RayBio® COVID-19 Nucleocapsid Protein Rapid Antigen Test Kit

Catalog number: TRF-CoV-N

User Manual
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INTRODUCTION

This kit is suitable for the quantitative detection of novel coronavirus (SARS-CoV-2) Nucleocapsid Antigen in human nasopharyngeal swabs and saliva taken in standard CDC viral transport media (VTM). The detection kit uses the principle of fluorescent immunochromatography: the separation of components in a mixture through a medium using capillary force and the specific and rapid binding of an antibody to its antigen. Each cassette is a dry medium that has been coated separately with fluorescent labeled mouse anti-SARS-CoV-Nucleocapsid antibody ("T" test line) and fluorescent labeled rabbit anti-IgG antibody ("C" control line). Once diluted a saliva or nasopharyngeal swab sample is applied to the release pad section, the fluorescent labeled mouse anti-SARS-CoV-Nucleocapsid antibody will bind to Nucleocapsid protein antigen present in the sample (if present), forming a complex. When these fluorescent labeled antibodies are excited by a light source from the fluorescent analyzer, the antibodies emits a fluorescent signal of a specific wavelength. This fluorescent signal can be measured by the fluorescence analyzer, which automatically converts this signal into a quantitative value through the signal conversion and calibration curve stored on the provided ID card. Once converted by the analyzer, the concentration of Nucleocapsid antigen in the sample can be detected, and that level can be compared against known positive and negative indications of positive and negative antigen samples.

PACKAGING SPECIFICATIONS

25 tests/box

PURPOSE

This kit is used for the quantitative detection of novel coronavirus (SARS-CoV-2) Nucleocapsid antigen in human saliva and nasopharyngeal swabs.

KIT COMPONENTS

Component	Specification	Quantity	Ingredients
Detection Cassette	1 unit / bag	25 bags / kit	Test cassette, desiccant
Sample Diluent	300 µl / tube	3 tubes / kit	Sample diluent, liquid
ID card (includes standard curve)	1 unit / box	1 unit per kit	ID card
Manual	1 unit / box	1 unit per kit	Manual

The components of the Detection Cassette are:

1. Mouse anti-Novel coronavirus Nucleocapsid antibody (fixed on porous capillary membrane)
2. Goat anti-rabbit IgG antibody (fixed on porous capillary membrane)
3. Fluorescent labeled mouse anti SARS-CoV-Nucleocapsid antibody (fixed on porous capillary membrane)
4. Fluorescent labeled rabbit anti-IgG antibody (fixed on porous capillary membrane)

Note: The components from different batches cannot be used interchangeably.

STORAGE AND EXPIRATION

Keep kits in a cool and dry place at 4-30°C. Correctly stored kits are valid for 12 months (see the box for expiration date).

REQUIRED INSTRUMENTS (NOT INCLUDED)

- Guangzhou Labsim Biotech Co.,Ltd Immunofluorescent Analyzer - single channel (AFS-1000)
- Vortex Mixer
- Microcentrifuge
- Pipettes
- Sterile nuclease-free pipette tips and microfuge tubes

SAMPLE REQUIREMENTS

Assay is suitable for nasopharyngeal swab samples with standard CDC Viral Transport Media (VTM). Samples should be used as soon as possible after collection.

1. Nasopharyngeal swab collection: Samples should be collected via swab and should be placed into the VTM buffer immediately.
2. Saliva collection: Samples should be collected via Collection Funnel and Saliva Collector.
3. During sample processing disposable filtered pipettes or pipette tips are required, and care must be taken to prevent cross-contamination.

SAMPLE PRESERVATION

Samples should be run as soon as possible after collection. Otherwise, samples should be kept at 2-8°C. If long-term storage is required, please store at -70 °C. Avoid repeated freezing and thawing**.**

TESTING METHOD

Read the instructions carefully before use. For detailed procedures of operating the Labsim AFS-1000 Immunofluorescent Analyzer, consult the manufacturers' protocol. Bring the Detection Cassette, Sample Diluent, and sample to room temperature before testing.

1. Equipment set up: Turn on the equipment, insert ID card to the equipment and press "read ID card" on the screen, then choose sample type and input sample number if needed.
2. Sample preparation: In an empty microcentrifuge tube, add 108ul of sample to 12ul sample diluent and mix thoroughly.
3. After mixing, add 100µl of the now prepared Sample to the Sample Pad (See Image 1 below)
4. Incubate the sample at room temperature for 15 minutes.
5. Insert the detection cassette into the reader, press "Read". The equipment will automatically detect the cassette, press "print" button to print the test results.
6. Results measured after 25 minutes are invalid and should be discarded.

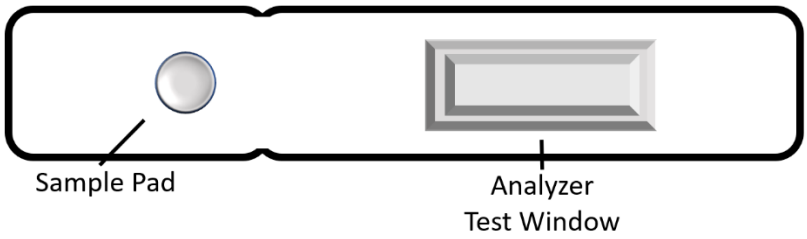

Figure 1: Schematic of the Cassette with labeled Sample pad and Analyzer Test Window Sections

INTERPRETATION OF TEST RESULTS

1. Positive for coronavirus antigen: A positive result for an unknown sample is considered as a pg/ml calculated value using the calibration curve of greater than 0.18 ng/ml.
2. Negative for coronavirus antigen: A negative result for an unknown sample is considered as a pg/ml calculated value using the calibration curve of less than 0.18 ng/ml.
3. Invalid: The equipment cannot read control line (C) band. The results are invalid; sample should be repeated with a different cassette.

PRECAUTIONS

1. This test is for Research Use Only (RUO) and is intended for use only in a research setting.
2. This test is not for personal use.
3. The assay should be performed as outlined in this manual, and in accordance with all instructions.
4. Do not use expired or damaged products.

5. Only use the matching diluent, ID card in the kit package. Diluents and ID card from different kit lots cannot be mixed.
6. Strictly control the time from loading sample to testing for 15 minutes.
7. Do not use tap water, purified water, or distilled water as negative controls.
8. The test should be used within 1 hour after opening. If the ambient temperature is higher than 30 °C, or the test environment is humid, the Detection Cassette should be used immediately.
9. If there is no movement of the liquid after 30 seconds of beginning the test, 1 additional drop of sample solution should be added.
10. Samples should be regarded as potentially infectious, requiring the use of appropriate biosafety measures.
11. Take care to prevent the possibility of virus infection when collecting samples. Wear disposable gloves, masks, etc., and wash your hands afterwards.
12. Inadequate or inappropriate specimen collection, storage, and transport may yield inaccurate test results.
13. This test card is designed for a single, one-time use. After use, the test card and samples should be regarded as medical waste with risk of biological infection and properly disposed of in accordance with national regulations.

This product is for research use only.