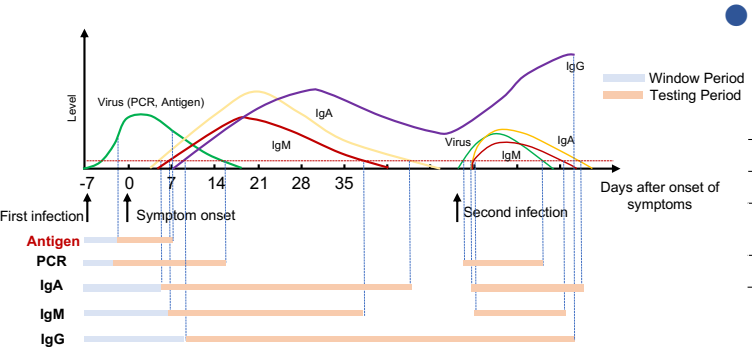
COVID-19 Ag Detection Kit
(Immunofluorescence-Based)

TORONTO BIOSCIENCE

WHEN TO USE ANTIGEN TEST?

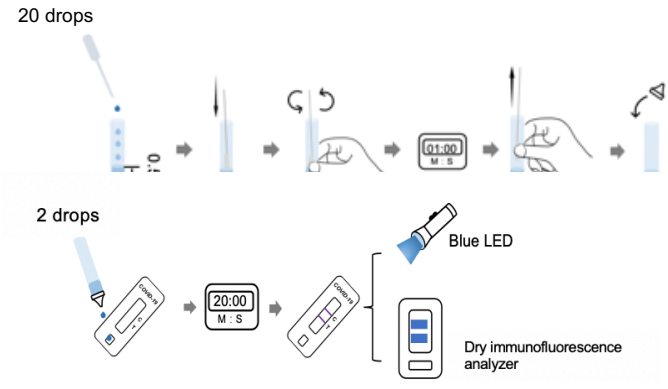


INTENDED USE

COVID-19 Ag Detection Kit (Immunofluorescence-Based) is an in vitro rapid test for the detection of SARS-CoV-2 antigen in direct nasal swabs from individuals suspected of COVID-19 within the first seven days of symptom onset.

COVID-19 Ag Detection Kit (Immunofluorescence-Based) is intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests.

ASSAY PROCEDURES:

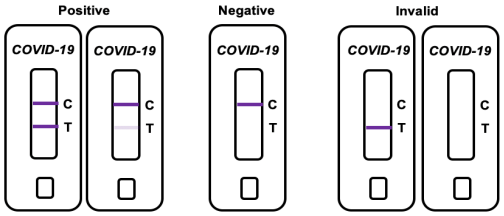


INTERPRETATION OF TEST RESULT

Dry Immunofluorescence Analyzer

Positive			Negative
Weak	Medium	Strong	
0.25 ≥ T/C > 0.15	2.5 ≥ T/C > 0.25	T/C > 2.5	≤ 0.15
+	++	+++	-

Blue LED Light



PERFORMANCE:

Clinical Performance

Reagents		RT-PCR		Total
		Positive	Negative	
COVID-19 Ag Detection Kit	Positive	74	1	75
	Negative	5	131	136
Total		79	132	211

Relative Sensitivity: 93.67%, 95% CI: 88.41%~98.93%;
Relative Specificity: 99.24%, 95%CI: 95.38%~99.31%.

Analytical Sensitivity

Concentration $TCID_{50}$/ml	Concentration copies/ml	Number Positive/Total	% Detected
93.3	5.67×10^5	20/20	100

The analytical sensitivity of COVID-19 Ag Detection Kit (Immunofluorescence-Based) is 93.3 $TCID_{50}$/ml.

Further information:
www.torontobioscience.com and
sales@torontobioscience.com

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IMPORTANT: Read the instruction manual before use. **For the best performance, direct nasal swabs should be tested preferably as soon as possible after collection.**

PROCEDURE CARD

ASSAY PROCEDURE

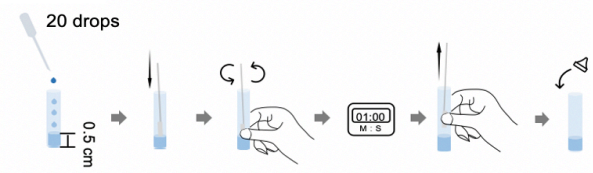
Specimen Preparation Procedure:
(Nasal swab)

•Transfer 20 drops (- 500 µL) of sample lysis buffer into an extraction tube using a transfer pipet.

•Insert the swab into an extraction tube. While squeezing the buffer tube, stir the swab more than 5 times and wait for 1 minute.

•Squeeze the wall of the tube to extract the liquid from the swab.

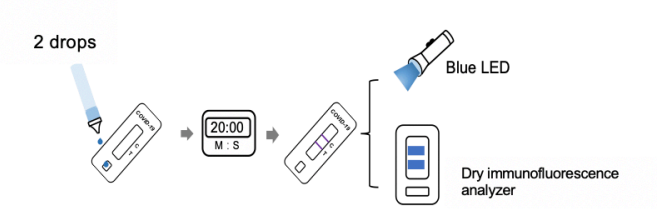
•Press the nozzle cap tightly onto the tube.



Analysis of Specimen:

•Apply 2 drops (~80 µL) of the extracted specimen to the specimen well of the test strip.

•Read the test result in 20 minutes.



RESULT INTERPRETATION

Dry Immunofluorescence Analyzer
Run Test with FIC-H1W

• Turn on the machine
• Select "QUICK TEST"
• Input patient information, including Name, Age, Sex.
• Insert the prepared test strip into the machine.
• Click "QUICK TEST" .
• The test result (RS) will be displayed on the screen within 5 seconds.

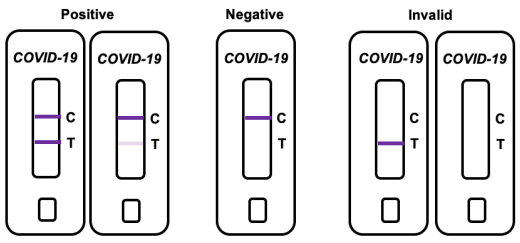
Positive			Negative
Weak	Medium	Strong	
0.25 ≥ T/C > 0.15	2.5 ≥ T/C > 0.25	T/C > 2.5	≤ 0.15
+	++	+++	-

Note: If the result is invalid, the test should be repeated.

Blue LED Light

If Portable fluorescent immunoassay analyzer is not available, a blue LED light also can be used to read the test result.

Wears glasses when reading results using blue LED light.



Positive: the presence of two lines as the control line (C) and the test line (T) in the result window.

Negative: the presence of a single line as the control line (C) in the result window.

Invalid: if the control line (C) is not visible within the result window after performing the test, the result is invalid.