

FoodChek™-E.coli Kit for the Detection and Quantification of E.coli O157

Product Information

Intended Use:

The FoodChek™-E. coli O157 assay is a rapid detection and quantification system for *Escherichia coli* O157 in raw ground beef. The test kit permits presumptive detection, identification and quantification of *Escherichia coli* O157 (including H7) when present at levels of 1 organism per 25 grams of sample. The system is comprised of a magnetic nanoparticle immunoassay (the FoodChek™ cassette), an automated magnetic reader for detection and quantification (the FoodChek™ reader) and a commercially available enrichment medium. This assay provides rapid results, and compared to most other methods, requires only six hours of enrichment, for a total test time of less than seven hours.

FoodChek™-E. coli O157 has been certified for use with raw ground beef by AOAC *Performance Tested Methods*SM.

Principle of Operation:

The kit is based on the use of antibody-coated super-paramagnetic nanoparticles in a lateral flow immunoassay format. Unlike typical lateral flow assays it does not depend on a visual inspection of the assay cassette to determine if the result is positive or negative – a procedure that is highly subjective at low concentrations of analyte. Instead the cassette is read in a magnetic detection system (the FoodChek™ reader), which confirms and quantifies the presence of *Escherichia coli* O157. Each batch of FoodChek™-E. coli O157 cassettes contains an embedded calibration curve, which allows the detector to provide a correlation between the strength of the magnetic signal and the number of *Escherichia coli* O157 organisms present.

Apart from the FoodChek™ reader the kit requires only standard laboratory equipment and supplies. A commercially available growth medium for enriching the sample is also required.

Kit Contents:

The kit contains the FoodChek™-E.coli cassette, which is a lateral flow immunochromatographic device. The cassette carries a printed label that contains written and bar-coded information on the identity of the cassette, the expiration date and the required values for automated analysis by the FoodChek™ reader. The cassette cannot be visually interpreted and requires the use of the FoodChek™ reader.

Additional Materials Required:

1. Modified Trypticase Soy Broth – The broth is prepared from dehydrated powder by re-suspension in distilled water, then autoclaving. Alternatively the media powder could be mixed directly with sterile water for immediate use. The recommended commercial broth is Oxoid CM0989 and is used in conjunction with a media supplement (see below).
2. Media Supplement – The media supplement provides additional selectivity to the enrichment broth to ensure growth of the target to the detection threshold. The media supplement is a lyophilized powder in a septum vial. The user hydrates the supplement with sterile distilled water before addition to the

enrichment broth. The recommended commercial media supplement is Oxoid VCC selective supplement SR0190

3. Small volume polypropylene or reusable glass tube with cap.
4. Serological pipette, sterile.
5. Stomacher bag with filter.
6. Distilled/deionized, sterile water.
7. Water bath at 39°C +/-1°C.
8. Pipette and tips for dispensing 200 µL.
9. Stomacher. Available from multiple sources such as Seward Model 400, VWR Scientific.
10. FoodChek™ Reader – available from Vacchi-Test Corporation.

Procedure:

NOTE: Microbiological tests such as FoodChek™-E.coli require trained laboratory personnel familiar with good microbiological laboratory practices. The enrichment process can produce substantial quantities of various pathogens and these need to be handled and disposed of with care.

Sample Preparation

1. Warm media base to 39°C. Note: for optimum assay performance it is critical that the media is equilibrated to 39°C before use. This is most easily done by holding media overnight (10-20 hours) in an incubator or for one hour in a water bath.
2. Reconstitute a vial of lyophilized media supplement by adding sterile water and mix. Store unused liquid portions refrigerated for up to 10 days.
3. Immediately prior to enrichment – add 960 µL (±0.5µL) of media supplement to 225 mL of pre-warmed media base. Mix thoroughly by swirling and inverting.
4. Add 75 mL of pre-warmed media (containing supplement) to 25 g of sample (e.g.; to) in a filter-equipped stomacher bag.
5. Stomach sample for 30 sec. at 265 rpm.
6. Close bag loosely and incubate the samples for enrichments for 6 hours at 39°C. If a large number of samples are to be analyzed, verify that the temperature of the water between the sample bags reaches 39°C before starting to record the incubation time. In order to quantify the number of organisms present by means of the built-in calibration curve it is important to precisely control the enrichment period.
7. After 6 hours remove the samples from the water bath and re-suspend the contents.

