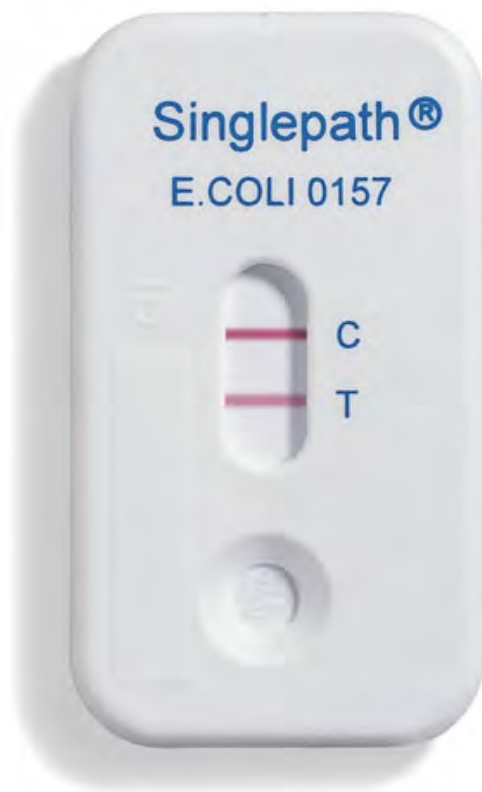


ЭКСПРЕСС-ТЕСТ SINGLEPATH E. COLI 0157



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Singlepath® E. coli O157

GLISA-Rapid Test (Gold Labelled ImmunoSorbent Assay) for the qualitative detection of E.coli O157 in food.

Intended Use

Singlepath® E. coli O157 is intended to be used in food-analysing laboratories for the presumptive qualitative detection of E. coli O157 (including H7) from a variety of foods. The test has been validated and received AOAC approval for use in raw ground beef and pasteurised whole milk from which levels as low as one E. coli O157 per 25 grams or ml of sample could be detected after 18 h enrichment.

Introduction

Amongst the E.coli human pathogens, Verotoxin (a Shiga like toxin) - forming strains (VTEC) have gained in importance in recent years. The group of enterohaemorrhagic E.coli (EHEC) with its highly pathogenic serovar O157:H7 strain is particularly interesting in this respect. EHEC are capable of initiating life-threatening illnesses, particularly in those with immune deficiency, young children and the elderly. The main sources of infection are contaminated, raw or insufficiently heated foods of animal origin, e.g. meat and dairy products. The reservoir for EHEC is the faeces of the cattle, sheep and goats. These microorganisms can enter food during the processing of meat and dairy products if hygienic conditions are inadequate.

The drastic increase in the incidence of food infection caused by E.coli O157 demands reliable and rapid methods of detection. Apart from traditional culture methods, immunological techniques are becoming more and more popular with users due to their better specificity and sensitivity.

Singlepath® E.coli O157 is an immunological screening test based on the immune flow principle and is designed for testing food and environmental samples in such a way that time-consuming and personnel intensive working steps are avoided.

Mode of Action

Singlepath® E.coli O157 (1.04141) is an immunochromatographic rapid test based on gold-labelled antibodies. The test device has a circular sample port, and an oval shaped test (T) and control (C) window.

1. The sample is applied to the chromatography paper via the circular sample port.
2. The sample is absorbed through the pad to the reaction zone containing colloidal, gold-labelled antibodies specific to E.coli O157.
3. Any E.coli O157 antigen present complexes with the gold-labelled antibody and migrates through the port until it encounters a binding zone in the test (T) area.
4. The binding zone (T) contains another anti-E.coli O157 antibody, which immobilises any E.coli O157-antibody complex present. Due to the gold-labelling, a distinct red line is then formed.

5. The rest of the sample continues to migrate to a second binding reagent zone within the control (C) zone, and also forms a second distinct red line (positive control). Regardless of whether any E.coli O157 is present or not, this distinct red line is always formed in the control (C) zone, thus ensuring the test is working correctly.

Storage / Stability

Singlepath® E.coli O157 is stable until the expiry date printed on the box, when stored at +2 to +8°C

Sample Material / Sample Enrichment

- Mix 25 g solid sample or 25 ml liquid sample with 225 ml enrichment medium 1 and homogenise with a Stomacher if necessary.
- Incubate for 18 - 24 h at +35 °C to +37°C.
- Allow to cool to room temperature

For dairy products, mTSB + Novobiocin selective enrichment broth is recommended.

