SPRING HEALTHCARE

SARS-COV-2 ANTIGEN RAPID TEST CASSETTE (SWAB)

montfort medical

Authorised Distributor for Spring Healthcare Services AG

The **Spring Healthcare** SARS-Cov-2 **Antigen Rapid Test Cassette** (swab) is an in vitro diagnostic test for the qualitative detection of novel coronavirus antigens in Nasopharyngeal swab, using the rapid immunochromatographic method.

It can detect acute infection in a fraction of the time as PCR tests. Rather than performing all of the analytical steps inside an expensive dedicated machine at a lab done with tests for the DNA or RNA of the virus, antigen tests build most of those steps into a paper-like strip that returns a simple yes or no answer, much like pregnancy tests.

Detection Time: 10-20 Minutes
Test Kits Per Box: 25
European Components: 100%
European Manufactured: 100%

The **Spring Healthcare** SARS-Cov-2 **Antigen Rapid Test Cassette** (swab) does not differentiate between SARS-CoV and SARS-CoV-2. Results from an antigen test need to be confirmed with a PCR test prior to making treatment decisions or to prevent the possible spread of the virus due to a false negative.

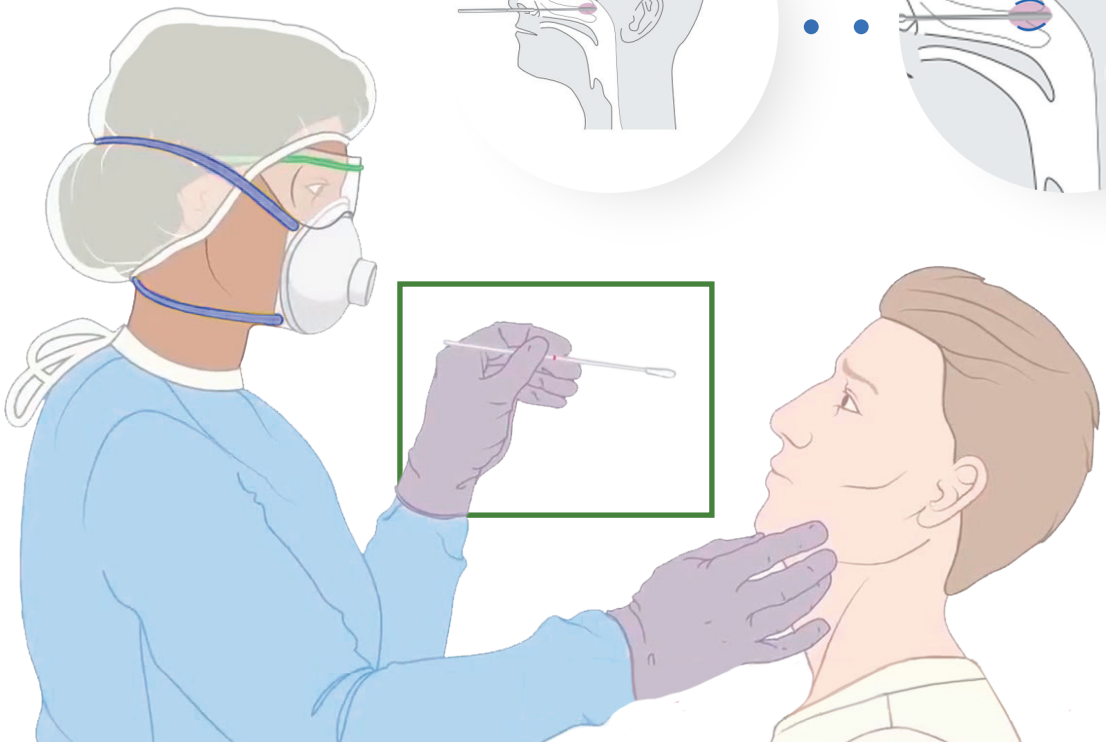
The identification is based on the monoclonal antibodies specific for the novel coronavirus antigen. It will provide information for clinical doctors to prescribe correct medications.

