Environmental COVID-19 (SARS-CoV-2) RBD Nucleic Acid Rapid Detection Kit (Isothermal Amplification Method)

Cat. No.	Product Description	Specification
COV3002	Environmental COVID-19 (SARS-CoV-2) RBD Nucleic Acid Rapid Detection Kit (Isothermal Amplification Method)	10 Tests/Box

This product is used for qualitative detection of COVID-19 (SARS-CoV-2) RBD antigen in aquatic products, e.g. fish and shrimp, livestock, e.g. pigs, cattle and sheep, and the environment.
This product is only used to provide preliminary results and cannot be used as the only basis for the COVID-19 (SARS-CoV-2) detection results.
This product is made for professional and laboratory use.
Please read through this manual carefully before use.

TESTING PRINCIPLE

This testing kit uses RT-LAMP (Reverse Transcription-Loop-mediated Isothermal Amplification) technology combining visualizing method to perform amplification detection of the RBD region in COVID-19 (SARS-CoV-2) virus RNA, which can detect and identify the RBD antigen of COVID-19 (SARS-CoV-2) virus in aquatic products, e.g. fish and shrimp, livestock, e.g. pigs, cattle and sheep, and the environment.

PACKAGE INFORMATION

10 Tests/Box

MAIN COMPONENT

Package content:

1. Magnetic stand (optional)
2. Metal bath (optional)
3. 1.5 mL centrifuge tube
4. PCR tube
5. Cotton swab
6. Reconstituted solution
7. Nucleic acid extraction reagent:
   Sample Lysis Solution L1, Sample Lysis Solution L2, Proteinase K, Magnetic Beads, Isopropanol, Washing Solution W1, Washing Solution W2, Elution Solution TB
8. Isothermal PCR amplification reagents:
   Bst4.0+ DNA Polymerase, 10X Primer Mix, 2X LAMP Buffer, RNase Free H_2O, Positive Control
9. Product manual

SAMPLE EXTRACTION

1. Sample processing: Repeatedly scrape the surface of the tested sample with cotton swab, cut the tip of the cotton swab and put it into a centrifuge tube containing approximately **200 µL Reconstituted solution**. Shake up the tube repeatedly.
2. Add **300 µL Sample Lysis Solution L1**, **300 µL Sample Lysis Solution L2** and **20 µL Proteinase K (20 mg/mL)** to a 1.5 mL centrifuge tube, then add 200 µL of the virus containing sample solution from step 1. Vortex to mix and then place the reaction tube at 55°C water bath for 15 minutes. Mix the sample by converting the tube upside down 3 to 4 times during the water bathing process.
3. Add **15 µL Magnetic Beads** and **300 µL Isopropanol,** mix well and incubate for 9 minutes in total. Every 3 minutes, shake and mix the sample for 1 minute.
4. Place the centrifuge tube on the magnetic stand for 30 seconds until the magnetic beads are completely attach to the surface of the tube. Discard the supernatant carefully.
5. Add **900 µL Washing Solution W1**, shake and mix for 2 minutes.
6. Place the centrifuge tube on the magnetic stand for 30 seconds until the magnetic beads are completely attach to the surface of the tube. Discard the supernatant carefully.
7. Add **500 µL Washing Solution W1**, shake and mix for 2 minutes.
8. Place the centrifuge tube on the magnetic stand for 30 seconds until the magnetic beads are completely attach to the surface of the tube. Discard the supernatant carefully.
9. Remove the centrifuge tube from the magnetic stand, add **900 µL Washing Solution W2,** shake and mix for 2 minutes.
10. Place the centrifuge tube on the magnetic stand for 30 seconds until the magnetic beads are completely attach to the surface of the tube. Discard the supernatant carefully.
11. Remove the centrifuge tube from the magnetic stand, add **300 µL Washing Solution W2**, shake and mix for 2 minutes.
12. Place the centrifuge tube on the magnetic stand for 30 seconds until the magnetic beads are completely attach to the surface of the tube. Discard the supernatant carefully.
13. Place the centrifuge tube on the magnetic stand and dry the sample under room temperature for 10-15 minutes.
    Note: The ethanol residue in the washing solution will inhibit the subsequent enzyme reaction. Make sure the ethanol evaporates completely. Also, do not dry the sample for too long in order to avoid the difficulty in DNA eluting.
14. Remove the centrifuge tube form the magnetic stand, add **50-100 µL Elution Solution TB**, shake and mix well. Then incubate at 56°C for 10 minutes. Invert the tube to mix for 3 times during the incubation.
15. Place the centrifuge tube on the magnetic stand for 2 minutes until the magnetic beads are completely attach to the surface of the tube.
16. Carefully transfer the supernatant containing sample DNA to a new centrifuge tube for further experiments or storing under appropriate conditions.

DETECTION PROCEDURE

Isothermal PCR amplification

1. Reaction preparation
   Add the following reagents to a 0.2 mL PCR tube

2X LAMP Buffer	10 µL
Bst4.0+ DNA Polymerase	2.5 µL
10X Primer Mix	2 µL
Sample	2 µL
RNase Free H_2O	3.5 µL

2. Place the PCR tube at **63°C** (preheated metal bath or constant temperature water bath) for 10-20 minutes for result interpretation. The reaction time should not exceed 20 minutes.

INTERPRETATION OF TEST RESULTS

Negative result: The sample solution stays red without color change after the reaction.
Positive result: There is an obvious color change form red to yellow during the reaction.

Negative

Positive

STORAGE CONDITION AND VALIDITY

Isothermal amplification reagents should be sealed and stored at -20°C to ensure their performance. Other reagents can be place at 2~8°C for long-term storage. Consumables, constant temperature metal bath and magnetic stand can be stored at room temperature, avoid direct sunlight, humidity and high temperature. The validity period of the product is 1 year.

WARNING and PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Do not reuse.
3. Do not use if the product seal or its packaging is compromised.
4. Do not use the kits beyond their expiration date shown on the pouch.
5. Do not mix and interchange different specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
7. Wash hands thoroughly after finishing the tests.
8. Do not eat, drink or smoke in the area where the specimens or kits are handled.
9. Clean up spillage thoroughly with appropriate disinfectants.
10. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
11. Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, regional or national regulations.
12. Keep out of children's reach.

PRODUCT USE LIMITATION

1. These products are intended for research use only.
2. Follow the instructions of the kit during the testing process.
3. The kit has good specificity and does not cross-react with influenza and other viruses.
4. Short reaction time and no additional professional equipment required.
5. The result is visible and easy to interpret.
6. High sensitivity, even the trace nucleic acid residues can be detected.
7. This method does not have the medical test efficacy
8. This method is only used for rapid screening of the environment and food.
9. A positive result of the test indicates the testing products have pass through a high-risk area. Be cautious and the report to the local health department is needed for the further confirmation.