bioPerfectus technologies

**Jiangsu Bioperfectus Technologies Co., Ltd.** CE



# Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit
# INSTRUCTIONS FOR USE

REF SC30107W-1T/2T/5T/10T/15T/20T/25T/50T

4℃-30℃

1T/2T/5T/10T/15T/20T/25T/50T

IVD For *In Vitro* Diagnostic Use Only
For Professional Use Only

05.2021

## 1. Intended Use

The Bioperfectus Technologies Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit is a rapid chromatographic immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab specimens, nasopharyngeal swab specimens or oropharyngeal swab specimens from symptomatic individuals who are suspected of COVID-19 or asymptomatic individuals who have had contact with confirmed COVID-19 patients but didn't show any symptoms.

## 2. Kit Components

**1T/2T/5T/10T/15T:**

| Cat. No. | SC30107W-1T | SC30107W-2T | SC30107W-5T | SC30107W-10T | SC30107W-15T |
|---|---|---|---|---|---|
| **Components Provided** | | | | | |
| **Cassette** | 1 cassette | 2 cassettes | 5 cassettes | 10 cassettes | 15 cassettes |
| **Prepacked extraction tube (Sample extraction buffer)** | 400μL x 1 | 400μL x 2 | 400μL x 5 | 400μL x 10 | 400μL x 15 |
| **Instructions for use** | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc |
| **Operation sketch card** | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc |
| **Swab** | 1 pc | 2 pcs | 5 pcs | 10 pcs | 15 pcs |
| **Waste bag** | 1 pc | 2 pcs | 5 pcs | 10 pcs | 15 pcs |

**20T/25T/50T:**

| Cat. No. | SC30107W-20T | SC30107W-25T | SC30107W-50T |
|---|---|---|---|
| **Components Provided** | | | |
| **Cassette** | 20 cassettes | 25 cassettes | 50 cassettes |
| **Sample extraction buffer** | 7.5ml x 2 | 7.5ml x 2 | 7.5ml x 4 |
| **Instructions for use** | 1 pc | 1 pc | 1 pc |
| **Operation sketch card** | 1 pc | 1 pc | 1 pc |
| **Swab** | 20 pcs | 25 pcs | 50 pcs |
| **Dropper cap** | 20 pcs | 25 pcs | 50 pcs |
| **Sample extraction tube** | 20 pcs | 25 pcs | 50 pcs |
| **Optional Components (External control)** | | | |
| **Positive control tube (With pipette)** | 1 pc | 1 pc | 1 pc |
| **Negative control tube (With pipette)** | 1 pc | 1 pc | 1 pc |

**NOTE:** *Components from different kit and batch can't be used interchangeably.

## 3. Storage

- The kit should be stored at 4℃-30℃ before expiration date indicated on the outer box.
- Store kit in a location out of direct sunlight and out of reach of children.
- The kit can be directly transported at ambient temperature of -20℃~45℃.
- When transporting or storing the kit, avoid the exposure to high temperature (over 45℃) for a period longer than 1 week.

## 4. Materials and Devices Required but Not Provided

- Biosafety cabinet
- Biohazard container
- Timer
- Disposable gloves
- Pencil or pen

## 5. Background Information

Coronavirus (CoV) belongs to the family *Coronaviridae* and is divided into three genera: α, β and γ. The α and β genus are only pathogenic to mammals. While the γ genus mainly causes bird infection. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence indicating that it can be transmitted through the fecal-oral route. CoV infections generally manifest as upper respiratory tract infections and/or gastrointestinal symptoms, and severe cases are more common in infants, the elderly, and people with lower immunity. Up to now, there have been six kinds of CoV (CoV-229E, CoV-OC43, CoV-NL63, CoV-HKU1, SARS-CoV and MERS-CoV) causing human respiratory diseases, which are important pathogens of human respiratory infection. Clinical manifestations of high fever, cough, sputum and dyspnea, rapid progress on the basis of pneumonia, and soon developed into respiratory failure, acute respiratory distress syndrome, and even life-threatening. Most patients have gastrointestinal symptoms such as diarrhea.

## 6. Product Description

This product is based on immunochromatographic technology. The detection area of the strip has a test line (T line) and a control line (C line). Novel corona virus (SARS-CoV-2) antibody is coated on the T line and recombinant streptococcal protein G (r-SPG) is coated on the C line. Another novel coronavirus (SARS-CoV-2) antibody is coated on the conjugate pad.

When starting the test, the sample will be added into the sample well of the cassette. After mixing with the colloidal gold-labeled antibody on the conjugate pad, the sample will then flow onto the nitrocellulose membrane. If novel coronavirus (SARS-CoV-2) antigen is present in the sample, the antigen will form a complex with the colloidal gold-labeled antibody coated on the conjugate pad. The complex will be captured by the novel corona virus (SARS-CoV-2) antibody coated in the T line area. In this case, a visible T line will appear on the detection area as the presence of novel coronavirus (SARS-CoV-2) antigen. The colloidal gold-labeled antibody will also be captured by the r-SPG in the C line area, resulting a colored C line as the indication of a valid test. If novel coronavirus (SARS-CoV-2) antigen does not present in the sample or antigen concentration is lower than the detection limit of this method, only a C line will be visible.

