NH IMMUNOCHROMATO II 0111 INSTRUCTIONS FOR USE

(2024 Revised: 5th edition)
[For Food Inspection Use Only]

* Be sure to read this manual before using the kit.

Uses

The NH Immunochromatographic IIO111 kit is used to qualitatively detect E. coli O111 in various food samples in laboratory settings.

- Not intended for clinical use.
- Designed for use by personnel trained in aseptic techniques.

Limit of Detection

Positive detection: 1×10^4 to 1×10^6 CFU/mL of E. coli O111 in enrichment cultures.

Sensitivity may vary by:

- E. coli O111 strain,
- type of enrichment medium,
- components in the food sample.

Introduction

Enterohemorrhagic Escherichia coli (EHEC) may cause:

- Hemorrhagic diarrhea,
- Hemorrhagic colitis,
- Hemolytic uremic syndrome (potentially fatal).

Transmission is typically through contaminated food or water.

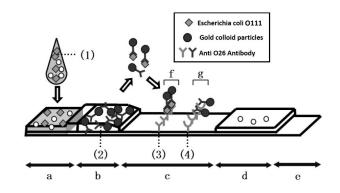
This test kit:

- Provides a rapid and easy-to-use immunochromatographic method for detecting E. coli O111.
- Requires no special equipment or expertise.

Kit Contents

1 pack of 20 test strips (Test §20 bag).

Detection Principle



1. Test Strip Components:

- a. Sample drop area
- b. Reagent inclusion zone
- c. Development section
- d. Absorption pad
- e. Handle
- f. Test zone
- g. Control zone

(Note: Do not touch parts a or c to avoid contamination.)

2. Principle:

- Sample moves from the sample drop area through the reagent zone.
- If E. coli O111 is present, it binds to colloidal gold-labeled antibodies.
- The complex forms visible red-purple lines in:
- Test zone (if positive),
- Control zone (always, to confirm test validity).

Precautions

1. Usage:

- Follow the manual precisely.
- Do not use expired kits.
- Results should be confirmed by other methods if positive.
- Not for clinical diagnostics.
- Validity of procedures must be confirmed per food type.

2. Safety:

- E. coli O111 is highly toxic even in trace amounts.
- Use protective gear (gloves, goggles).
- Follow biosafety protocols.
- Seek medical care if exposed or if symptoms occur.

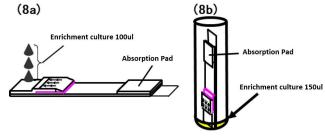
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Required Equipment (Not Included)

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

Test Procedure

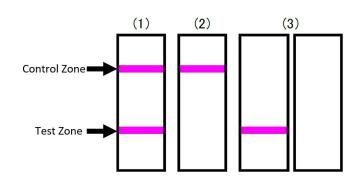
- 1. Add 25 g of test food and 225 mL enrichment medium to stomacher bag.
- 2. Homogenize for 1 minute.
- 3. Incubate at $42 \pm 1^{\circ}$ C for 22 ± 2 hours.
- 4. Shake gently to mix culture.
- 5. Transfer 5 mL of enrichment broth into test tube.
- 6. (Optional) Sterilize broth for safety, then cool to room temperature.
- 7. Open test strip pouch just before use. Let it come to room temp if refrigerated.
- 8. Apply enrichment broth via either method:
 - a) Drop 100 µL directly on strip (twice if needed),
- b) Put 150 μ L in tube and insert strip until it reaches sample zone.



9. Wait 15 minutes before reading results.

Result Interpretation

Result Type | Appearance



Positive | Red-purple line in both test and control zones

Negative | Line in control zone only

Invalid | No line in control zone → retest required

- Positive results should be confirmed using official methods.
- Ensure enrichment meets detection thresholds.

Disposal

Sterilize and dispose of test materials according to local regulations (autoclaving preferred).

Storage and Expiry

Storage: $2-30^{\circ}$ C, away from light and moisture. Do not freeze.

Expiry date is listed on the outer packaging and strip pouch.

Warranty Disclaimer

No express or implied warranty.

Contact distributor or manufacturer for issues.

Use and result interpretation is the user's responsibility.

Reference

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

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