Swab Samples (Plastic)

1. Pre-moisten a sterile, cotton tipped swab with DE broth.
2. Sample a 1 x 1 inch square of the surface by rubbing the swab in a backward and forward motion for 30 seconds.
3. Place the swab into a sterile bag or container for either transportation to the lab or sample enrichment.
4. Add 10 – 20 mL of prepared RapidChek® *Listeria* NextDay™ media. Make sure that the media completely covers the tip of the swab.
5. Place the sample bag into a mechanical homogenizer and homogenize for 30 seconds or hand massage the bottom of the bag.
6. Incubate for 44 to 48 hours at 30 ± 2 °C.
7. Proceed to the RapidChek® detection procedure.



RapidChek®
Listeria monocytogenes



D. 25 g Food Sample Enrichment (Frozen Breaded Chicken, Hot Dogs, Cured Ham, Ice Cream)

1. Add 25 grams of the sample to be analyzed into a sterile bag.
2. Add 225 mL of prepared RapidChek® *Listeria* NextDay™ Media to the bag containing the sample.
3. Place the sample bag into a mechanical homogenizer and homogenize for 30 seconds or hand massage the bottom of the bag.
4. Close the bag loosely and incubate for 44 – 48 hours at 30 ± 2 °C.
5. Proceed to the RapidChek® detection procedure.

E. 25g Frozen Cooked Shrimp

1. Add 25 grams of the sample to be analyzed into a sterile bag.
2. Add 225 mL of prepared RapidChek® *Listeria* NextDay™ Media with supplement to the bag containing the sample.
3. Place the sample bag into a mechanical homogenizer and homogenize for 30 seconds or hand massage the bottom of the bag.
4. Close the bag loosely and incubate for 44 – 48 hours at 30 ± 2 °C.
5. Proceed to the RapidChek detection procedure.



RapidChek®
Listeria monocytogenes



RapidChek® *Listeria monocytogenes* Detection Procedure

1. For each sample enrichment, place a labeled plastic tube into a test tube rack.
2. Take one transfer pipette from the bag, squeeze and hold the bubble on top of the pipette, and place into the sample enrichment. Release the bulb, filling the barrel of the pipette.

Note: The bubble will not completely fill with solution.

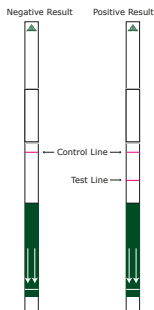
3. Dispense sample enrichment from transfer pipette into the plastic tube. Alternatively, sample transfer can be carried out utilizing a calibrated pipette capable of dispensing 400 μ L.
4. Remove a test strip from the canister and insert the strip into the tube with **arrows facing down**.
5. Let the strip develop for 10 minutes and read the results.
6. The appearance of **one red line** (control) on the strip indicates a negative result.
7. The appearance of **two red lines** on the strip indicates a positive result.



RapidChek® *Listeria monocytogenes*



Illustration of Positive and Negative Results



At least one line, the Control Line, should always develop. A red line in this position indicates that the strip is functioning properly. If the test strip displays 2 red lines, the test is complete and the sample is positive for *Listeria monocytogenes*.

If at 10 minutes the test strip only shows a clearly visible Control Line, then the sample is negative for *Listeria monocytogenes*. If no control line develops within 10 minutes, the test is invalid and needs to be repeated.

Note: Test strip results should be interpreted after 10 minutes. Test strips interpreted after 20 minutes are invalid.

Confirmation

Presumptive positive results must be confirmed according to the appropriate reference method confirmation procedure. Follow the USDA-FSIS MLG 8.10 method (Isolation and Identification of *Listeria monocytogenes* from red meat, poultry, egg products, and environmental samples) for meat and poultry; or the FDA BAM Chapter 10 2017 method (Detection and Enumeration of *Listeria monocytogenes* in Foods) for shrimp and environmental samples; or the AOAC OMA 993.12 method (*Listeria monocytogenes* in Milk and Dairy Products) for ice cream. The website locations of these methods are:

1. <https://www.fsis.usda.gov/wps/wcm/connect/1710bee8-76b9-4e6c-92fc-fdc290dbfa92/MLG-8.pdf?MOD=AJPERES>
2. <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071400.htm>
3. http://www.eoma.aoc.org/gateway/readFile.asp?id=993_12.pdf



RapidChek® ***Listeria monocytogenes***



Alternatively, streak enrichments directly to MOX and/or ALOA agar plates. Incubate plates at 35 ± 1 °C. Examine plates at 24 h for typical colonies. If no typical colonies are observed, examine again at 48 h. Transfer typical colonies to TSAYE, streaking for isolation. Incubate TSAYE plates at 35 ± 1 °C for 22 ± 4 h. Confirm colonies on TSAYE with API *Listeria* (bioMérieux, St. Louis, MO).

Disposal

Decontaminate RapidChek® test strips, pipettes and media by autoclave, bleach, etc., in accordance with local, state and federal regulations.

Product Shelf life

The expiration date for the product is displayed along with the part and lot number on the Product Label located on the re-sealable canister. The test strips have 18 months shelf life from the date of manufacture under desiccated room temperature (15 – 30 °C) conditions. Contact customer service with any questions about product shelf life.



RapidChek®
Listeria monocytogenes



Precautions

1. *Listeria monocytogenes* is a significant human pathogen. Immunocompromised individuals, such as pregnant women, should not be in the vicinity of samples being enriched or tested for *Listeria* as they represent particularly susceptible populations. Extreme care should be used in handling samples which could potentially contain this pathogen. Ensure all biohazardous waste is disposed of appropriately.
2. If polypropylene bottles are used for sample enrichment instead of sample bags, the bottles should be lined with a disposable plastic bag to eliminate potential protein carryover, which will produce erroneous results.
3. The test method gives a positive reaction with *Listeria marthii*.
4. Enrichments with pH values less than 6 may cause erroneous test results due to non-specific binding.
5. Storage conditions higher than room temperature may adversely affect performance of the test strip.
6. Follow standard Good Microbiological Practices where appropriate.



RapidChek®
Listeria monocytogenes



Warranty and Liabilities

The user assumes all risk in using Romer Labs products and services. Romer Labs will warrant that its products and services meet all quality control standards set by Romer Labs and Romer Labs will, at its option, repair or replace any product, components, or repeat services which prove to be defective in workmanship or material within product specific warranty periods or expiration dates and which our examination shall disclose to our satisfaction to be defective as such. This warranty is expressly in lieu of all other warranties, expressed or implied, as to description, quality, merchantability, fitness for any particular purpose, productiveness, or any other matter. Romer Labs shall be in no way responsible for the proper use of its products. Romer Labs hereby disclaims all other remedies, warranties, guarantees or liabilities, expressed or implied, arising by law or otherwise, and it shall have no liability for any lost profits or damage, direct, indirect or otherwise, to person or property, in connection with the use of any of its products or services. This warranty shall not be extended, altered or varied except by a written instrument signed by an authorized representative of Romer Labs.



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