## 7. Warnings and Precautions

- For *in vitro* diagnostic use.
- Inadequate or inappropriate specimen collection and storage can adversely affect results.
- To obtain correct results, read the instructions fully before starting the procedure.
- Leave the cassette sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
- Wash hands thoroughly or use hand sanitizer after handling.
- Use of Nitrile, Latex (or equivalent) gloves is recommended when conducting testing.
- Do not mix components from different kit lots.
- Testing should be performed in an area with adequate ventilation.
- Individuals with color-impaired vision may not be able to adequately interpret test results.
- Read the results within the specified time. To ensure the accuracy of the interpretation, DO NOT read the result in the dim place.
- Do not touch swab tip when handling the swab sample. Only use the nasal swab(s)provided in the kit.
- Do not use kit past its expiration date.
- All test pieces are single use items. Do not use with multiple specimens. DO NOT reuse the used test devices, tubes, or swabs.
- Keep testing kit and kit components out of the reach of children and pets before and after use.
- Dispose of kit components and samples according to all local regulations.
- Additional controls could be carried out according to guidelines or requirements of local, state and/or federal regulations or accrediting organizations.
- The Reagent Solution contains harmful chemicals. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice.

## 8. Sample type

- Nasal swab specimen, Nasopharyngeal swab specimen, Oropharyngeal swab specimen.

## 9. External control (Optional)

The external control process is conducted while first use a box of the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit or continue to use the kit after a long interval.

**Operation procedure:**

- Restore the cassette, sample extraction buffer and positive/negative control tubes to room temperature before testing.
- Remove the positive/negative control tubes and droppers from the foil pouches.
- Add 3 drops of sample extraction buffer to the positive control tube and negative tube, respectively.
- Thoroughly mix the solution in the tubes.
- Remove 2 cassettes from the foil pouches and place them horizontally on the table.
- Take out all the solution from the positive control tube with the provided dropper and add to the sample well of a cassette.
- Take out all the solution from the negative control tube with the provided dropper and add to the sample well of the other cassette.
- Read result 15 minutes after the eluate is added. DO NOT interpret result after 30 minutes.

**Acceptance criteria:**

Positive control: Two clear colored lines appear, one at the T area and the other at the C area.

Negative control: Only one colored line appears at the C area.

**NOTE:** *If the results don't meet the acceptance criteria, please contact your supplier.

## 10. Sample collection procedure

**Nasal swab specimen collection:**

1) Remove the swab from the container, being careful not to touch the soft end, which is the absorbent tip.
2) Insert the entire absorbent tip of the swab into the nostril, but do not insert the swab more than ¾ of an inch (1.5 cm) into the nose.
3) Slowly rotate the swab in a circular path against the inside of the nostril at least 4 times for a total of 15 seconds. Be sure to collect any nasal drainage that may be present on the swab.
4) Gently remove the swab.
5) Using the same swab, repeat steps 2~4 in the other nostril.

**Nasopharyngeal swab specimen collection:**

1) Remove the swab from the container, being careful not to touch the soft end, which is the absorbent tip.
2) Insert the swab into the nostril, reaching the surface of the posterior nasopharynx.
3) Slowly rotate, push the swab until resistance is met at the level of the turbinate.
4) Rotate the swab a few times against the nasopharyngeal wall.
5) Gently remove the swab.

**Oropharyngeal swab specimen collection:**

1) Remove the swab from the container, being careful not to touch the soft end, which is the absorbent tip.
2) Insert the swab into the oral cavity avoid contact with the tongue, teeth, cheeks or palate.
3) After reaching the oropharynx, rub the swab on the posterior wall for 10~15 seconds.

4) Gently remove the swab.

## 11. Sample storage and transport

- Freshly collected samples are required to be tested as soon as possible.
- If samples cannot be tested in time, keep the swabs in dry and clean tubes and store at 2~8℃ for no more than 24 hours. DO NOT FREEZE the swabs. (**Preferred**)
- If samples cannot be tested in time, the swabs can also be kept in virus transport medium (VTM) and store at 2~8℃ for no more than 24 hours. Please note that the use of VTM may decrease the detectable rate.
- Transport samples at 2~8℃.

**Applicable Virus Transport Medium**

| Virus Transport Medium (VTM) | Recommended Storage Condition |
|---|---|
| Copan UTM™ Universal Transport Media | 2~8℃ within 24 hours |
| Yocon Viral Transport Medium | 2~8℃ within 24 hours |
| CDC Viral Transport Medium | 2~8℃ within 24 hours |

## 12. Sample Preparation Procedure

**Sample preparation procedure of prepacked extraction tube:**

1) Take out the prepacked extraction tube from the kit.
2) Keep the prepacked extraction tube head upwards and shake the tube 2-3 times.
3) Unscrew the purple cap from the tube.
4) Insert the swab into the tube and squeeze the swab head through the tube 10 times.
5) Remove the swab while keeping the center of the tube squeezed.
6) Break the swab and leave the head in the tube. Dispose the handle of the swab into the waste bag.
7) Screw the purple cap from the tube, and make sure the cap is tightened.

