Rapid Nucleic Acid Diagnostics

Molecular Testing, Anywhere!

Disposable Nucleic Acid Detection Device（Type 3）

CE

REVISION DATE: 05/16
SM-D03-ENG-2
REF D001-03 (20 Tests)

IVD

TRADE NAME AND INTENDED USE

The Disposable Nucleic Acid Detection Device is for detecting an amplified specific nucleic acid fragment. For research use only.

INTRODUCTION

The Disposable Nucleic Acid Detection Device is packed with a detection strip utilizing an antibody based immunochromatographic sandwich mechanism. Detection is performed in a sealed cartridge preventing cross-contamination from amplified products. Preparation requires just 1-2 min and results appear in 10-15 min after placing the tube in the cassette. In contrast to traditional electrophoresis, it offers a rapid, cross-contamination proof, non-toxic and instrument-free method for the visualization of nucleic acid amplification products.

If the Disposable Nucleic Acid Detection Device is not purchased with the kit, or if using amplification methods other than those provided by Ustar, be sure to label two primers or probes, one labeled with Biotin and one labeled with Fitc. The labeled products are captured on the T-line resulting in the appearance of a red line. The control line appears irrespective of amplification and indicates that the strip is functioning properly.

KIT COMPONENTS

Detection Device	Packed in individually sealed aluminum pouch with desiccant Store at 2℃ to 30℃	20 devices
Spare vacuole		2 pieces
Instructions For Use		1 copy

STORGE AND STABILITY OF THE DEVICE

- The device is shipped at 2-30℃. The diagnostics kit internal controls indicate that the device has not been damaged during transport.
- Store the device in its original box at 2-30℃.
- Once open the packing, use as soon as possible to avoid the nucleic acid detection strip is affected with damp.
- Performance of the device after the first opening is stable up to the expiry date of the device when stored at 2-30℃.
- After first use, the device cannot be used.

SAFETY AND PRECAUTIONS

- The detection device just for professional to use.
- The detection device just for in vitro diagnostics.
- Dispose of all used nucleic acid detection device, and other materials used with the kit as biohazardous waste.
- Do not use the device affter the expiry date.
- Before use, please check the vacuole without leakage and in position. If the vacuole fall off within the packaging of inner core, install it in position according to Figure 1.If it is leakage, please use the spare vacuole.
- In order to prevent pollution and false positive, the detection device may not be forced open after the reaction.
- The detection device stored at the tempreture less than 1℃ or has been frozen may cause the false result.
- Use the detection in violation of or not according to the instruction may cause the false result.
- The liquid in the vacuole is very little may cause the result will not show or extension of time.
- The operator weak in color or insufficient light may cause the false result.
- This product is a disposable product, please do not reuse. Please read carefully and in strict accordance with the instruction before using.
- Repeat detection same nucleic acid, may cause contamination.

EQUIPMENT AND MATERIAL REQUIRED BUT NOT PROVIDE

- Laboratory time or watch

ASSAY PROCEDURE

IMPORTANT: Strict adherence to the assay procedure will ensure optimal assay performance. Any procedure deviation may lead to aberrant results.

1. Determine how many devices you need for testing the specimens and controls. You need one device for each test. Each device must be labeled to enable identification of different specimens.
2. Place the tube into the holder of the device cartridge, then fold to close the cartridge.
3. Insert the cartridge into the Detection Device, push the handle to the locked position (refer to Figure 1).
4. Wait for 15 to 30 minutes to read the result. Results read after 30mins are invalid.

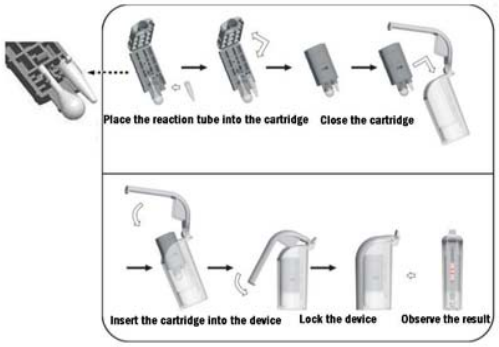

Figure 1 Operation of Detection Device

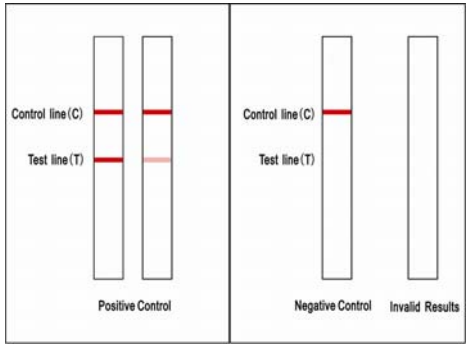

Figure 2 Interpretation of Test Results

INTERPRETATION OF THE RESULTS

A valid test results MUST fulfill the following requirements (refer to Figure 2).

1. Positive - two bands should appear：One control line and one test line. Positive result indicates that the sample contain the objective nucleic acid.
2. Negative - ONLY control line shall appear. Negative result indicates that the sample does not contain the objective nucleic acid.
3. Invalid- no band appear：No control line and test line. It suggests that the amplification reagents are damaged, failure or incorrect operation. Then should read the instructions carefully, and repeat the amplification and detection of the original sample. If the problem still exists, should stop using the batch number of product immediately, and contact with the local supplier.

BIBLIOGRAPHY

1.Wing Huen A. Chow, Cindy McCloskey, Yanhong Tong, Lin Hu, **Qimin You**, Ciarán P. Kelly, Huimin Kong, Yi-Wei Tang, and Wen Tang, (2008), "Application of isothermal helicase-dependent amplification with a disposable detection device in a simple sensitive stool test for toxigenic Clostridium difficile", The Journal of Molecular Diagnostics，Vol 10 No 5，Published before print on line.

TECHNICAL PROBLEMS / COMPLAINTS

Should there be a technical problem / complaint:

1. Note the kit(s) lot number(s) and the expiry date.
2. Retain the kit(s) and the test device(s).
3. Contact Ustar Biotechnologies (Hangzhou) Ltd. or your local distributor.

DESCRIPTION OF SYMBOLS USED

The following are graphical symbols used in or found on **Ustar Nucleic Acid Diagnostics** products and packaging. These symbols are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the British and European Standard BS EN 980: 2003.

	Use by Synonym for this :Expiry Date	IVD	In vitro diagnostic medical device
LOT	Batch Code Synonyms for this are: Lot Number Batch Number	EC REP	Authorized Representative in the Europern Community
	Attention.See Instruction for Use		Limit of Temperature
	Manufacturer	REF	Catalogue Number
Σ	Contains sufficient for <n> tests	CONT	Contents
	Do not reuse	CE	Conformite Europeenne

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