



Test Kit Component

REAGENTS AND MATERIALS PROVIDED

Specifica tion Component	1 test/ kit	1 test/ kit	1 test/ kit	6 tests/ kit	20 tests/ kit	20 tests/ kit	20 tests/ kit
Test Cassette	1	1	1	6	20	20	20
Dropper	/	/	1	6	/	/	20
sample tube with extraction reagent	1×0.5 mL	1×0.5 mL	/	/	20×0. 5 mL	20×0. 5 mL	/
Nasal Swab	1	/	/	/	20	/	/
Instruction for use	1	1	1	1	1	1	1

Materials needed but not provided

Timer or watch.

Differences between professional test reagents and self-test reagents

We have conducted the comparison between the test kit for professional use and the lay person use. Here is the form includes all the information we included in the comparison.

Content	Professional use	Lay person use
Device name	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)
Type/model	Nasal Swab	Nasal Swab
Accessories	Test Cassette, Dropper, sample tube with extraction reagent, Nasal Swab, Instruction for use, Timer or watch.	Test Cassette, Dropper, sample tube with extraction reagent, Nasal Swab, Instruction for use, Timer or watch.
IFU	Refer to <11_Instruction for Use>.	Refer to <11_Instruction for Use>.
Labelling	Refer to <06_Example of Packaging Diagram>.	Refer to <06_Example of Packaging Diagram>.
Package	Refer to <06_Example of Packaging Diagram>.	Refer to <06_Example of Packaging Diagram>.
Target user	Who are suspected of COVID-19	Who are suspected of COVID-19
Sample for test	To collect a nasal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, rotate the swab against the wall of the	To collect a nasal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, rotate the swab against the wall of the



	nostril into the patient's nostril to the nasal palate, and then slowly remove it while wiping.	nostril into the patient's nostril to the nasal palate, and then slowly remove it while wiping.
Result interpretation	<p>1. Positive: A red line appears on the test line (T) and the control line (C). NOTE: A positive result does not rule out co-infections with other pathogens.</p> <p>2. Negative: Only the control line (C) appears, and no red line appears on the test line (T). NOTE: A negative result does not exclude infection.</p> <p>3. Invalid: There is no red line at the position of the control line (C). Regardless of whether the TEST line (T) is displayed, it is an invalid result and the sample should be tested again.</p>	<p>1. Positive: A red line appears on the test line (T) and the control line (C). NOTE: A positive result does not rule out co-infections with other pathogens.</p> <p>2. Negative: Only the control line (C) appears, and no red line appears on the test line (T). NOTE: A negative result does not exclude infection.</p> <p>3. Invalid: There is no red line at the position of the control line (C). Regardless of whether the TEST line (T) is displayed, it is an invalid result and the sample should be tested again.</p>

From the form above, we can find that there is no difference between the components and labels of professional test reagent and self-testing test reagent, only in the instructions:

- a) The instructions of self-testing reagent added the description of self-testing.
- b) The instructions of self-testing reagent added a detailed schematic diagram of the nasal swab sampling test procedure.