**Sample preparation procedure of general sample extraction tube:**

For freshly collected swabs and swabs kept in dry, clean tubes:

1) Add 400μL of sample extraction buffer (to the scale line on the tube) into the sample extraction tube.
2) Insert the swab into the tube and squeeze the swab head through the tube 10 times.
3) Remove the swab while keeping the center of the tube squeezed.
4) Discard the swab and cover the tube with a dropper cap.

For swabs kept in virus transport medium:

1) Add 200μL of sample extraction buffer into the extraction tube.
2) Add 200μL of virus transport medium eluate into the same tube.
3) Cover the tube with a dropper cap and thoroughly mix the liquid.

## 13. Performing the Test

1) Read the instructions for use carefully before beginning the test.
2) Restore the cassette and sample to room temperature before testing. Thoroughly mix the sample before use.
3) Remove the cassette from the foil pouch and place it horizontally on the table. Record the sample information.
4) Gently squeeze the tube to dispense 2-3 drops of the liquid onto the sample well of the cassette.
5) Read result 15 minutes after the liquid is added. DO NOT interpret result after 30 minutes.

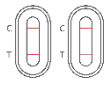
**NOTE:**

* DO NOT move the cassette during the test.
*Appropriate increase the volume of the assay buffer if the sample is viscous.
*The shades of test line (T line) do not affect the result. As long as the test line is colored, it can be judged as positive.
*When an exception occurs, retest the sample is recommended.
*Discard all the test pieces into the waste bag/biohazard container in accordance with the applicable local regulations.

## 14. Limitations

- The assay is used only for the qualitative testing of Novel Coronavirus (SARS-CoV-2) antigen in human respiratory tract samples, and cannot be used as a quantitative reagent.
- The positive result only indicates the presence of Novel Coronavirus (SARS-CoV-2) antigen, which cannot be used as the only criterion for the diagnosis of COVID-19. A definite diagnosis should combine the test result with clinical symptoms and other diagnostic techniques.
- The negative result cannot exclude the possibility of infection. It may result from a low Novel Coronavirus (SARS-CoV-2) antigen level. Therefore, it is recommended to recheck with other diagnostic techniques or make the diagnosis in combination with other clinical methods.
- The test results are for clinical reference only and cannot be used as a basis for diagnosis or exclusion of cases alone. Making a definite diagnosis should combine the test results with clinical examination, patient history and test results of other diagnostic techniques.
- The amount of samples to be added should be strictly in accordance with the instructions.
- The use of virus transport medium may increase the risk of false negative results.

## 15. Result Interpretation

| | | |
|---|---|---|
| Positive | Two colored lines appear, one at the T area and the other at the C area. Caution: No matter how faint the colored band is in the T area, the result should be considered as positive |  |
| Negative | Only one colored line appears at the C area. |  |
| Invalid | No line appears at the C area even if a colored line appears at the T area. No line appears at the C area or T area |  |

## 16. Performance Characteristics

- **Limit of Detection (LoD)**

The LoD of Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit was determined by testing series diluted heat inactivated virus. The virus was provided at a concentration of 2 x $10^5$ PFU/mL. In this study, presumed negative nasopharyngeal swab specimens obtained from healthy donors and confirmed negative for SARS-CoV-2 were eluted in sample extraction buffer. Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 virus was diluted in this matrix pool to generate virus dilutions for testing. Sample extraction buffer was used for the subsequent diluting process. An initial range finding study was performed testing devices in triplicate using a 10-fold dilution series. A concentration was chosen between the last dilution to give 3 positive results and the first to give three negative results. The LoD was further refined with a 2-fold dilution series at this concentration. The last dilution to give 3 positive results was then tested in an additional 20 replicates tested in the same way.

The Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit LoD in sample extraction buffer was confirmed as 1x$10^2$ PFU/mL

| Concentration | No. Positive/Total | % Positive |
|---|---|---|
| 1x$10^2$ PFU/mL | 19/20 | 95% |

