



RapidChek® SELECT™ *Salmonella* Test Kit



Part #: 7000188-7000197

AOAC Approved Protocols:

This test kit's performance was reviewed by AOAC Research Institute and was found to perform to the manufacturer's specifications.



Intended Use

The RapidChek SELECT *Salmonella* Test Kit is designed to detect pathogenic *Salmonella* bacteria.

The test was validated for the detection of *Salmonella* in raw ground beef (including 375g composite samples), raw ground chicken, liquid eggs, chicken carcass rinsates, sliced cooked turkey, and environmental surfaces (see Package Insert for 7000198). The test kit permits the presumptive detection and identification of the target pathogen in 22 to 44 hours (depending on the sample type) when present at levels of one *Salmonella* organism per sample. The intended user is a laboratory worker with the appropriate microbiological training in aseptic technique and the handling of pathogenic bacteria.

Principle of the Test

The test uses novel, highly selective enrichment technologies coupled to immunochemical detection of *Salmonella*. The immunoassay test uses a lateral flow test strip in a double antibody sandwich format. A specific *Salmonella* antibody that is immobilized on the surface of the test strip membrane comprises the "test line." A second antibody reagent that also recognizes *Salmonella* is labeled with colloidal gold and is contained within a reagent pad upstream from (below) the test line. As the sample moves by capillary action from the filter pad into the antibody-gold pad, the antibody-gold reagent specifically binds *Salmonella* (if it

is present in the sample) and moves with the liquid sample into the membrane. The sample passes through the test line where the immobilized *Salmonella* antibody captures the antibody-gold-antigen complex, causing the formation of an antibody-antigen "sandwich" and the development of red color at the test line. Antibody-antigen sandwiches are not formed in the absence of *Salmonella*, 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.

Contents of Kits

7000190 (Food System Kit)

<u>Description</u>	<u>Quantity</u>
RapidChek SELECT <i>Salmonella</i> Strips	100
Tubes	100
Transfer Pipettes	100
RapidChek SELECT Primary Media	500 g
RapidChek SELECT Supplement	250mL
RapidChek SELECT Secondary Media	10 g
Package Insert/s	

7000191 (Test Strips)

<u>Description</u>	<u>Quantity</u>
RapidChek SELECT <i>Salmonella</i> Strips	50
Tubes	50
Transfer Pipettes	50
Package Insert/s	

7000196 (Media System)

<u>Description</u>	<u>Quantity</u>
RapidChek SELECT Primary Media	500 g
RapidChek SELECT Supplement	250mL
RapidChek SELECT Secondary Media	10 g



7000195 (Carcass Rinsate System)

<u>Description</u>	<u>Quantity</u>
RapidChek SELECT Primary Media	500 g
RapidChek SELECT Supplement	250mL
RapidChek SELECT Secondary Media	4x10 g
RapidChek SELECT <i>Salmonella</i> Strips	8x50
Tubes	400
Transfer Pipettes	400
Package Insert/s	

7000188 (High Volume Strips)

<u>Description</u>	<u>Quantity</u>
RapidChek SELECT <i>Salmonella</i> Strips	500
Package Insert/s	

7000197 (High Volume Food System Kit)

<u>Description</u>	<u>Quantity</u>
RapidChek SELECT <i>Salmonella</i> Strips	1000
RapidChek SELECT Primary Media	5 kg
RapidChek SELECT Supplement	10 x 250mL
RapidChek SELECT Secondary Media	100 g
Package Insert/s	

Storage of Reagents

The RapidChek SELECT *Salmonella* Test Kit should be stored at room temperature (15-30°C) with one exception: **The RapidChek SELECT *Salmonella* Primary Supplement should be kept refrigerated (2-8°C).** The RapidChek SELECT *Salmonella* test strips used in this kit should be kept in the plastic canister with the humidity indicating card. The humidity indicating card should be blue in color. After opening the canister, care should be taken to close the lid tightly to protect the test strips from moisture.

Materials Required but Not Supplied

Stomacher-type bags or equivalent
 Stomacher machine (optional)
 Balance with an accuracy of ± 0.2 grams
 Incubator capable of maintaining 42 ± 2°C

Media Preparation (See second section for Carcass Rinsate Samples)

Media Preparation

A. Primary Media Preparation (1 L)

1. Weigh 20.0 ± 0.2g of RapidChek SELECT *Salmonella* Primary Media and add to 1 liter

of deionized water. Shake vigorously until the media is dissolved.

