



**RapidChek® *Campylobacter*
Test System**

**Part #: 10005433,
10006041 – 10006045**

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RapidChek® *Campylobacter*



Intended Use

The RapidChek® *Campylobacter* Test System is designed to detect *C. jejuni*, *C. coli* and *C. lari* in chicken carcass rinses. The test kit permits the presumptive detection and identification of the target pathogen in a minimum of 47 hours when *Campylobacter* 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 *Campylobacter* is sprayed and immobilized in a line on the surface of a membrane comprising a “test line”. A second antibody reagent, also recognizing *Campylobacter* 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 *Campylobacter* and moves with the liquid sample into the test membrane. The sample passes through the test line where the immobilized *Campylobacter* antibody captures the *Campylobacter*–antibody–gold complex, causing the formation of an antibody–*Campylobacter* “sandwich” and development of red color at the test line. Antibody–*Campylobacter* sandwiches are not formed in the absence of *Campylobacter*, 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**

10005433

<u>Description</u>	<u>Quantity</u>
RapidChek® <i>Campy</i> Test Strips (10005434)	50
Transfer pipettes (400 µL)	50
Plastic tubes (12 x 75 mm)	50
Package Insert	1

10006044

<u>Description</u>	<u>Quantity</u>
RapidChek® <i>Campy</i> Test Strips (10005434)	5
Transfer pipettes (400 µL)	5
Plastic tubes (12 x 75 mm)	5
Package Insert	1
RapidChek® <i>Campy</i> Media	11 g

10006045

<u>Description</u>	<u>Quantity</u>
RapidChek® <i>Campylobacter</i> Test Strips	500

10006041

<u>Description</u>	<u>Quantity</u>
RapidChek® <i>Campylobacter</i> Test Combs	384 tests
Cluster Tubes	384
Cluster Tube Rack	
Package Insert	1

10006043

<u>Description</u>	<u>Quantity</u>
RapidChek® <i>Campylobacter</i> Media	500 g

10006042

<u>Description</u>	<u>Quantity</u>
RapidChek® <i>Campylobacter</i> Media	5 kg



Storage of Reagents

The RapidChek® *Campylobacter* Test Kit (media and strips) should be stored at room temperature (15 – 30 °C). The RapidChek® *Campylobacter* 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.

Materials Required but Not Supplied

Plastic test tube rack (Fisher Scientific, dimensions 20 x 10 cm, holds 75 x 12 mm tubes)

Incubator capable of maintaining 42 ± 2 °C

Balance with an accuracy of ± 0.1 gram

Media Preparation and Sample Enrichment

A. Media Preparation (Carcass Rinses)

1. Add 55.2 ± 0.2 g of RapidChek® *Campylobacter* Media to 1 liter of sterile room temperature water. Shake until completely dissolved.

Note: Do not autoclave.

B. Sample Enrichment (Carcass Rinses)

1. Add carcass sample to a large sample 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 poultry rinse sample to a vented culture flask.
4. Add 30 mL of RapidChek® *Campylobacter* Media.
5. Homogenize sample by gently shaking.



RapidChek® *Campylobacter*



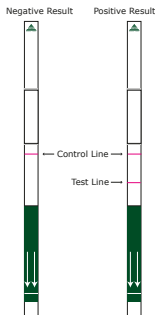
6. Close the culture flask and incubate under aerobic conditions for 47 to 49 hours at 42 ± 2 °C.
7. Proceed to the RapidChek® detection procedure.

RapidChek® *Campylobacter* 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.
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 µL.
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 **20 minutes** and read the results. Results must be interpreted within 30 minutes.
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.



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 *Campylobacter*.

If at 20 minutes the test strip only shows a clearly visible Control Line, then the sample is negative for *Campylobacter*. If no control line develops within 20 minutes, the test is invalid and needs to be repeated.

Note: Test strip results should be interpreted after 20 minutes.

Test strips interpreted after 30 minutes are invalid.

Confirmation

Presumptive positive results must be confirmed according to the appropriate reference method confirmation procedure. Follow the USDA-FSIS MLG 41.04 method (Isolation and Identification of *Campylobacter jejuni/coli/lari* from poultry rinse, sponge and raw product samples). The website location is below:

<https://www.fsis.usda.gov/wps/wcm/connect/0273bc3d-2363-45b3-befb-1190c25f3c8b/MLG-41.pdf?MOD=AJPERES>

Alternatively, streak enrichments directly to R&F *Campylobacter* agar. Incubate plates at 41 – 42 °C under microaerophilic conditions for 48 ± 2 hours. Examine plates for typical colonies. Perform microscopic examination and latex agglutination as per USDA MLG 41.04.

Disposal

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



RapidChek® *Campylobacter*



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 a 6 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.

Precautions

1. *Campylobacter* is a human pathogen. Extreme care should be used in handling samples which could potentially contain this pathogen. Ensure all biohazardous waste is disposed of appropriately.
2. Storage conditions higher than room temperature may adversely affect performance of the test strip.
3. Follow standard Good Microbiological Practices where appropriate.



Warranty and Liabilities

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