- **Analytical specificity**

| Name | Concentration | Cross-Reactivity (Yes/No) |
|---|---|---|
| Human coronavirus 229E | 1x$10^5$ PFU/mL | No |
| Human coronavirus OC43 | 1x$10^5$ PFU/mL | No |
| Human coronavirus NL63 | 1x$10^5$ PFU/mL | No |
| MERS-coronavirus | 1x$10^5$ PFU/mL | No |
| SARS-coronavirus | 1x$10^5$ PFU/mL | N/A |
| Human coronavirus HKU1 | 1x$10^5$ PFU/mL | No |
| Adenovirus (e.g. C1 Ad. 71) | 1x$10^5$ PFU/mL | No |
| Human Metapneumovirus (hMPV) | 1x$10^5$ PFU/mL | N/A |
| Parainfluenza virus 1 | 1x$10^5$ PFU/mL | No |
| Parainfluenza virus 3 | 1x$10^5$ PFU/mL | No |
| Parainfluenza virus 4 | 1x$10^5$ PFU/mL | No |
| Influenza A | 1x$10^5$ PFU/mL | No |
| Influenza B | 1x$10^5$ PFU/mL | No |
| Enterovirus | 1x$10^5$ PFU/mL | No |
| Respiratory syncytial virus | 1x$10^5$ PFU/mL | No |
| Rhinovirus | 1x$10^5$ PFU/mL | No |
| Haemophilus influenzae | 1x$10^5$ PFU/mL | N/A |
| Streptococcus pneumoniae | 1x$10^6$ CFU/mL | No |
| Streptococcus pyogenes | 1x$10^6$ CFU/mL | N/A |
| Candida albicans | 1x$10^6$ CFU/mL | No |
| Pooled human nasal wash – representative of normal respiratory microbial flora | / | No |
| Bordetella pertussis | 1x$10^6$ CFU/mL | N/A |
| Mycoplasma pneumoniae | 1x$10^6$ CFU/mL | No |
| Chlamydia pneumoniae | 1x$10^6$ CFU/mL | No |
| Legionella pneumophila | 1x$10^6$ CFU/mL | N/A |
| Staphylococcus aureus | 1x$10^6$ CFU/mL | No |
| Staphylococcus epidermidis | 1x$10^6$ CFU/mL | N/A |
| Mycobacterium tuberculosis | 1x$10^6$ CFU/mL | N/A |
| Pneumocystis jirovecii (PJP) | 1x$10^6$ CFU/mL | N/A |

**NOTE:** *N/A means the organisms are still under evaluation.

Cross reactivity and potential interference of Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit was evaluated by testing SARS-CoV-2 related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen. Each of the organism, viruses, and yeast were tested in triplicate in the absence or presence of heat inactivated SARS-CoV-2 virus at 3xLoD. No cross-reactivity or interference was seen with the above microorganisms when tested at the concentration presented in the table above.

- **Analytical precision**

Precision data of Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit is determined by testing the precision reference for 10 times with 3 different batches of kits.

The test strips within and between batches showed consistent results and uniform color rendering, indicating good consistency and repeatability.

- **Interference substances**

| Potential interfering substances | Concentration | Interference (Yes/No) |
|---|---|---|
| Whole Blood | 4% | No |
| Mucin | 0.5% | No |
| Chloraseptic (Menthol/Benzocaine) | 1.5 mg/mL | No |
| Naso GEL (NeilMed) | 5% v/v | No |
| CVS Nasal Drops (Phenylephrine) | 15% v/v | No |
| Afrin (Oxymetazoline) | 15% v/v | No |
| CVS Nasal Spray (Cromolyn) | 15% v/v | No |
| Zicam | 5% v/v | No |
| Homeopathic (Alkalol) | 1:10 dilution | No |
| Sore Throat Phenol Spray | 15% v/v | No |
| Mupirocin | 10 mg/mL | No |
| Fluticasone Propionate | 5% v/v | No |
| Tamiflu (Oseltamivir Phosphate) | 5 mg/mL | No |
| Beclomethasone | 100mg/L | No |
| Dexamethasone | 100mg/L | No |
| Flunisolide | 100mg/L | No |
| Triamcinolone | 100mg/L | No |
| Budesonide | 100mg/L | No |
| Mometasone | 100mg/L | No |
| Histamine dihydrochloride | 100mg/L | No |
| Alpha interferon | 100units/L | No |
| Zanamivir, | 5mg/L | No |
| Ribavirin | 0.2g/L | No |
| Peramivir | 100mg/L | No |
| Lopinavir/ ritonavir | 200mg/100mg/L | No |
| Tobramycin | 10mg/L | No |

Various substances were evaluated with the Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit. The substances were tested in triplicate in the absence or presence of heat inactivated SARS-CoV-2 virus at 3xLoD. No interference was noted with this assay for any of the substances tested.

- **Hook effect**

The hook effect of Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit is evaluated by testing different concentrations of inactivated virus.
Positive weakening or false negative due to hook effect was not observed on heat-inactivated virus at concentration of 2 x$10^5$ PFU/mL Clinical performance.

- **Clinical performance**

The clinical performance of Bioperfectus Technologies Novel Corona Virus Ag Rapid Test Kit was evaluated by testing specimens collected and enrolled from symptomatic or asymptomatic individual who have signs suggest of COVID-19 or have had contact with confirmed COVID-19 patients.

295 nasopharyngeal swab specimens were collected from individuals with signs and symptoms suggest of COVID-19.

**Clinical performance of the Bioperfectus Technologies Novel Corona Virus Ag Rapid Test Kit against the comparator method on nasopharyngeal swab specimens for symptomatic individuals**

| Bioperfectus | PCR results | | |
|---|---|---|---|
| | Positive | Negative | Total |
| **Positive** | 58 | 5 | 63 |
| **Negative** | 2 | 230 | 232 |
| **Total** | 60 | 235 | 295 |

Sensitivity: 96.67%, 95%CI: 88.64%～99.08%
Specificity: 97.87%, 95%CI: 95.12%～99.09%
Accuracy: 97.63%, 95%CI: 95.18%～98.85%

989 nasal swab specimens were collected from individuals with signs and symptoms suggest of COVID-19.

