COVID-19 Ag Detection Kit

(Immunofluorescence-Based)
Catalog Numbers 41A255

(Please read this instruction manual before use.)
WARNING! Wear appropriate protective eyewear, clothing, and gloves.

INTENDED USE

COVID-19 Ag Detection Kit (Immunofluorescence-Based) is a lateral flow test for the detection of SARS-CoV-2 Nucleocapsid protein (NP) in direct nasal swabs from individuals suspected of COVID-19 within the first seven days of symptom onset, which is intended to be used by healthcare professionals. This test is intended for a Point-of-Care setting.

SUMMARY

The spread of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) has caused a worldwide COVID-19 pandemic. Rapid identification and isolation of COVID-19 patients and asymptomatic carriers is the main strategy to contain this pandemic.
COVID-19 Ag Detection Kit (Immunofluorescence-Based) is a rapid flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2 from nasal swab.

ASSAY PRINCIPLE

COVID-19 Ag Detection Kit (Immunofluorescence-Based) is an immunochromatographic membrane assay that uses highly-specific monoclonal antibodies to detect SARS-CoV-2 NP from nasal swab specimens. An anti-SARS-CoV-2 NP monoclonal antibody is pre-coated on the nitrocellulose membrane as the test line, while the chicken IgY is pre-coated as the control line.
During the test, the sample reacts with another fluorescent microspheres-conjugated anti-SARS-CoV-2 NP monoclonal antibody in the conjugation pad. The fluorescent microspheres-conjugated goat anti-chicken IgY in the conjugation pad serves as the control particles. The sample migrates upward on the membrane by capillary action and reacts with the test line and control line. The result can be read within 15-20 minutes using a dry immunofluorescence analyzer or a blue LED light. If the sample contains SARS-CoV-2 NP, a fluorescent signal can be detected from the test line, revealing a positive result. If the sample does not contain SARS-CoV-2 NP, no fluorescent signal can be detected from the test line, indicating a negative result. As a procedural control, a fluorescent signal can be detected from the control line.

REAGENTS AND MATERIALS

1. COVID-19 Ag strip (20 tests/kit)
2. Sample lysis buffer (500 µL/tube)
3. Extraction Tubes (20 tubes/kit)
4. Swabs (20 nasal swabs/kit)
5. Positive Control Swab: Non-infectious recombinant SARS-CoV-2 nucleocapsid antigen dried onto a swab
6. Negative Control Swab: The use of sterile swab to ensure a negative result is obtained
7. Product Insert
8. Procedure Card

OTHER MATERIALS REQUIRED, BUT NOT PROVIDED

1. Timer or other equipment for time recording.
2. If clinical samples other than nasal secretions need to be measured, other kinds of swab may be required (such as throat swabs).
3. Dry immunofluorescence analyzer (FIC-HIW, ImmunoDiagnostics Ltd. or UNT2000I, Guangdong Uniten Biotechnology).

PRECAUTIONS

- All reagents are for *in vitro* research use only.
- All operations linked to the use of the test must be performed following Good Laboratory Practices (GLP).
-All reagents should be equilibrated to room temperature before use.
- Avoid touching nitrocellulose membrane with your fingers.
- Wears gloves, mask FFP2 or FFP3, lab glasses when handling samples. Otherwise, run the test under a Laminar Air Flow cabinet.
- Reagents cannot be mixed from different kits.
-The quality of expired reagents cannot be guaranteed if reagents are not stored under required conditions as indicated in the manual.
- Do not use the strip if the pouch is damaged or the seal is broken.
- Do not reuse the used test strip.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- INVALID RESULTS may occur when an insufficient volume of sample lysis buffer is added to the test strip.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.

STORAGE

- Store kit at 4-30 °C. The Kit is stable until the expiration date marked on the package label.
- Avoid freezing strips and buffer.

- The test strip is stable until the expiry date only if it has not been opened and kept in the sealed aluminum pouch.
- Do not open the sealed pouch until use. Once opened, the strip should be used within 1 hour.

QUALITY CONTROL

Good laboratory practice suggests the use of positive and negative controls to ensure the test reagents are working and the test is correctly performed. Both a **Positive Control Swab** and a **Negative Control Swab** are included in this kit, which can be used to monitor the entire assay. Test these swabs once with each new shipment received and each untrained operator. Further controls may be tested to fulfill the need from local regulations, accrediting groups, or lab's standard Quality Control procedures.

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support during business hours before testing patient specimens.

SPECIMEN COLLECTION AND HANDLING

Improper specimen collection or sample handling/storage/transport may yield wrong results.

Nasal Swab

To collect a nasal swab sample, carefully insert the swab less than one inch (about 2 cm) into the nostril parallel to the palate until resistance is met at turbinate. Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall 5 times or more for a total of 10 seconds. Slowly removing the swab, insert it into the other nostril and repeat the process.