2. Autoclave for 15 minutes at 121°C or filter sterilize (pore size of 0.2µm) the rehydrated media.

Note: Autoclaved media may be stored for up to 4 weeks at 2-8°C or room temperature. Filter sterilized media may be stored for up to 2 weeks at 2-8°C.

3. Alternatively, rehydrate media in one liter of sterile, deionized water. In this manner, rehydrated media should be used within 3 hours of preparation. For best results, use the media as soon as it is prepared.
4. **Just prior to use:** Add 10 mL of supplement per 1 liter of base media. Shake to mix. Use within 3 hours of preparation.

Note: Do not autoclave the media after the supplement has been added.

B. Secondary Media Preparation (100 mL)

1. Weigh 7.4 ± 0.2g of RapidChek SELECT *Salmonella* Secondary Media and add to 100 mL of deionized water. Shake vigorously until the media is dissolved.
2. Bring to a boil while stirring. After boiling, the media can be stored for 2 weeks at 2-8°C.
3. **Alternative Method:** Instead of boiling the media, add 7.4 grams of media to 100 mL of sterile, deionized water. In this manner, rehydrated media should be used within 3 hours of preparation. For best results, use the media as soon as it is prepared.
4. Dispense 1 mL per sample tested of the prepared RapidChek SELECT Secondary Media into the supplied tubes. One tube is needed per enrichment tested.

Note: The RapidChek SELECT Secondary Media is turbid, light green and presents a white precipitate.

Sample Enrichment

A. High burden samples (Raw foods with greater than 1000 cfu/gram microbial load)

1. Add 25g of the sample to be analyzed into a sterile Stomacher bag.
2. Add 225 mL of pre-warmed (42 ± 2°C) supplemented RapidChek SELECT Primary Media to the Stomacher bag containing the sample.



3. Place the sample bag into a Stomacher device and stomach for 30 seconds or hand massage the bottom of the bag.
4. Close the bag loosely and incubate for 16-22 hours at $42 \pm 2^\circ\text{C}$.
5. Transfer 0.1 mL of enriched sample to a tube containing 1.0 mL of RapidChek SELECT Secondary Media.
6. Lightly cover the tubes and return to the 42°C incubator and incubate for an additional 16-22 hours. After incubation gently shake the tubes.
7. Proceed to RapidChek SELECT *Salmonella* detection procedure.

B. Low burden samples (Processed foods with less than 1000 cfu/gram microbial load)

1. Add 25g of the sample to be analyzed into a sterile Stomacher bag.
2. Add 225 mL of pre-warmed ($42 \pm 2^\circ\text{C}$) supplemented RapidChek SELECT Primary Media to the Stomacher bag containing the sample.
3. Place the sample bag into a Stomacher device and stomach for 30 seconds or hand massage the bottom of the bag.
4. Close the bag loosely and incubate for a 16-22 hours at $42 \pm 2^\circ\text{C}$.
5. Transfer 0.1 mL of enriched sample to a tube containing 1.0 mL of RapidChek SELECT Secondary Media.
6. Lightly cover the tubes and return to the 42°C incubator and incubate for an additional 6-8 hours. After incubation gently shake the tubes.
7. Proceed to RapidChek SELECT *Salmonella* detection procedure.

C. 375g Ground Beef Samples

1. Add 375g of the sample to be analyzed into a sterile Stomacher bag.
2. Add 1L of pre-warmed ($42 \pm 2^\circ\text{C}$) supplemented RapidChek SELECT Primary Media to the Stomacher bag containing the sample.
3. Place the sample bag into a Stomacher device and stomach for 30 seconds or hand massage the bottom of the bag.
4. Close the bag loosely and incubate for 16-22 hours at $42 \pm 2^\circ\text{C}$.

5. Transfer 0.1 mL of enriched sample to a tube containing 1.0 mL of RapidChek SELECT Secondary Media.
6. Lightly cover the tubes and return to the 42°C incubator and incubate for an additional 22 hours. After incubation gently shake the tubes.
7. Proceed to RapidChek SELECT *Salmonella* detection procedure.