**Clinical performance of the Bioperfectus Technologies Novel Corona Virus Ag Rapid Test Kit against the comparator method on nasal swab specimens for symptomatic individuals**

| Bioperfectus | PCR results | | |
|---|---|---|---|
| | Positive | Negative | Total |
| **Positive** | 165 | 7 | 172 |
| **Negative** | 5 | 812 | 817 |
| **Total** | 170 | 819 | 989 |

Sensitivity: 97.06%, 95%CI: 93.30%～98.74%
Specificity: 99.15%, 95%CI: 98.25%～99.59%
Accuracy: 98.79%, 95%CI: 97.89%～99.30%

204 nasal swab specimens were collected from asymptomatic individuals who have had contact with confirmed COVID-19 patients but didn't show any symptoms.

**Clinical performance of the Bioperfectus Technologies Novel Corona Virus Ag Rapid Test Kit against the comparator method on nasal swab specimens for asymptomatic individuals**

| Bioperfectus | PCR results | | |
|---|---|---|---|
| | Positive | Negative | Total |
| **Positive** | 89 | 1 | 90 |
| **Negative** | 14 | 100 | 114 |
| **Total** | 103 | 101 | 204 |

Sensitivity: 86.41%, 95%CI: 78.47%～91.73%
Specificity: 99.01%, 95%CI: 94.60%～99.83%
Accuracy: 92.65%, 95%CI: 88.22%～95.49%

## 17. Appendix

**Index of Symbols**

| | | | |
|---|---|---|---|
| CE | CE certification | EC REP | Authorized representative in the European Community |
| IVD | In vitro diagnostic Medical device | | Use-by date |
| | Manufacturer | | Date of manufacture |
| REF | Catalogue number | 4℃ 30℃ | Temperature limit |
| | Consult instructions for use | Σ | Contains sufficient for <n> tests |
| LOT | Batch code | | Do not reuse |
| | Keep away from sunlight | | This side up |

### Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit

Jiangsu Bioperfectus Technologies Co., Ltd.
Address: 3rd and 4th floors of Building A(G19), 4th floor of Building F(G14), Ground floor of Building G20, Shuaiyu Village, Fuye village, Sixiang town, Taizhou National Medical, Hi-tech Development Zone, 225300 Taizhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA.

EC REP MedNet EC-REP GmbH
Borkstrasse 10·48163 Muenster·Germany CE

### Sterile Specimen Collection Swabs

Medico Technology Co., Ltd.
Address: Room 201 of Building 14th and Building 17th, Hengyi Lane, Yuanhu Road, Zhangbei Industrial Park, Longcheng Street, Longgang district, Shenzhen, Guangdong, China.

EC REP Wellkang Ltd(www.CE-marking.eu)
Enterprise Hub, NW Business Complex,1
BeraghmoreRd Derry, BT488SE. N, Ireland UK CE0413

## 18. Contact and Support

For more information about Bioperfectus Technologies, please visit our website at: http://www.bioperfectus.com or contact at E-mail: info@bioperfectus.com
For detailed programming instructions regarding the use of the Bioperfectus Technologies Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit, please contact our Technical Support at E-mail: support@bioperfectus.com

bioPerfectus technologies

# PRODUCT CATALOGUE

## Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit


TÜV SÜD EN ISO 13485 CE BfArM approved EU Common List Included

## FEATURES

- **PEI evaluated performance**
- **Able to detect asymptomatic cases**
- **Mutation free from B.1.1.7, B.1.351, P.1, B.1.617.2, C.37, B.1.427/B.1.429, P.2, P.3, B.1.525, B.1.526, B.1.617.1**
- Technique: Lateral Flow Method
- Clinical Sensitivity: **97.06%**
- Clinical Specificity: **99.15%**
- Limit of Detection: $1.0 \times 10^2$ PFU/mL
- Easy-to-use: Operate simple process with all components provided
- Fast: Results in 15 minutes
- Storage temperature: 4~30°C
- Transportation temperature: -20~45°C

## COMPONENT*

*The amount of each component depends on the number of tests in each package.
For 5T, 10T and 15T packaging, we provide a single operation card instead of printing it on the inner box.