Sample Transport and Storage

For the best performance, direct nasal swabs should be tested preferably as soon as possible after collection. Based on data generated with SARS-CoV-2 COVID-19 Ag Detection Kit (Immunofluorescence-Based), nasal swabs are stable for up to 48-hours at 2~8°C. For long term storage, samples can be stored at -60~80°C up to 1 year.

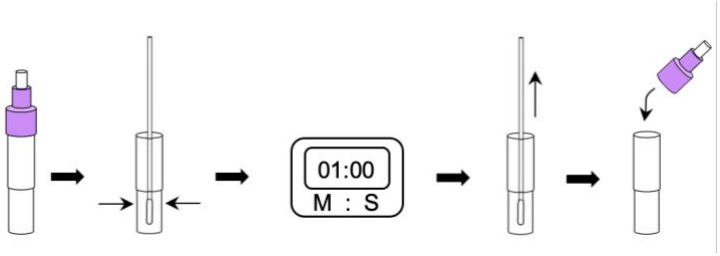
TEST PROCEDURE

Preparation of Test:

Equilibrate kit components in unopened packaging to room temperature (15-30 °C) before starting the test.
Clearly label the extraction tube with patient's information.

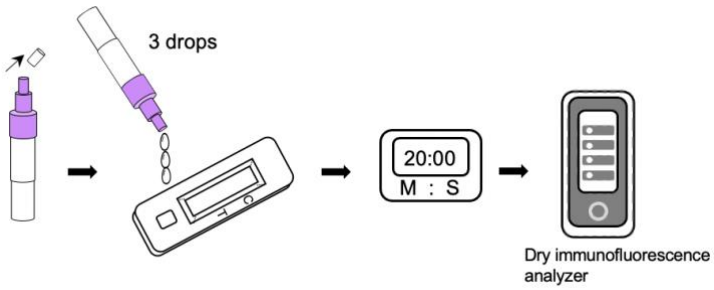
Assay Procedure:

1. Open the extraction tube.
2. Insert the swab into an extraction tube. While squeezing the tube, stir the swab more than 5 times and wait for 1 minute.
3. Squeeze the wall of the tube to extract the liquid from the swab.
4. Remove the swab and screw the nozzle cap tightly onto the tube.



Analysis of Specimen:

5. Open the pouch and remove the strip.
6. Invert the extraction tube and add 3 drops (~80 µL) of the extracted specimen to the specimen well (S).
7. Read the test result at 20 minutes using dry immunofluorescence analyzer.



Do not interpret the result after 25 minutes.

INTERPRETATION OF TEST RESULT

The fluorescent signal from test line and control line cannot be seen with the naked eyes. A dry immunofluorescence analyzer should be used for reading the result.

Dry immunofluorescence analyzer

Run Test with FIC-H1W

QUICK TEST/STANDARD TEST Mode

a. Turn on the machine

b. Select "QUICK TEST" or "STANDARD TEST".
c. Input patient information, including Name, Age, Sex. As shown in the example below.

d. Insert the prepared test strip into the machine.
e. Click “QUICK TEST” or STANDARD TEST.
f. The test result (RS) will be displayed on the screen within 5 seconds.
g. Click “NEW” to start a new test or Click “MENUS” to return to the homepage.
The test result is determined by T/C value. The following information will be displayed on the screen. The results can be automatically printed if a printer is connected.
Value: T/C-ratio of fluorescent signal from test line and control line. T/C higher than 0.15 is positive, and T/C lower than 0.15 is negative (including 0.15).
Result (RS): “+”=Weak Positive; “++”=Medium Positive; “+++”=Strong Positive; “-”=Negative
Reference 0-0.15: T/C range for negative results

For example: This display shows a positive result.

For example: This display shows a negative result.

Interpretation of result

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.

For example: This display shows an invalid result.

LIMITATION OF TEST

- A negative test result may occur if the level of the extracted antigen in a specimen is below the sensitivity of the test or if a poor-quality specimen is obtained.
- Negative test results do not rule out the possibility of SARS-CoV-2 infection, which should be further confirmed by RT-PCR.
- Positive test results do not rule out co-infections with other pathogens.
- COVID-19 Ag Detection Kit (Immunofluorescence-Based) was evaluated using the procedures provided in this product insert only. Any modification of procedures may affect the performance of the test.
- The test result must always be evaluated with other data available to the physician.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.

WASTE DISPOSAL

- Dispose of gloves, swabs, extraction tubes, used strips in accordance with GLP.
- Each user is responsible for the management of any waste produced and must ensure that it is disposed of in accordance with the applicable legislation.

PERFORMANCE CHARACTERISTICS

Clinical Performance

The COVID-19 Ag Detection Kit (Immunofluorescence -Based) has been evaluated with specimens obtained from COVID-19 patients (within 7 days of onset). Tests were conducted by operators who are representative of the intended users. Patients who presented within 7 days of symptom onset were included in the primary analysis. The results show that the COVID-19 Ag Detection Kit (Immunofluorescence-Based) has high sensitivity and specificity.

