



RapidChek® SELECT™ *Salmonella* species and *Salmonella Enteritidis* Test System



Part #: 7000199

Intended Use

The RapidChek SELECT *Salmonella* and *S. Enteritidis* Test Kit is designed to detect *Salmonella* species and more specifically, *Salmonella Enteritidis* (including other Group D1 serovars) in chicken house drag swabs. The test kit permits the presumptive detection and identification of the target pathogen in 32 to 44 hours, when present at levels of 1 *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 Assay

Each immunoassay test used in this system employs a double antibody sandwich format. The species specific strip utilizes an antibody specific for *Salmonella* whereas the *Salmonella Enteritidis* (SE) specific strip utilizes an antibody specific for Group D1 including *S. Enteritidis*. The antibodies are sprayed and immobilized on the surface of a membrane comprising a "test line". A second antibody reagent, also recognizing either *Salmonella* or SE and labeled with colloidal gold, is contained within a reagent pad upstream from the test line on the membrane. As the sample moves by capillary action from the filter pad into the antibody-gold pad, the antibody-gold reagent specifically binds to *Salmonella* species or *Salmonella Enteritidis* and moves with the liquid sample onto the test membrane. The sample passes through the test line where the immobilized *Salmonella* or SE antibody captures the antigen-antibody-gold complex, causing the formation of an antibody-antigen "sandwich" and development of red color at the test line. Antibody-antigen sandwiches are not formed in the absence of the *Salmonella* species or Group D1 including *S. Enteritidis*, 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 strip has 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 Kit

7000199:

Description	Quantity
RapidChek SELECT Primary Media	500 g
RapidChek SELECT Supplement	250 mL
RapidChek SELECT Secondary Media	4x10g
RapidChek SELECT Test Strips	250
Transfer pipettes (100 µL)	250
Test Tubes	250
Package Insert/s	

3000027:

Description	Quantity
RapidChek SELECT SE Test Strips	50

Storage of Reagents

The RapidChek SELECT *Salmonella* and *S. Enteritidis* Test Kit should be stored at room temperature (15-30°C) with one exception.

The RapidChek SELECT Primary Supplement should be kept refrigerated (2-8°C).

The RapidChek SELECT *Salmonella* and *S. Enteritidis* test strips used in this kit should be kept in their plastic canisters 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 or equivalent (optional)
Balance with an accuracy of ± 0.2 g
Incubator capable of maintaining 42 ± 2°C



RapidChek Media Preparation and Sample Enrichment

A. Primary Media Preparation (1 L)

1. Weigh 20.0 ± 0.2 g of RapidChek SELECT 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 $2\text{-}8^\circ\text{C}$ or room temperature. Filter sterilized media may be stored for up to 2 weeks at $2\text{-}8^\circ\text{C}$.
3. Alternatively, rehydrate media in one liter of sterile, de-ionized 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 ± 0.2 g of RapidChek SELECT 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 $2\text{-}8^\circ\text{C}$.
3. **Alternative Method:** Instead of boiling the media, add 7.4 grams of media to 100 mL of sterile, de-ionized 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.

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

Sample Enrichment

Chicken House Drag Swab Samples

1. Add 100 mL of pre-warmed ($42 \pm 2^\circ\text{C}$) supplemented RapidChek SELECT Primary media to the sample bag containing the drag swab.

2. Place the sample bag into a Stomacher device and stomach for 30 seconds or hand massage the bottom of the bag.
3. Close the bag loosely and incubate for 16-22 hours at $42 \pm 2^\circ\text{C}$.
4. Transfer 0.2 mL of the enriched sample to a tube containing 2 mL of RapidChek SELECT Secondary Media.

Note: Using the pipettes included in the kit, this will require filling up the pipette and transferring twice.

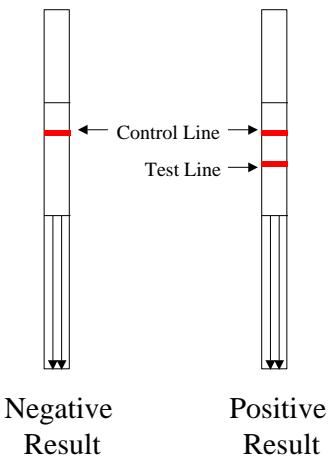
5. Lightly cover the tubes and return to the 42°C incubator and incubate for an additional 16-22 hours. After incubation gently shake the tubes.
6. Proceed to RapidChek SELECT *Salmonella* and *S. Enteritidis* Detection Procedure.

RapidChek SELECT *Salmonella* and *S. Enteritidis* Detection Procedure

1. Remove the required number of *Salmonella* species test strips from the canister (purple).
2. Insert the strip with arrows facing down into the tube.
3. Let the strip develop for 10 minutes.
4. The appearance of one red line (control) on the strip indicates a negative result.
5. The appearance of two red lines on the strip indicates a positive result.
6. If any of the samples indicate a positive result, remove those *Salmonella* species strips and lay them onto a folded paper towel.
7. Remove the required number of *Salmonella* Enteritidis test strips from the canister (orange).
8. Insert the strip with arrows facing down into the tubes that were previously positive for *Salmonella* species.
9. Let the strip develop for 10 minutes.
10. The appearance of one red line (control) on the strip indicates a negative result.
11. The appearance of two red lines on the strip indicates a positive result for SE or another Group D1 serovar.



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 a presumptively positive for *Salmonella* or *S. Enteritidis* (or another Group D1 serovar) dependent upon which strip is being used.

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

Chicken House Drag Swab Samples: All presumptive positive results must be taken through an immunomagnetic separation (IMS) procedure prior to cultural confirmation. Please see insert of the IMS confirmation kit (7000225) for details of the protocol. Enriched samples used in the RapidChek Test Procedure can be used for the IMS protocol followed by cultural confirmation. For confirmation procedures see the following:

- (1) RapidChek CONFIRM SE IMS Kit Package Insert (7000225)
- (2) Environmental Sampling and Detection of *Salmonella* in Poultry Houses, October 2008, US FDA
<http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/ucm114716.htm>

Disposal

Decontaminate used 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 canister. 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 will produce erroneous results.
3. Storage conditions higher than room temperature may adversely affect performance of the test strip.
4. Do not use test strips beyond the expiration dating on the kit package label.
5. 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.[®]

For Technical & Customer Service:

Romer Labs Technology Inc.
130 Sandy Drive
Newark, DE 19713, USA

Phone: 855-337-6637
E-mail: rapidchek@romerlabs.com