1 Operation sketch card
2 Instruction for use
3 Waste bag
4 Swab
5 Prepacked extraction tube
6 Cassette

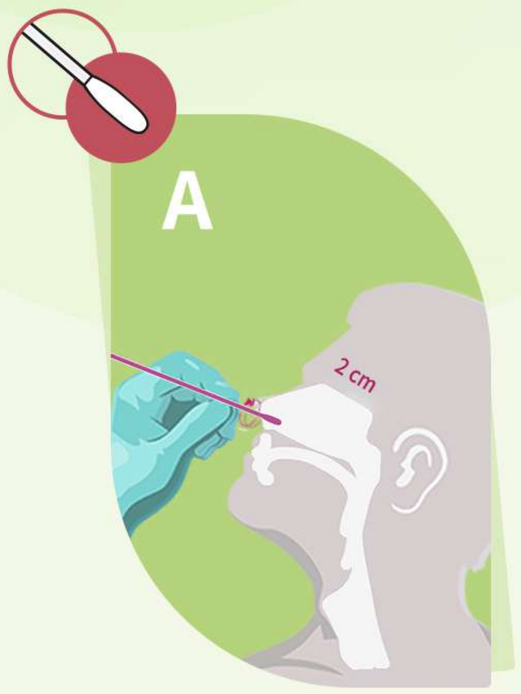
| Catalog | Package* | Instruction for use | Cassette | Operation sketch card | Swab | Prepacked extraction tube | Waste bag |
|---|---|---|---|---|---|---|---|
| SC30107W-1T | 1 Test/Kit | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc |
| SC30107W-2T | 2 Tests/Kit | 1 pc | 2 pcs | 1 pc | 2 pcs | 2 pcs | 2 pcs |
| SC30107W-5T | 5 Tests/Kit | 1 pc | 5 pcs | 1 pc | 5 pcs | 5 pcs | 5 pcs |
| SC30107W-10T | 10 Tests/Kit | 1 pc | 10 pcs | 1 pc | 10 pcs | 10 pcs | 10 pcs |
| SC30107W-15T | 15 Tests/Kit | 1 pc | 15 pcs | 1 pc | 15 pcs | 15 pcs | 15 pcs |

*We also offer 20T, 25T and 50T packaging. For more information please contact us via info@bioperfectus.com.

## SAMPLE TYPE

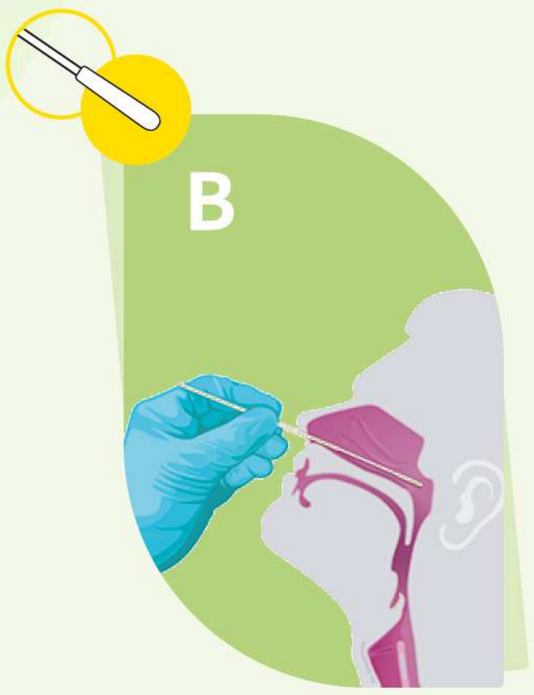
Nasal swab, nasopharyngeal swab, oropharyngeal swab

## OPTIONAL SWAB



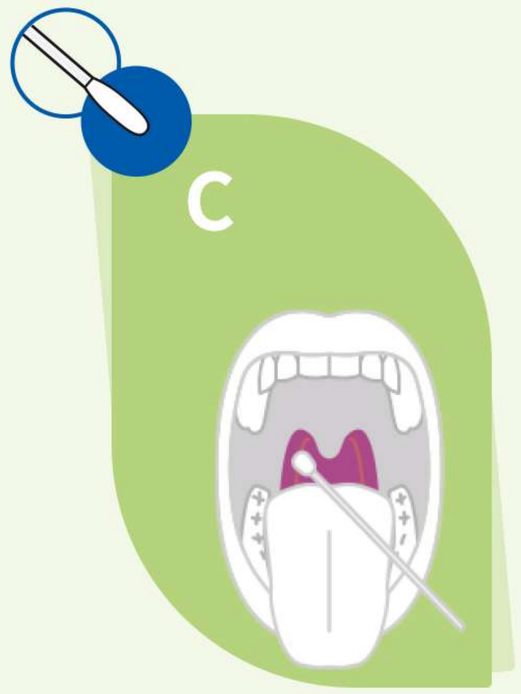

**Nasal swab**

**A swab:**
nasal swab is used for collecting sample from the uppermost part of your nose




**Nasopharyngeal swab**

**B swab:**
nasopharyngeal swab is used for collecting sample from the back of nose and throat




**Oropharyngeal swab**

**C swab:**
oropharyngeal swab is used for collecting sample from the rear wall of mouth

## SAMPLE COLLECTION

### Nasal swab

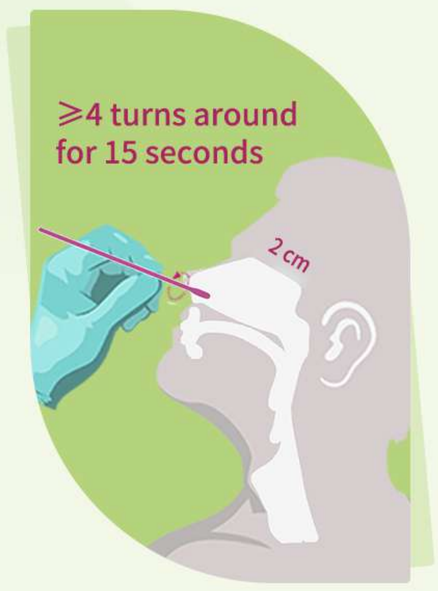
1. Insert the swab into the nostril.
2. Rotate the swab at least 4 times for 15 seconds to collect nasal drainage.
3. Remove the swab, and use the same swab to collect the sample in the other nostril.

