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

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

4℃-30℃

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 testing, the test 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.

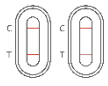
NOTE:

* 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 1x10^2 PFU/mL

Concentration	No. Positive/Total	% Positive
1x10^2 PFU/mL	19/20	95%

- **Analytical specificity**

Name	Concentration	Cross-Reactivity (Yes/No)
Human coronavirus 229E	1x10^5 PFU/mL	No
Human coronavirus OC43	1x10^5 PFU/mL	No
Human coronavirus NL63	1x10^5 PFU/mL	No
MERS-coronavirus	1x10^5 PFU/mL	No
SARS-coronavirus	1x10^5 PFU/mL	N/A
Human coronavirus HKU1	1x10^5 PFU/mL	No
Adenovirus (e.g. C1 Ad. 71)	1x10^5 PFU/mL	No
Human Metapneumovirus (hMPV)	1x10^5 PFU/mL	N/A
Parainfluenza virus 1	1x10^5 PFU/mL	No
Parainfluenza virus 3	1x10^5 PFU/mL	No
Parainfluenza virus 4	1x10^5 PFU/mL	No
Influenza A	1x10^5 PFU/mL	No
Influenza B	1x10^5 PFU/mL	No
Enterovirus	1x10^5 PFU/mL	No
Respiratory syncytial virus	1x10^5 PFU/mL	No
Rhinovirus	1x10^5 PFU/mL	No
Haemophilus influenzae	1x10^5 PFU/mL	N/A
Streptococcus pneumoniae	1x10^6 CFU/mL	No
Streptococcus pyogenes	1x10^6 CFU/mL	N/A
Candida albicans	1x10^6 CFU/mL	No
Pooled human nasal wash – representative of normal respiratory microbial flora	/	No
Bordetella pertussis	1x10^6 CFU/mL	N/A
Mycoplasma pneumoniae	1x10^6 CFU/mL	No
Chlamydia pneumoniae	1x10^6 CFU/mL	No
Legionella pneumophila	1x10^6 CFU/mL	N/A
Staphylococcus aureus	1x10^6 CFU/mL	No
Staphylococcus epidermidis	1x10^6 CFU/mL	N/A
Mycobacterium tuberculosis	1x10^6 CFU/mL	N/A
Pneumocystis jirovecii (PJP)	1x10^6 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 x10^5 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

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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