For meat and meat products, mEC + Novobiocin selective enrichment broth should be used.

Test Procedure

Sample Preparation (optional boiling step)

The following boiling step is not mandatory for the test performance but can be done in order to reduce the potential risk of contamination when handling live bacteria.

1. Transfer approx. 1-2 ml of enrichment culture to an appropriate (polypropylene) tube. Cover with a loose-fitting cap.
2. Place tubes in boiling water bath for 15 min.
3. Remove and allow cooling to room temperature (18 - 26 °C), prior to use.

Allow test devices to warm to room temperature if stored at +2 to +8°C.

Procedure

1. Remove the foil pouches from the required number of Singlepath® E.coli O157 devices. Place the test device(s) on a flat surface and label with appropriate sample identification. (Note: Perform the tests within a period of 2 hours after opening!).
2. Using a micro pipette and disposable pipette tip, draw up 150 µl from the boiled or non-boiled and cooled enrichment. Dispense 150 µl of the sample into the circular sample port on the test device.
Alternatively using a disposable transfer pipette, squeeze the pipette bulb, insert the stem into the boiled sample and release pressure on bulb. This will draw sample up into the pipette. Dispense five (5) free falling drops (about 150-160µl) into the circular sample port on the test device.

Singlepath® E. coli O157

- Incubate the test device at room temperature and observe the test result immediately 20 minutes after applying the sample to the device.

Interpretation of Results

The test can be regarded as working correctly if a distinct red line appears in the control zone (C) within 20 minutes.

A sample can be considered POSITIVE if at or prior to 20 minutes, red lines appear on both test (T) and control (C) zones.

A sample can be considered NEGATIVE if no red line appears in the test (T) zone but does appear distinctly in the control (C) zone 20 minutes after application of sample to the device.

Technical Specifications

Detection limit

1 colony-forming unit of E. coli O157 (including H7) in a 25 gram food sample can be regarded as being the lowest detection limit. These levels meet the minimum detectable limits as defined by the AOAC Research Institute. These data were verified by an independent testing laboratory.

Interferences

Singlepath® E. coli O157 has been validated and received AOAC approval for use in raw ground beef and pasteurised whole milk. Results obtained to date on numerous food samples indicate that there is no interference of Singlepath® E. coli O157 with food ingredients.

The test has been developed based on using mEC + N and mTSB + N selective enrichment broths from enrichment broth + cefixime, cefsulodin and vancomycin. Interference from other types of selective enrichment broths and other brands cannot be excluded. In particular use of broth of red-brown colour could potentially mask weak signals due to background coloration of the test zone.

Sensitivity (according to AOAC trials)	>99 %
Specificity (according to AOAC trials)	>99 %
False-negative rate	<1 %
False-positive rate	<1 %
Efficiency	>99 %

Trouble-shooting

Problem	Measures
No line appears in either zone after 20 minutes test period	Re-run sample

Precautions

E. coli O157 (including H7) isolates have been shown to be infective at very low dosage (<50 bacteria). Users of Singlepath® E. coli O157 must be familiar with the appropriate aseptic techniques for the isolation and identification of E. coli O157 (including H7). Extreme care must be kept in handling samples, enriched culture media and devices.

Disposal

Decontaminate Singlepath® devices, tubes, pipettes, and culture media by autoclave, bleach, etc. in accordance with local, state, and federal regulations.

Ordering Information

Product	Merck Cat. No.	Pack size
Singlepath® E. coli O157	1.04141.0001	25 tests
mEC Novobiocin selective enrichment broth	1.14582.0500	500 g
mTSB Novobiocin selective enrichment broth	1.09205.0500	500 g

Additionally required materials and instrumentation

- Stomacher/Stomacher bags
- Incubators +35 °C and +42 °C
- Distilled or deionized water
- Autoclave
- Water bath for boiling of samples (optional)
- Disposable Polypropylene tubes for boiling of samples (optional)
- Disposable plastic transfer pipettes and/or appropriate micro pipettes and disposable tips for dispensing 1-2 ml (sample for boiling) and 150 µl (application of boiled sample onto tests)



Singlepath® E. coli O157
Test result negative



Singlepath® E. coli O157
Test result positive



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