### Nasopharyngeal swab

1. Insert the swab into the nostril to reach the surface of the posterior nasopharynx.
2. Rotate and push the swab until resistance is met at the level of the turbinate.
3. Rotate the swab a few times against the nasopharyngeal wall.

### Oropharyngeal swab

1. Insert swab into the oral cavity without touching tongue, teeth, cheeks or palate.
2. Rub the swab on the posterior wall for 10~15 seconds.



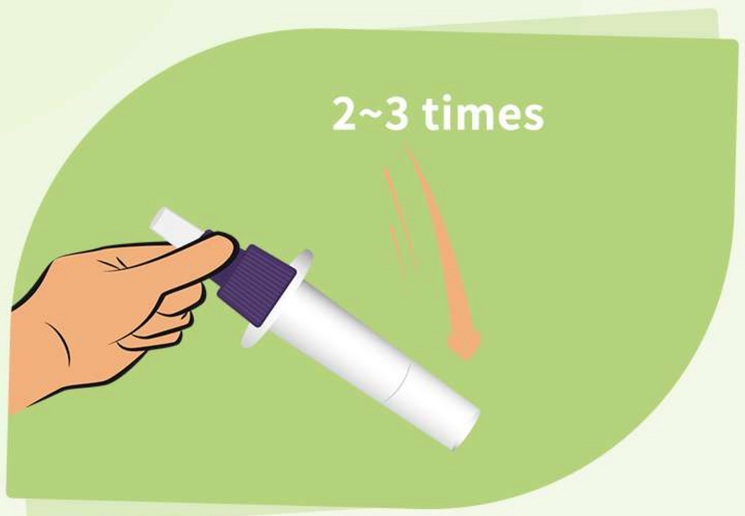

**Nasal swab**

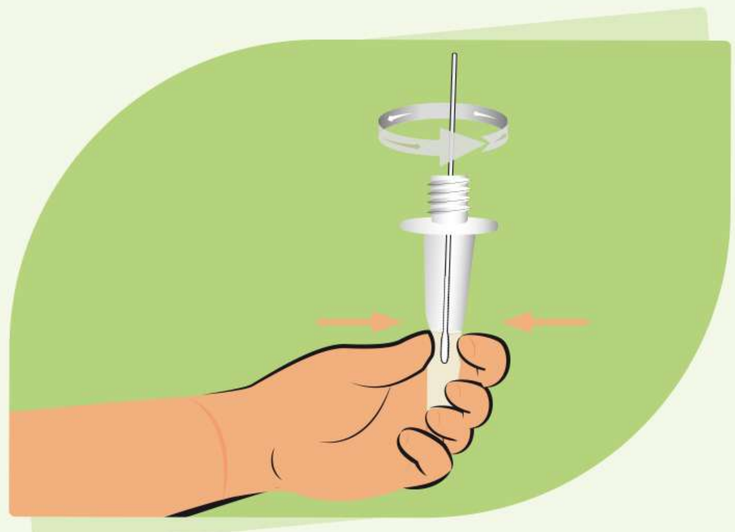
**Nasopharyngeal swab**

**Oropharyngeal swab**

## SAMPLE EXTRACTION

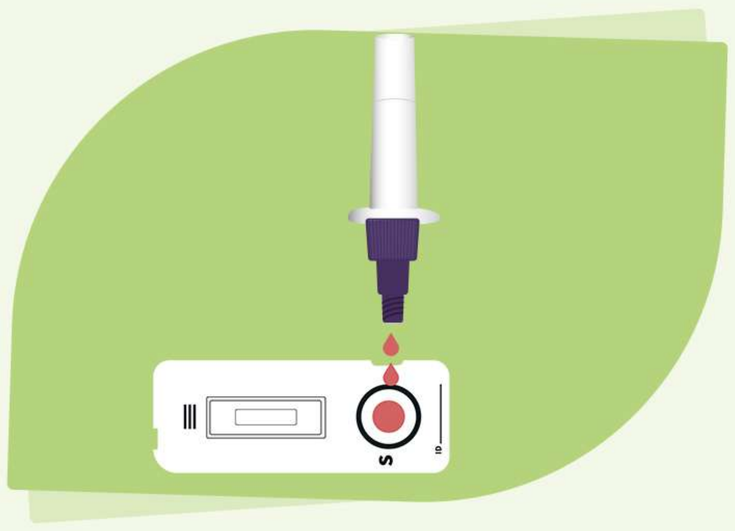
1. Shake the prepacked  extraction tube 2~3 times.
2. Put the swab into the tube and squeeze the absorbent tip of the swab through the tube.