General Preparation

1. Bring the required number of cassettes to ambient temperature at least 10 minutes prior to use.
2. Turn on the FoodChek™ reader. Initialization will take a few minutes. When instrument is ready for use display will show four pictograms. Touch the pictogram which represents a cassette.

Analysis

1. Place one identified tube (with the cap removed) for each sample into the rack.
2. Mix sample thoroughly and transfer 5.0 ml (± 0.2 mL) of the enriched samples to the tubes. Cap the tubes.
3. Heat the samples in boiling water for 15 minutes.
4. After heating, let the samples cool to ambient temp and hold for at least 3 minutes.
5. Using a micropipette, transfer 200 μ L of (cooled) heat-treated sample directly to the sample port of a FoodChek™-E. coli O157 cassette at ambient temperature. Change pipette tips between samples.
6. Allow the assays to develop for 30 minutes at ambient temperature before reading in the FoodChek™ reader. Note: interpreting results before 25 minutes or after 50 minutes may yield inaccurate results.
7. Open the door on the front of the detector and insert the cassette.
8. Closing the detector door initiates the reader and generates an output on the LCD screen and a printed result on paper tape.

Interpretation and Test Result Report

Results are reported on both the instrument LCD display and the instrument printout. Result is indicated as either "Positive (+)" or "Negative (-)". In the case of a Positive (+) result the reader will also provide an estimate of the number of Colony Forming Units (CFU) of *Escherichia coli* O157 originally present in the sample after various periods of enrichment (6, 7 and 8 hours). Also in the case of an error, a message describing the error will appear.

Since FoodChek™-E.coli is approved as a screening test for *E.coli* O157 all positive samples should be culturally confirmed by an approved USDA/FSIS or HC/CFIA confirmatory method.

Product Storage and Shelf Life:

Store the product at 2°C – 8°C until ready for use. The shelf life of the kit is 18 months from date of manufacture, as marked on the cassette.

Disposal:

Dispose of all used cassettes, pipettes and enrichment medium by autoclaving or according to an approved practice. Ensure that all biohazardous waste is disposed of according to local, municipal, provincial, state and federal regulations.

Precautions:

Extreme care should be taken in handling test samples and enrichment broths since *E.coli* O157 has a very low infective dose (estimated to be 50 organisms). Cassettes that have been used with properly heat-treated samples are not hazardous and can be stored at room temperature.

Terms and Conditions:

Vacci-Test makes no representations and warranties concerning its products other than those stated herein. All Product(s) delivered hereunder by Vacci-Test, its affiliates or any other person on its behalf shall, at the time of delivery, be manufactured to meet Vacci-Test's specifications and all applicable laws. All other terms, conditions and warranties, including any warranty of merchantability, quality, fitness or suitability for a particular or intended purpose, implied by common law or statute, (implied warranties) are expressly excluded.

Vacci-Test warrants its new equipment to the original Customer only for a period of one (1) year after date of delivery against defects in material and workmanship and defects arising from failure to conform to Vacci-Test's specifications applicable on the date of delivery. Vacci-Test's sole obligation under this warranty shall be to replace or repair the defective product or part, for any defect found to have occurred under normal use during the one (1) year period. This warranty does not cover replacement of products damaged due to misuse, abuse, alteration, self repair, loss or theft.

Catalogue Number:

VTC-01 - FoodChek™-E.coli Kit for the Detection and Quantification of E.coli O157

For further information please contact:

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