

SARS-CoV-2 Antigen RAPID TEST KIT

(Fluorescence Immunochemistry)

This rapid kit is used for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen (hereinafter referred to as SARS-CoV-2 N-antigen) in human serum and nasopharyngeal swab and/or oropharyngeal swab samples

PRINCIPLE

This rapid kit uses a fluorescence immunochemistry method to detect SARS-CoV-2 N antigen. The sample to be tested is applied to the sample window of the test cassette.

The SARS-CoV-2 N-antigen in the sample forms a complex with the antibody labeled with fluorescent microspheres. This complex migrates along the membrane and reaches the test region (T-line) on which a second antibody against the SARS-CoV-2 N-antigen is applied. Unbound fluorescent microspheres migrate along the membrane to the control region (C-line) and are bound by the control region antibody. The test result in the test window is made visible with a UV lamp with a wavelength of 365 nm. If both the T-line and the C-line fluoresce, the test result is SARS-CoV-2 N-antigen positive; if only the C-line fluoresces and no T-line becomes visible, the test result is SARS-CoV-2 N-antigen negative. If no C-line becomes visible the test result is invalid and the sample must be retested with a new test cassette.

COMPONENTS:

- 25 Test Cassettes
- 25 Pipettes
- 1 Instruction For Use
- 25 Swabs
- 2 Extraction Buffer (4 mL)
- 25 Extraction Vials/Caps

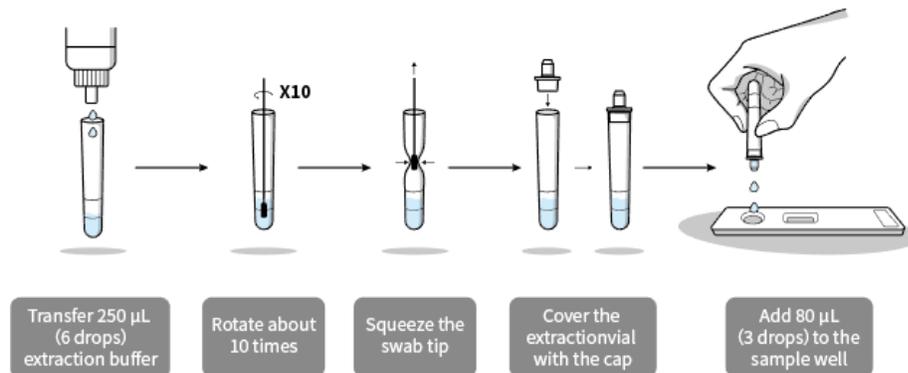
TEST PROCEDURE FOR SWAB SAMPLES

Step 1: Transfer 250 μ L (6 drops) extraction buffer to the sample extraction vial.

Step 2: Insert the swab which has collected secretions into the extraction buffer and rotate about 10 times to dissolve the sample in the buffer as much as possible.

Step 3: Squeeze out the swab tip by pressing the side of the extraction tube to keep as much liquid as possible in the tube.

Step 4: Cover the vial with the cap.

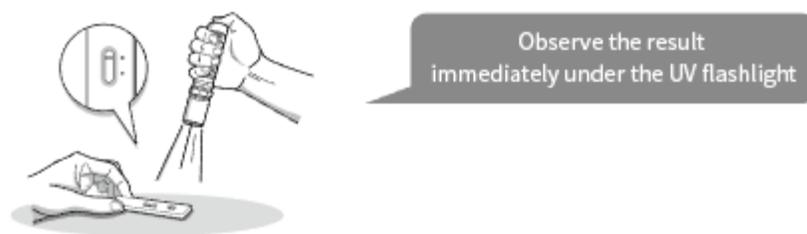


Step 5: Tear open the aluminum foil bag, take out the test cassette and place it on a horizontal surface.

Step 6: Write the sample number on the test cassette.

Step 7: Apply 80 μ L (3 drops) of the sample extract into the sample hole of the test cassette. Ensure that there is no bubble during the operation.

Step 8: After 15 minutes have elapsed observe the test results by illuminating the interpretation window with the fluorescent flash light. Interpret the result within 10 seconds under the illumination of the fluorescent flash light. Long time exposure under the UV light will cause a diminishing of the fluorescent signal and may affect the interpretation of the result.



TEST PROCEDURES FOR SERUM SAMPLES

Step 1: Take out the test cassette and sample to be tested and let it reach room temperature.

Step 2: Tear open the aluminium foil bag, take out the test cassette and place it on a horizontal surface.

Step 3: Write the sample number on the test cassette.

Step 4: Pipette 80µL (3 drops with the included pipette) of the sample to be tested and apply it into the sample hole on the test cassette. Ensure that there is no bubble during the operation.

Step 5: After 15 minutes have elapsed observe the test results by illuminating the interpretation window with the fluorescent flash light. Interpret the result within 10 seconds under the illumination of the fluorescent flash light. Long time exposure under the UV light will cause a diminishing of the fluorescent signal and may affect the interpretation of the result.

