



Singlepath® E.coli 0157

In the last couple of years, the pathogenic E.coli O157 has become well known by food manufacturers as well as consumers due to some spectacular outbreaks of foodborne disease. "Hamburger disease" became the new term for food-borne E.coli O157 infections caused by contaminated minced beef.

Despite the potential severity of that disease, regulatory authorities hesitated a long time before taking action. The new USDA regulation requires that food manufacturers apply a HACCP system in their production and if necessary test for the presence of E.coli. Due to the belated arrival of regulations the market for testing of E.coli 0157 in the food industry world-wide is still relatively small except in the USA and Japan. Official Standards to test for E.coli 0157 are not available except for one AOAC approved method and one German DIN norm.

At the moment, the most commonly used techniques to test food products for E.coli O157 are traditional methods based on culture media. These currently used methods for the isolation and identification of the bacteria are time-consuming as well as labour-intensive.

The requirement of food manufacturers for quicker release of finished products and for cost savings are calling for a change in these methods. Rapid methods,

especially highly convenient tests like immunochromatographical one-step devices are therefore increasingly interesting to food manufacturers and distributors as well as to public health authorities.

The general expectation for a rapid test is to be sufficiently sensitive and specific, user friendly and cost effective. Although DNA probes are more specific than immunological tests, they do not always fulfil other relevant user criteria. Immunological tests are therefore often the preferred choice among users of rapid tests.

Singlepath E.coli 0157 is intended to be used in food-analysing laboratories for the presumptive qualitative detection of E.coli 0157 (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 0157 per 25 grams or ml of sample could be detected after 18 h enrichment.

Your benefits

| | Reliable | As sensitive as | the official | culture media | method. |
|--|----------|-----------------|--------------|---------------|---------|
|--|----------|-----------------|--------------|---------------|---------|

Exceeds the performance criteria of USDA-FSIS.

Provides accurate results:

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

Fast Result in just 20 minutes.

Ease-of-use One-step format avoids working errors during handling.

Convenient Simply add sample and read off the result.

Safe Clear and distinct positive or negative test

results with a built-in positive control.

Economical Rapid results save labour and inventory costs and

reduce labour-intensive plating methods. No capital investment required for example for instrumentation

such as automated systems.

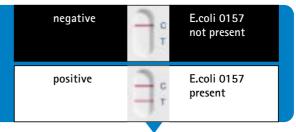
Flow-diagram of Singlepath® GLISA E.coli 0157 test procedure



- Sample 25 g/ml in 225 ml mTSB + Novobiocin or mEC Broth + Novobiocin
- Incubate at 35-37 °C for 18-24h

• Transfer 150 µl to test device and read result after

20 min.



If positive result: Streak onto CT-SMAC agar for confirmation Optional: Check Verotoxin production of positive isolate(s) with Duopath® Verotoxins (AoAC approved)

Product list

| Product | Pack size | Cat. No. | | |
|--|-----------|--------------|-----------------|--|
| mEC selective enrichment broth w/Novobiocin | 500 g | 1.14582.0500 | Enrichment | |
| mTSB selective enrichment broth w/Novobiocin | 500 g | 1.09205.0500 | | |
| Singlepath® E.coli 0157 | 25 tests | 1.04141.0001 | Detection | |
| Duopath® Verotoxins | 25 tests | 1.04144.0001 | | |
| SMAC agar | 500 g | 1.09207.0500 | Isolation media | |
| CT-supplement | 16 vials | 1.09202.0001 | | |

Confirmation

Lateral flow tests For the rapid detection of pathogens in food



Same safety standard as the classical detection method:

Simple to perform, reliable results in just 20 minutes, considerable savings in time and costs.



Wider product range:

Lateral flow tests detect important pathogens in food: E.coli 0157, Verotoxin-producing E.coli, Salmonella, Campylobacter and Listeria.



Additional plus:

Especially adapted media for precise and reliable results.

Merck KGaA

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