

Environmental COVID-19 (SARS-CoV-2) RBD Antigen Rapid Detection Kit (Colloidal Gold-Based)

Cat. No.	Product Description	Specification
COV2001	Environmental COVID-19 (SARS-CoV-2) RBD Antigen Rapid Detection Kit (Colloidal Gold-Based)	50 Tests/Box

INTENDED USE

This product is used for qualitative detection of COVID-19 (SARS-CoV-2) virus 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) virus detection results.

This product is made for professional and laboratory use.

Please read through this manual carefully before use.

TESTING PRINCIPLE

The detection kit can detect as well as identify 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 by using colloidal gold immunochromatography. The reagent pad contains anti-COVID-19 (SARS-CoV-2) virus RBD antibody conjugated with colloidal gold particles and the secondary antibody against anti-COVID-19 (SARS-CoV-2) virus RBD antibody are immobilized in a line across the reaction membrane as a test line (T line). The COVID-19 (SARS-CoV-2) virus RBD is first captured by colloidal gold conjugated anti-RBD antibody and the antigen-antibody-conjugate complex is formed during testing process. The Ag-Ab complex then is detected by the secondary antibody coated on the T line while migrates across the reaction membrane and a visible pink signal band is formed. If there is no COVID-19 (SARS-CoV-2) virus RBD antigen contained in the sample, no pink band will appear at the T line.

The quality control line (C line) on the reaction membrane is an indicator of product effectiveness. No matter whether the signal at T line appears or not, a pink line should always appear at C line. If no pink signal is shown at C line, it indicated that the test result is invalid and additional testing is required.

PACKAGE INFORMATION

50 Tests/Box

MAIN COMPONENT

Package content:

1. Package content: test strip (50 cards/box), desiccant
2. Sample diluent solution (5x 10 ml)
3. Product manual

OTHER MATERIAL REQUIRED BUT NOT PROVIDED

1. Pipette or dropper
2. Cotton swab
3. Test tube (1.5 ml or 2 ml)

STORAGE CONDITION AND VALIDITY

The test strips and reagents should be sealed and stored at 2°C -30°C to avoid direct light, humidity and high temperature. The validity period is 12 months.

SAMPLE PREPARATION

1. **Collection:** Use a cotton swab gently wipe the surface of the sample to be tested, e.g. fish, shrimp, pork, beef, mutton and countertop. (Note that the sample should be kept intact, not shredded or stained, so as not to affect the detection results.)
2. **Reconstitution:** Put the cotton swab from step (1) into a test tube containing 1 ml Sample diluent solution, stir 3~5 times and soak for one minute, then apply the soaking solution to the testing card for detection.

DETECTION PROCEDURE

The sealed bag, including test strips and desiccant, and samples should be returned to room temperature before use.

1. Tear the slit of the sealed bag, take out the test strip from the sealed bag, then place the test strip on a flat and dry surface.
2. Add 120 µL of the prepared sample solution to the sample pad (upper part of the sample hole near the test window) with pipette.
3. Read the result after 15 minutes.

Note: The interpretation result is invalid after 20 minutes.

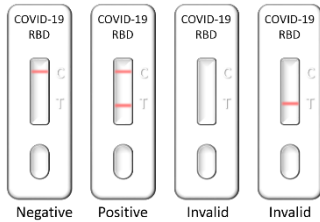


INTERPRETATION OF TEST RESULTS

Negative results: If only the quality control line (C line) shows color and test line (T line) does not develop color and the result is negative.

Positive results: Both of the quality control line (C line) and the test line (T line) develop color.

Invalid result: If the quality control line (C line) does not develop color, regardless of whether the test line (T line) develops color, the result is invalid, and the test needs to be performed again.



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. Humidity and temperature will adversely affect the results.
3. Follow the instructions of the kit during the testing process.
4. The presence of interfering substances in the sample or factors beyond the manufacture control, such as product related technical or procedural errors, may lead to incorrect results.
5. Although this product shows high accuracy in detecting COVID-19 (SARS-CoV-2) virus antigen, there is still a low probability of false results.