HOW TO USE

SPECIMEN COLLECTION

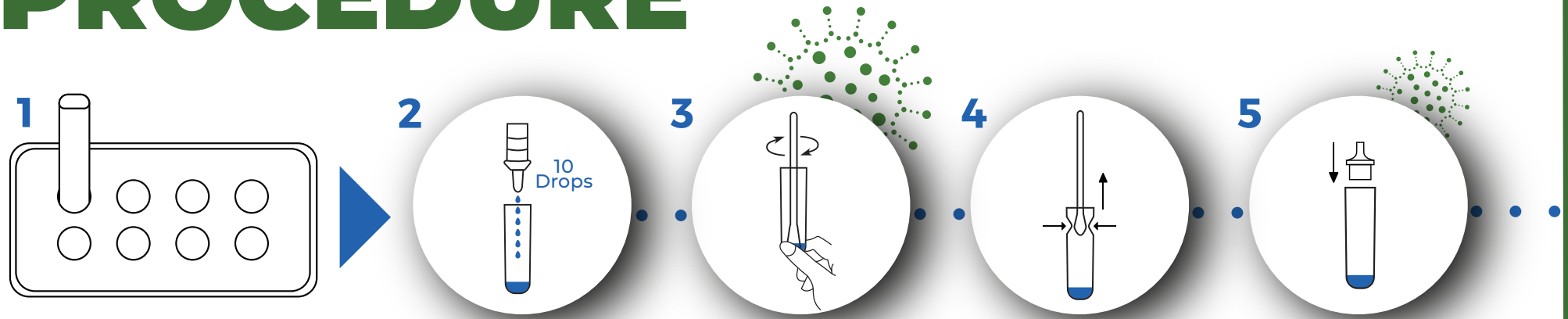
Nasopharyngeal Swab

- insert the sterilized swab supplied in this kit into the nasal basin.
- swab several times to collect the epidermal cells of the mucus.



PREPARATION

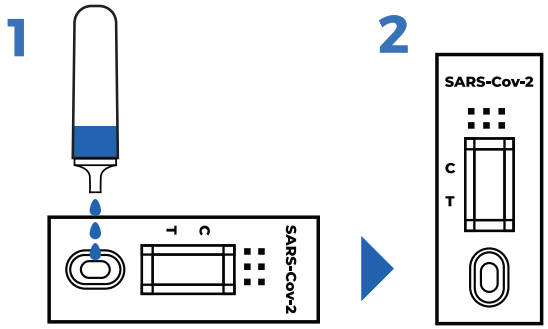
SAMPLE PREPARATION PROCEDURE

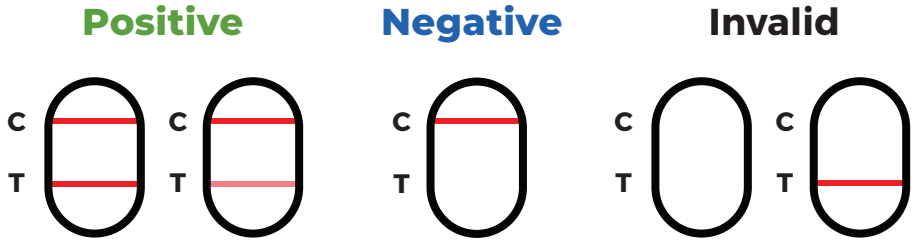


1. Insert the test extraction tube into the tube stand. Make sure that the tube is standing firm.
2. Add 0.3 mL (about 10 drops) of the sample extraction buffer into the extraction tube.
3. Place the sterilized swab specimen in the sample extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
4. Remove the sterilized swab while squeezing the sterilized swab head against the inside of the buffer as you remove it to expel as much liquid as possible from the swab. Discard the sterilized swab in accordance with your local biohazard waste disposal protocol.
5. Screw on and tighten the cap onto the specimen collection tube.

TEST

TEST PROCEDURE





1 **Add 3 drops of the solution (approx.80ul) to the sample well and then start the timer.**

2 **Read the result at 10~20 minutes. Do not interpret the result after 20 minutes.**

Interpretation Of Results

POSITIVE: Two red lines appear. One red line appears in the control region(C), and one red line in the test region(T). The shade of color may vary, but it should be considered positive whenever there is even a faint line.

NEGATIVE: Only one red line appears in the control region(C), and no line in the test region(T). The negative result indicates that there are no coronavirus particles in the sample or the number of viral particles is below the detectable range.

INVALID: No red line appears in the control region(C). The test is invalid even if there is a line on test region(T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device.

EVALUATION

CLINICAL EVALUATION

Clinical evaluation was performed to compare the results obtained by SARS-Cov-2 Antigen Rapid Test Cassette (swab) and PCR. The results were summarized below:

Table: SARS-Cov-2 Antigen Rapid Test Cassette (swab) and PCR.

		SARS-Cov-2 Antigen Rapid Test		Total Results
		+	—	
PCR	+	27	5	32
	—	0	200	200
Total Results		27	205	232

Relative Sensitivity: 96.17%

Relative Specificity: >99%

Accuracy: 97.8%

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