試験結果の判定

1. 鉄性、試験液の滴下から15分後にテストストリップとコントロールゾーンに赤茶色のラインが観察される。 IndianapolisヒトH型糖尿病の検査に準じて、試験の結果は陰性と判定されます。
2. 基本的な操作方法は以下の通りです。 他に試験を希望する場合は、日本サプライズ株式会社までお願いいたします。

【考察範囲】

1. 基本的な操作方法は以下の通りです。 他に試験を希望する場合は、日本サプライズ株式会社までお願いいたします。

【参考文献】

1. (1) 金板監修「1201 第14版 酸塩類検査大図鑑 細菌型」日本薬剤検査法協会2015.01.01
2. (2) 金板監修「1202 第14版 酸塩類検査大図鑑 細菌型」日本薬剤検査法協会2015.01.01

【問い合わせ】

ご不明点のある方は製品を直接お問い合わせください。
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日本サプライズ株式会社 中央研究所
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NH IMMUNOCROMATO O111 "Instruction Manual"

Read this manual before you start using this test kit.

[Introductory use]

NH Immunochromato O111 is intended for use in food testing laboratories for qualitative detection of E. coli O111 from various food products. Not intended for diagnostic use. This kit is intended for use by personnel familiar with the appropriate aseptic techniques for the isolation and identification of E. coli O111.

[Introduction]

Enterohemorrhagic Escherichia coli (EHEC) strains can cause bloody diarrhea or hemorrhagic colitis in humans. Hemorrhagic colitis can progress to potentially fatal hemolytic uremic syndrome. EHEC is transmitted to humans through consumption of contaminated foods and water. Although the most prevalent serogroup of EHEC is O157, non-O157 EHEC, such as O26, O111, and O103, has been increasingly detected all over the world.

NH Immunochromato O111 is an immunochromatographic test kit for simple and rapid testing of E. coli O111. The kit does not require skilled personnel or well-equipped laboratory.

[Kit contents]

A: Test strip 2 tests x 10 packs (20 tests)
B: Instruction manual 1 sheet
C: Plastic bag with zipper 1 piece

1) Illustration of test strip

(a) Sample application zone
(b) Reactant zone
(c) Nitrocellulose membrane
(d) Absorbent pad
(e) Test zone
(f) Control zone

Note 1: Do not scratch or touch with bare fingers on the sample application zone (a) or nitrocellulose membrane (c).

2) Principle of assay

When a sample solution is applied to the sample application zone of the test strip, it is wicked through reactant zone. E. coli O111 (b) in the sample binds to the colloidal gold-labeled anti-E. coli O111 antibody (2) in the reactant zone. The pathogen-antibody complex flows through the nitrocellulose membrane which contains a zone of antibody specific to E. coli O111. The immune complex is captured and concentrated in the zone (test zone) (3), eventually forms a reddish purple line. The membrane also contains a control zone where the gold-labeled anti-E. coli O111 antibody is captured. The control line forms in the control zone (4) regardless of the presence of E. coli O111 in the sample solution. The control line ensures the test is working correctly.

[Detection limit]

The test using 7 strains of E. coli O111 revealed that enriched samples including 1x10^3 CFU/mL of E. coli O111 will yield a positive result.

Note 2: Lower detection limit of the kit may vary depending on the strain and components of the test solution.

[Precautions]

1. E. coli O111 has been shown to have low infective dose.
2. Control line forms in the control zone (4) regardless of the presence of E. coli O111 in the sample solution. The control line ensures the test is working correctly.
3. Use a pH meter to confirm the pH of the sample solution is within the acceptable range.
4. It is recommended to avoid using refrigerated samples in this test. Refrigeration can decrease the activity of enzymes and other biological samples.
5. If the sample solution is too thick, it may affect the test result.
6. Make sure there is no dust or debris on the test strip to avoid interference.
7. Do not re-use test strips. The expiration date is indicated on the aluminum pouches and the box.
8. Good microbiological laboratory practices should be followed to prevent contamination of samples, lab workers, and the environment.

[Additionally required materials and instruments]

1. Enrichment broth (e.g. mECC with novobiocin, mECC)
2. Starchomer and starchamer bags (preferably with a filter)
3. Autoclave
4. Incubator (42±1°C)
5. Balance (capable of weighing 25 g)
6. Disposable plastic transfer pipettes and/or appropriate micro pipettes and disposable tips
7. Timer
8. Disposable polypropylene tubes for sterilization of samples (optional)

[Test procedures]

1. Weigh 25-g sample into the stomacher bag and add 225-mL enrichment broth, e.g. mECC with novobiocin, mECC.
2. Homogenize with a stomacher for 1 minute.
3. Incubate the homogenized sample at 42±1°C for 22±2 hours.
4. Remove the stomacher bag from the incubator and mix the culture gently using side-to-side motion.
5. Transfer approximately 5-mL enriched sample to an appropriate test tube with a sterilized pipette (Note 3). Cap with a loose-fitting cap.
6. Sterilize enriched sample by autoclaving (121°C, 20 minutes) or boiling (15 minutes). The sterilized sample solutions should be applied to test strips after cooling to room temperature (Note 4).
7. Allow the test strips warm to room temperature (20-25°C) before opening the aluminum pouch. Open the pouch immediately before use (Notes 5, 6).

*Enriched sample should be applied to a test strip by either of following procedures (6a or 6b).

[Interpretation of the test results]

1. Positive results: Reddish purple lines appear in the test zone and the control zone in 15 minutes after application of sample solutions.
2. Negative results: A reddish purple line appears in the control zone.
3. Invalid results: No reddish purple line appears in the control zone.

Note 6: Presumptive positive results should be confirmed according to authorized methods 5. The enriched samples prepared for testing with the kit can be used in confirmatory tests.

[Disposal]

Decontaminate used test strips, test tubes, pipettes, and enriched culture by autoclave, etc. in strict compliance with local, state and federal disposal regulations.

[Storage and expiration date]

1. Storage: NH immunochromato O111 should be stored at 2-8°C under protection from the light. NH immunochromato O111 must not be frozen.
2. Expiration date: 12 months from the date of manufacture.

[NH Foods Ltd.] makes no warranty, whether expressed or implied, if any materials are defective. Distributor or NH Foods Ltd. will provide a replacement of the product. There is no warranty of merchantability or fitness for a particular purpose. Each user is expected to verify the appropriateness of each operating procedure and the application to individual food materials. NH Foods Ltd. shall not be liable for any damages, including special or consequential damage, or expense arising directly or indirectly from the use of this product.

[References]

1. MHLW Notice No. 1120 Article 3, from the Inspection and Safety Division: "Detection Methods for Enterohemorrhagic E. coli O26, O103, O111, O121, O145 and O157 from foods"

[Technical assistance]

For technical assistance, please contact distributor or manufacturer.

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- Manufacturer
  - R&D Center, NH Foods Ltd.
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