Reagents		RT-PCR		Total
		Positive	Negative	
COVID-19 Ag Detection Kit	Positive	79	13	92
	Negative	5	412	417
Total		84	425	509
Positive Agreement: 79/84 94.03% (95%CI: 88.47%-98.96%)				
Negative Agreement: 412/425 96.94% (95%CI: 94.12%-98.35%)				

Relative Sensitivity: 94.03%, 95% CI: 88.47%~98.96%;
Relative Specificity: 96.94%, 95%CI: 94.12%~98.35%.

For initial validation, the COVID-19 Ag Detection Kit (Immunofluorescence -Based) has also been used to test the presence of SARS-CoV-2 NP in serum sample from 58 COVID-19 patients (1:10 dilution), and the result show that half of the patients are NP positive.

Analytical Performance

Analytical Sensitivity

The limit of detection was determined by evaluating different concentration of inactivated SARS-CoV-2 virus, which was diluted in natural nasal swab matrix pool to generate virus dilutions for test.

$TCID_{50}$/ml	Number Positive/Total	% Detected
93.3	19/20	95

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

High Dose Hook Effect

No high dose hook effect was noted when tested with up to a concentration of 2.8×10^6 $TCID_{50}$ /ml of inactivated SARS-CoV-2 virus with COVID-19 Ag Detection Kit (Immunofluorescence-Based).

Endogenous Substances Interference Test

Substances with test concentration in the table do not affect the performance of COVID-19 Ag Detection Kit (Immunofluorescence-Based).

Substance	Concentration	Substance	Active Ingredient	Concentration
Mucin	2% w/v	OTC Nasal Drop	Phenylephrine	12% v/v
Benzocaine	5 mg/ml	OTC Nasal Spray 1	Cromolyn	15% v/v
Tobramycin	5 ug/ml	OTC Nasal Spray 2	Oxymetazoline	15% v/v
Oseltamivir phosphate	10 mg/ml	OTC Nasal Spray 3	Fluconazole	5% w/v
Arbidol	5 mg/ml	OTC Homeopathic Nasal Spray 1	Zincum gluconium	5% w/v
Triamcinolone	10 mg/ml			
Mupirocin	10 mg/ml	OTC Homeopathic Nasal Spray 2	Alkalol	10% v/v
Zanamivir	5 mg/ml			
Ribavirin	5 mg/ml	OTC Homeopathic Nasal Spray 3	Fluticasone Propionate	5% v/v
Dexamethasone	5 mg/ml			

Cross Reactivity and Microbial Interference

Cross reactivity and potential interference of COVID-19 Ag Detection Kit (Immunofluorescence-Based) was tested in microorganisms listed in the table that may be present in the nasal cavity. No cross reactivity or interference was noted when tested at current concentration presented in the table.

Type	Human Cross Reactant	Test Concentration
Coronavirus	Human coronavirus HKU1	1×10^5 $TCID_{50}$/ml
	Human coronavirus OC43	1×10^5 $TCID_{50}$/ml
	Human coronavirus NL63	1×10^5 $TCID_{50}$/ml
	Human coronavirus 229E	1×10^5 $TCID_{50}$/ml
	MERS-coronavirus	10 μg/ml
	SARS-coronavirus	10 μg/ml
Virus	Rhinovirus	1×10^5 PFU/ml
	Adenovirus	1×10^5 $TCID_{50}$/ml
	Human Metapneumovirus	1×10^5 $TCID_{50}$/ml
	Parainfluenza 1	1×10^5 $TCID_{50}$/ml
	Parainfluenza 2	1×10^5 $TCID_{50}$/ml
	Parainfluenza 3	1×10^5 $TCID_{50}$/ml
	Parainfluenza 4	1×10^5 $TCID_{50}$/ml
	Influenza A	1×10^5 $TCID_{50}$/ml
	Influenza B	1×10^5 $TCID_{50}$/ml
	Enterovirus	1×10^5 $TCID_{50}$/ml
	Respiratory syncytial virus	1×10^5 PFU/ml
Bacteria	Bordetella pertussis	1×10^6 cells/ml
	Chlamydia pneumoniae	1×10^6 IFU/ml
	Haemophilus influenzae	1×10^6 cells/ml
	Legionella pneumoniae	1×10^6 cells/ml
	Mycoblasma pneumoniae	1×10^6 U/ml
	Streptococcus pneumoniae	1×10^6 cells/ml
	Streptococcus pyogenes	1×10^6 cells/ml
	Mycobacterium tuberculosis	1×10^6 cells/ml
	Staphylococcus aureus	1×10^6 org/ml
	Staphylococcus epidermidis	1×10^6 cells/ml
Yeast	Candida albicans	1×10^6 cells/ml
Pooled human nasal wash		-

Note: $TCID_{50}$ -Median Tissue Culture Infectious Dose; PFU-Plaque Forming Unit

SYMBOLS

	Manufacturer	CE	EC Declaration of Conformity
	Expiry date		Consult Instruction
LOT	Lot number		Store
REF	Catalog number		Caution
IVD	In Vitro Diagnostic Device	EC REP	Name and Address of EU REP

CE IVD