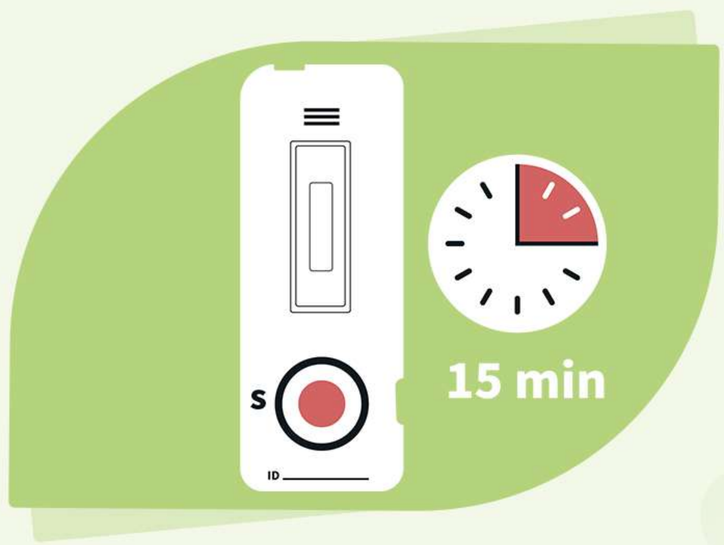


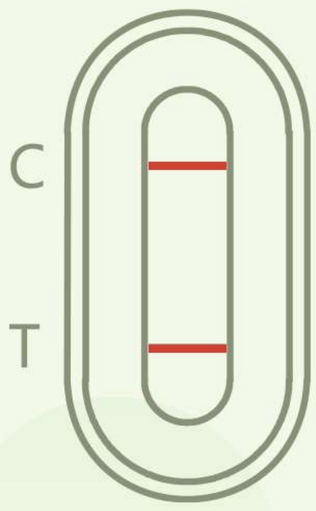
## TESTING

1. Add 2~3 drops of swab eluates in the prepacked extraction tube to the sample well of the cassette.
2. The result will be present in 15 minutes. DO NOT interpret result after 30 minutes.



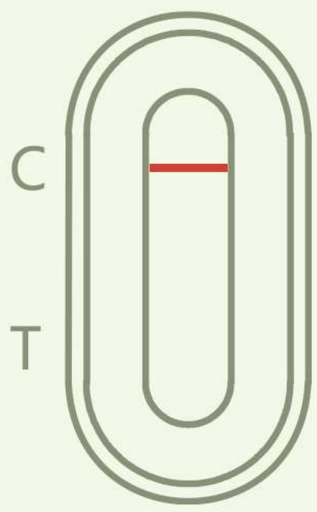



## Result Interpretation



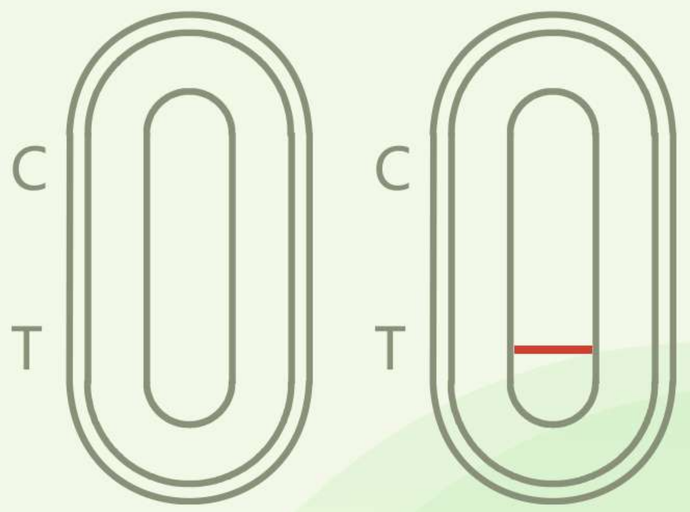

**Positive**

Two colored lines appear at the T and C area.




**Negative**

Only one colored line appears at the C area.




**Invalid**

No colored line appears at the C area.

**The result interpreted 30 minutes later will be invalid**

**For operating details please refer to the IFU and operation card in the kit.**

# JIANGSU BIOPERFECTUS TECHNOLOGIES CO., LTD.


2nd floor, Block 10, No.188 Xinjun Ring Road,
Pujiang High-Tech Park, Caohejing  Development Area,
Shanghai, China.

3rd & 4th floors of Building A(G19), 4th floor of Building F(G14),
Ground floor of Building G20, Shuaiyu Village, Fuye village,
Sixiang town, Taizhou National Medical Hi-tech Development Zone,
225300 Taizhou, Jiangsu P.R. China.

info@bioperfectus.com

www.bioperfectus.com


## AUTHORIZED DISTRIBUTOR