NH IMMUNOCHROMATO II 0157 INSTRUCTIONS FOR USE

(Revised May 2024, 1st Edition)
[For Food Inspection Use Only]

**Please read this manual thoroughly before use.

Purpose

NH Immunochromato Π O157 is designed for qualitative detection of E. coli O157 in various food samples in food testing laboratories. It is not intended for clinical use. The kit is meant for use by qualified personnel with experience in aseptic techniques.

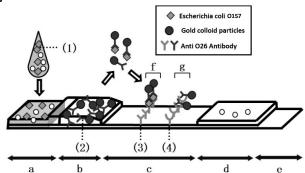
Introduction

Enterohemorrhagic E. coli (EHEC) causes hemorrhagic diarrhea and colitis, which can lead to hemolytic uremic syndrome and even death. EHEC is transmitted via contaminated food or water. NH Immunochromato II O157 is a simple and rapid immunochromatographic kit for detecting E. coli O157, requiring no special detection equipment or technical expertise.

Kit Contents

- 1 Test strip × 20 bags (20 tests).
- Detection Principle
- 1) Parts of the Test Strip:
- a. Sample drop section (do not touch)
- b. Reagent inclusion section
- c. Development section (do not touch)
- d. Absorption pad
- e. Handle
- f. Test zone
- g. Control zone

2) Detection Mechanism:



After dropping the sample onto the strip, it flows through the reagent area. If E. coli O157 is present, it binds to colloidal gold-labeled antibodies forming a complex. This complex moves and accumulates at the

test zone, creating a red-purple test line. A control line appears regardless of the result, ensuring proper test execution.

Limit of Detection

Enrichment cultures containing 1×10^4 – 10^6 CFU/mL of E. coli O157 are judged as positive. Detection sensitivity may vary depending on the bacterial strain, medium, and food matrix.

Precautions for Use

1) General Precautions:

- Read and follow the instructions carefully.
- Verify each procedure and application for different foods.
- Do not use expired kits (expiration on outer label and pouch).
- Not for clinical diagnostics.
- False positives/negatives may occur; confirm positives by another method.
- Check with manufacturers for correct usage of reagents and equipment.
- Specifications are subject to change without notice.

2) Safety Precautions:

- E. coli O157 is highly toxic even in small amounts; wear protective equipment.
- Follow standard microbiological safety protocols.
- In case of accidental contact, rinse with water and seek medical attention.
- Report any physical abnormalities after testing to a physician.

Required Equipment (Not Included)

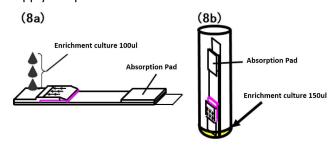
- Enrichment medium (e.g., novobiocin-added mEC)
- Stomacher and filtered stomacher bag
- Autoclave
- Incubator (42 ± 1°C)
- Balance (capable of weighing 25g)
- Pipettes and disposable tips
- Timer
- Sterile polypropylene test tubes

Test Procedure

1. Mix 25g of sample with 225 mL of enrichment broth in a stomacher bag.

NH IMMUNOCHROMATO II 0157 INSTRUCTIONS FOR USE

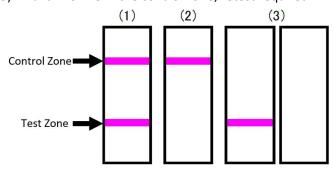
- 2. Stomach for 1 minute.
- 3. Incubate at $42 \pm 1^{\circ}$ C for 18-24 hours.
- 4. Shake bag gently to mix culture.
- 5. Dispense ~5 mL into sterile test tube.
- 6. Sterilize broth if desired and cool to room temperature.
- 7. Open test strip just before use (ensure it's at room temp if refrigerated).
- 8. Apply sample:



- a) Drop 100 μL directly on strip (in 1-2 steps).
- b) Alternatively, dispense 150 μL into tube and immerse strip.
- 9. Read results 15 minutes after sample application.

Result Interpretation

- 1) Positive: Red-purple lines in both test and control zones.
- 2) Negative: Line appears only in the control zone.
- 3) Invalid: No line in the control zone; retest required.



Confirm positive results using official methods. Enrichment may not ensure detection threshold—optimize as needed.

Citrobacter freundii and Salmonella Kumasi (O30) may cause false positives.

Disposal

Sterilize all used materials (strips, tubes, pipettes, enrichment cultures) via autoclaving per local regulations before disposal.

Storage and Expiration

- 1) Store between 2–30°C, protected from light and moisture. Do not freeze.
- 2) Expiry dates are listed on the packaging.

Warranty Disclaimer

Nippon Ham Co., Ltd. offers no guarantees, explicit or implicit. In case of product defect, contact the distributor or Nippon Ham for a replacement. Product specifications are subject to change without notice. Usage and results are the sole responsibility of the user. The company is not liable for damages arising from use.

References

1) Food Safety Bureau Directive No. 1120-1: 'Testing Methods for Enterohemorrhagic E. coli O26, O103, O111, O121, O145, and O157'

Contact Information

Manufacturer: Central Research Laboratories, Nippon

Ham Co., Ltd.

Address: 3-3 Ryokugahara, Tsukuba City, Ibaraki 300-

2646

Phone: 029-847-7825

Email: nh.kit@nipponham.co.jp

Website: https://www.rdc.nipponham.co.jp