Carcass Rinsate Samples-Media Preparation and Sample Enrichment

Media Preparation

A. Primary Media Preparation (1 L)

1. Weigh $40.0 \pm 0.2\text{g}$ of RapidChek SELECT *Salmonella* Primary Media and add to 1 liter of deionized water. Shake vigorously until the media is dissolved.
2. Autoclave for 15 minutes at 121°C or filter sterilize (pore size of $0.2 \mu\text{m}$) the rehydrated media.

Note: Autoclaved media may be stored for up to 4 weeks at $2-8^\circ\text{C}$ or room temperature. Filter sterilized media may be stored for up to 2 weeks at $2-8^\circ\text{C}$.

3. Alternatively, rehydrate media in one liter of sterile, deionized water. In this manner, rehydrated media should be used within 3 hours of preparation. For best results, use the media as soon as it is prepared.
4. Just prior to use: Add 20 mL of supplement per 1 liter of base media. Shake to mix. Use within 3 hours of preparation.

Note: Do not autoclave the media after the supplement has been added.

B. Secondary Media Preparation (100 mL)

1. Weigh $7.4 \pm 0.2\text{g}$ of RapidChek SELECT *Salmonella* Secondary Media and add to 100 mL of deionized water. Shake vigorously until the media is dissolved.
2. Bring to a boil while stirring. After boiling, the media can be stored for 2 weeks at $2-8^\circ\text{C}$.
3. Alternative Method: Instead of boiling the media, add 7.4 grams of media to 100 mL of sterile, deionized water. In this manner, rehydrated media should be used within 3 hours of preparation. For best results, use the media as soon as it is prepared.
4. Dispense 1 mL per sample tested of the prepared RapidChek SELECT Secondary Media into the supplied tubes. One tube is needed per enrichment tested.



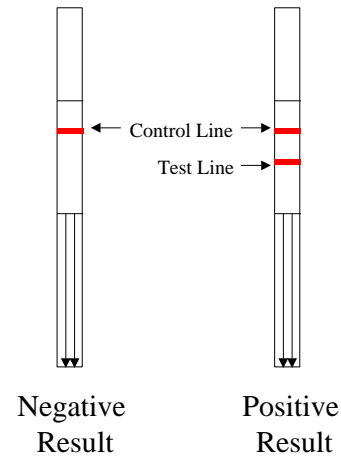
Sample Enrichment

1. Add carcass sample to a large Stomacher bag.
2. As per the recommended USDA-FSIS method, add 400 mL of Buffered-peptone water (BPW) into the cavity of the bird and shake for 1 min.
3. Transfer 30 mL of the rinsate to a separate stomacher bag.
4. Add 30 mL of 2X RapidChek SELECT *Salmonella* Primary Media with 2X Supplement to the 30 mL of the rinsate.
5. Place the sample bag into a Stomacher device and stomach for 30 seconds or hand massage the bottom of the bag.
6. Close the bag loosely and incubate for 16-22 hours at $42 \pm 2^\circ\text{C}$.
7. Transfer 0.1 mL of enriched sample to a tube containing 1.0 mL of RapidChek SELECT Secondary Media.
8. Lightly cover the tubes and return to the 42°C incubator and incubate for an additional 16-22 hours. After incubation gently shake the tubes.
9. Proceed to RapidChek SELECT *Salmonella* detection procedure.

RapidChek SELECT *Salmonella* Detection Procedure

1. Remove the required number of test strips from the canister and insert the strip with arrows facing down into the tube.
2. Let the strip develop for 10 minutes.
3. The appearance of one red line (control) on the strip indicates a negative result.
4. The appearance of two red lines on the strip indicates a positive result.

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 *Salmonella*.

If at 10 minutes the test strip only shows a clearly visible Control Line, then the sample is negative for *Salmonella*. 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 by streaking to selective agar plates as described in USDA/FSIS or Bacteriological Analytical Manual (BAM) methods for the detection of *Salmonella*.

