

Working Principle

This product uses lateral flow dual-antibody sandwich assay for rapid detection of nucleic acid amplification products. Compared with traditional agarose gel electrophoresis detection, the nucleic acid detection test strip is simple to operate, rapid to interpret, contains no toxic substances, and requires no instruments or equipment. Users only need to label one primer/probe with Biotin and the other primer/probe with FITC or 6-FAM during the first detection sequence primer design, and label one primer/probe with FAM and the other primer/probe with Digoxin during the second detection sequence primer design. There are 2 labeling schemes available, see the table below. Ensure that both labels can be simultaneously incorporated into the double-stranded amplification product to use this product for detection. If using internal reference design, please design the internal reference fragment label as Digoxin.

Labeling Scheme: 5'Biotin----5'FAM(FITC), 5'Digoxin-----5'Biotin

Intended Use:

Detection of nucleic acid amplification products.

Package Specification/Cat. No.:

Package Specification: 10 strips/package × 5, aluminum foil bag moisture-proof packaging.

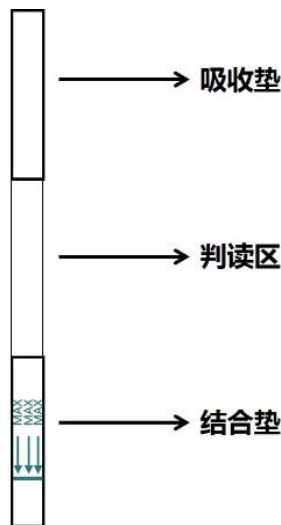


Figure 1. Schematic Diagram of Disposable Nucleic Acid Detection Test Strip Structure

Storage Conditions and Shelf Life:

Storage Conditions: Store in a dark and dry place at 4-30° C.

Shelf Life: 12 months.

Procedure:

1. Take out the corresponding number of test strips according to the number of samples to be tested, and mark them on the absorbent pad (Figure 1). Each test strip can only be used for single detection of a single sample. When the amplification product volume is 50-100 μL, the nucleic acid product can be directly detected in a 200 μL PCR

reaction tube. When the product volume is less than 50 μL , ultrapure water needs to be added to the PCR tube to make up the volume to 50 μL , mix thoroughly by pipetting, and then detection can be performed.

2. After PCR, RPA, or RAA reaction is completed, open the PCR reaction tube and insert the conjugate pad end (arrow end) of the test strip into the PCR reaction tube (Figure 1). The liquid level must not exceed the top of the conjugate pad. Wait for the reading zone to be fully wetted (approximately 1-2 minutes; when the ambient temperature is low, such as in winter, the wicking speed will be reduced and the wetting time of the reading zone will be extended). After the control line (C line) develops color, the test strip can be removed. Read the detection result directly according to the color development of the test strip.
3. Observe the results within 10 minutes after the control line (C line) develops color. Reading after 10 minutes is invalid.
4. Record the detection results and seal and discard the test strips in a safe place.

Interpretation of Results:

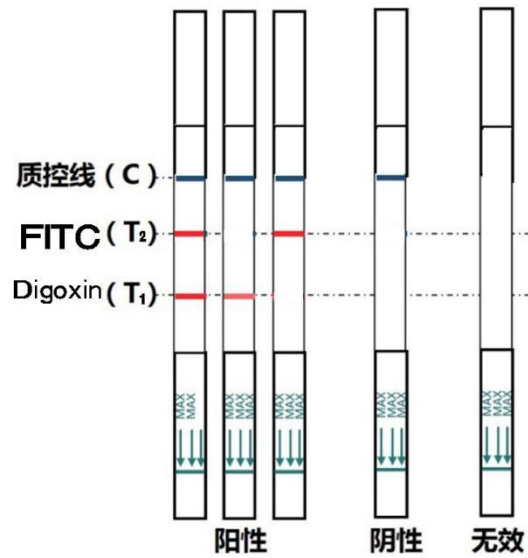


Figure 2. Schematic Diagram of Disposable Nucleic Acid Detection Test Strip Result Interpretation

1. **Positive (+):**
The test strip shows one blue band at the control line (C line) and 2 red bands at the test line (T line). A positive result indicates that the sample contains the nucleic acid fragment to be tested, and its quantity is \geq the minimum detectable limit of the test strip. When the target nucleic acid product concentration is low, the test strip C line appears blue and the T line appears light red or even light pink, and this result should also be judged as positive. When the target nucleic acid product concentration is high, both the C line and T line appear red, and this result should also be judged as positive.
2. **Negative (-):**
A blue band appears at the control line (C line) of the test strip, and no band appears at the test line (T line). A negative result indicates that the sample does not contain the target nucleic acid fragment, or its quantity is below the minimum detectable limit of the test strip.
3. **Invalid:**
No bands appear at both the control line (C line) and the test line (T line) of the test strip, indicating that the test strip or amplification reagent used may be damaged, invalid, or there was an operational error.
In this case, read the instructions carefully, re-amplify and re-test. If the problem persists, stop using the product from the same batch immediately and contact the local supplier.

Warnings and Precautions:

- 1. This product is for research use only. Please read the instructions carefully before use and operate strictly according to the instructions. Violation or failure to operate according to the instructions may lead to erroneous results.**
- 2. The product should be stored under appropriate environmental conditions and temperature according to the instructions and used within the validity period. Improper storage or expired product may lead to erroneous results. Use the test strips as soon as possible after opening the package to avoid affecting the test results due to moisture. Insufficient lighting in the detection environment, operator color weakness, and other factors may lead to erroneous results.**
- 3. After use, put the test strips into a sealed bag as soon as possible and dispose of them properly. This product is for single use only. Do not reuse.**
- 4. After receiving this product, test each indicator separately with this product. After amplification of each indicator, it should be at the accurate position without false positives. Then verify the sensitivity of the primer system for that indicator. When the 2 indicators are at the same sensitivity level, amplify with the dual-primer system. Then test with this product.**