Enriched food samples used in the RapidChek Test Procedure can be used for this confirmation. Details can be found in the following references:

- (1) FSIS/USDA/MLG – 5th Edition, Chapter 4: Isolation and identification of *Salmonella* from meat, poultry and egg products
http://www.fsis.usda.gov/PDF/MLG_4_05.pdf
- (2) FDA/BAM - *Salmonella* (Chapter 5) In: US Food, Drug and Administration, Center for Food Safety and Applied Nutrition, Bacteriological Analytical Manual



<http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/UCM070149>

AFNOR Certified Protocol:

The AFNOR Certification has validated the RapidChek System for detecting Salmonella in all human food products, animal feeding samples and environmental samples (excluding breeding samples). In the context of AFNOR VALIDATION, test portions weighing more than 25 grams have not been tested.



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ALTERNATIVE ANALYTICAL METHODS FOR AGRIBUSINESS
Certified by AFNOR Certification
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Certificate: SDI 34/01 – 04/10
Expiration: 02.04.2018
Reference: ISO 6579-2002
Scope: All human food products, animal feed and environmental samples, excluding breeding samples.

Media Preparation and Sample Enrichment

Media Preparation

A. Primary Media Preparation (1 L)

1. Weigh 20.0 ± 0.2 g of RapidChek SELECT *Salmonella* Primary Media and add to 1 liter of deionized water. Shake vigorously until the media is dissolved.
2. Autoclave for 15 minutes at 121°C or filter sterilize (pore size of $0.2\mu\text{m}$) the rehydrated media.

Note: Autoclaved media may be stored for up to 4 weeks at $2-8^{\circ}\text{C}$ or room temperature. Filter sterilized media may be stored for up to 2 weeks at $2-8^{\circ}\text{C}$.

3. Alternatively, rehydrate media in one liter of sterile, deionized water. In this manner, rehydrated media should be used within 3 hours of preparation. For best results, use the media as soon as it is prepared.
4. As a third option, pre-made, rehydrated media can be purchased for use. Please contact your local vendor for more information on purchasing ready-to-use primary media base.
5. **Just prior to use:** Add 10 mL of supplement per 1 liter of base media.

Shake to mix. Use within 3 hours of preparation.

Note: Do not autoclave the media after the supplement has been added.

B. Secondary Media Preparation (100 mL)

1. Weigh 7.4 ± 0.2 g of RapidChek SELECT *Salmonella* Secondary Media and add to 100 mL of deionized water. Shake vigorously until the media is dissolved.
2. Bring to a boil while stirring. After boiling, the media can be stored for 2 weeks at $2-8^{\circ}\text{C}$.
3. Alternative Method: Instead of boiling the media, add 7.4 grams of media to 100 mL of sterile, deionized water. In this manner, rehydrated media should be used within 3 hours of preparation. For best results, use the media as soon as it is prepared.
4. Third Option: Rehydrated, pre-made secondary media can be purchased for use. Please contact your local vendor for more information on purchasing ready-to-use secondary media.
5. Dispense 1 mL per sample tested of the prepared RapidChek SELECT Secondary Media into the supplied tubes. One tube is needed per enrichment tested.

Note: The RapidChek SELECT Secondary Media is turbid, light green and presents a white precipitate.

Sample Enrichment

A. Food Samples

1. Add 25g of the sample to be analyzed into a sterile Stomacher bag.
2. Add 225 mL of pre-warmed (41.5°C) supplemented RapidChek SELECT Primary Media to the Stomacher bag containing the sample.
3. Place the sample bag into a Stomacher device and stomach for 30 seconds or hand massage the bottom of the bag.
4. Close the bag loosely and incubate for a 16-22 hours at 41.5°C .
5. Transfer 0.1 mL of enriched sample to a tube containing 1.0 mL of RapidChek SELECT Secondary Media.
6. Lightly cover the tubes and return to the 41.5°C incubator and incubate for an additional 6-8 hours. After incubation gently shake the tubes.
7. Proceed to RapidChek SELECT *Salmonella* detection procedure.



B. Swab Samples

1. Pre-moisten a sterile, cotton tipped swab (Fisher Scientific) with DE broth or another neutralizing buffer.
2. Sample a one 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 20 mL of pre-warmed (41.5°C) supplemented RapidChek SELECT Primary Media to the Stomacher bag containing the sample.
5. Place the sample bag into a Stomacher device and stomach for 30 seconds or hand massage the bottom of the bag.
6. Close the bag loosely and incubate for a 16-22 hours at 41.5°C.
7. Transfer 0.1 mL of enriched sample to a tube containing 1.0 mL of RapidChek SELECT Secondary Media.
8. Lightly cover the tubes and return to the 41.5° C incubator and incubate for an additional 6-8 hours. After incubation gently shake the tubes.
9. Proceed to RapidChek SELECT *Salmonella* detection procedure.

C. Sponge Samples

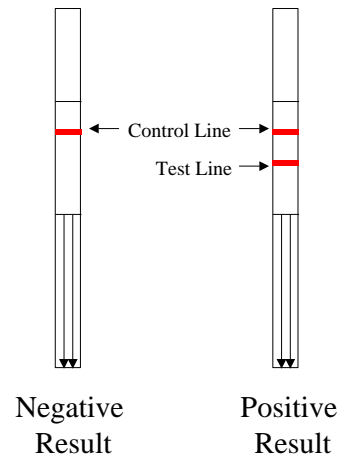
1. Pre-moisten, 7.5 x 4 cm cellulose, non-bactericidal sampling sponge with 10 mL of DE broth or another neutralizing buffer used for sampling.
2. Sample a 4 inch square surface by wiping the sponge on the surface in a backward and forward motion for 30 seconds. Place the sponge into a sterile bag for either transportation to the lab or sample enrichment.
3. Add 25 mL of prepared RapidChek SELECT *Salmonella* Primary Media with Supplement.
4. Place the sample bag into a Stomacher device and stomach for 30 seconds or hand massage the bottom of the bag.
5. Close the bag loosely and incubate for 16 to 22 hours at 41.5°C.
6. Transfer 0.1 mL of enriched sample to a tube containing 1.0 mL of RapidChek SELECT Secondary Media.

7. Lightly cover the tubes and return to the 41.5° C incubator and incubate for an additional 6-8 hours. After incubation gently shake the tubes.
8. Proceed to the RapidChek SELECT *Salmonella* detection procedure.

RapidChek SELECT *Salmonella* Detection Procedure

1. Remove the required number of test strips from the canister and insert the strip with arrows facing down into the tube.
2. Let the strip develop for 10 minutes.
3. The appearance of one red line (control) on the strip indicates a negative result.
4. The appearance of two red lines on the strip indicates a positive result.

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 *Salmonella*.

If at 10 minutes the test strip only shows a clearly visible Control Line, then the sample is negative for *Salmonella*. 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

In the context of AFNOR Validation, all samples identified as positive by the RapidChek method must be confirmed:

- 1) Starting from the RapidChek SELECT enriched secondary media and streaking onto two different selective agars such as XLD and ASAP, continue with biochemical and serological tests described in ISO 6579 (Microbiology of food and animal feeding stuffs – Horizontal method for the detection of *Salmonella* spp.)

In the event of discordant results (positive with the alternative method, non-confirmed by one of the means described above) the laboratory must follow the necessary steps to ensure validity of the result obtained.

Restriction of Use

This method does not allow the detection of *Salmonella* belonging to the group "O : 18" (K for the old designation).

Quality Control

All lots of lateral flow test strips manufactured undergo rigorous quality control procedures using both positive and negative control microorganisms. Therefore, the user is not required to run such controls with the test.

Disposal

Decontaminate test strips, pipettes and media by autoclave, bleach, etc., in accordance with local, state and federal regulations and in compliance with Good Laboratory Practices.

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 canister or bottles. The strips have a 1 year shelf life from the date of manufacture when stored under desiccated room temperature (15°C-30°C) conditions. Contact customer service with any questions about product shelf life.

Precautions

1. *Salmonella* is a human pathogen. Extreme care should be used in handling samples, enriched media and used test strips. Ensure all biohazardous waste is disposed of appropriately.
2. If polypropylene bottles are used for sample enrichment instead of Stomacher bags, the bottles should be lined with a disposable plastic bag to eliminate potential protein carryover, which may produce erroneous results.
3. Storage conditions higher than room temperature may adversely affect performance of the test strip.
4. Follow standard Good Microbiological Practices where appropriate.

Warranties and Liabilities

The user assumes all risk in using Romer Labs, Inc.® products and services. Romer Labs, Inc.® will warrant that its products and services meet all quality control standards set by Romer Labs, Inc.®, and Romer Labs, Inc.® 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, Inc.® shall be in no way responsible for the proper use of its products. Romer Labs, Inc.® 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, Inc.®

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