

Test COMBO 4w1 Core profesjonalny

Test COMBO 4w1 CorDx Grypa A/B + COVID-19 + RSV Combo Ag jest testem immunochromatograficznym do diagnostyki in vitro. Jest przeznaczony do jakościowego, różnicowego wykrywania antygenu białka nukleokapsydu wirusa grypy typu A, wirusa grypy typu B, wirusa RSV i wirusa SARS-CoV-2 w próbkach wymazu z nosa. Opakowanie zbiorcze 25 sztuk. Wysoka dokładność tego testu pozwala na niezawodne wyniki, które otrzymujemy już po 15 minutach! 1 wymaz = 4 wyniki Produkt przeznaczony do użytku profesjonalnego.

NAZWA	Test COMBO 4w1 Core profesjonalny
VAT	8%
MATERIAŁ PRÓBK	wymaz z nosa
WYNIK	po 15 minutach
GRYPA TYPU A DOKŁADNOŚĆ	99,5%
GRYPA TYPU B DOKŁADNOŚĆ	99,7%
COVID-19 DOKŁADNOŚĆ	98,8%
RSV DOKŁADNOŚĆ	98,8%
PRZEZNACZENIE	dla profesjonalistów
OPAKOWANIE ILOŚĆ	25 szt.
OPAKOWANIE ROZMIAR	20x12, 5x8.5 cm
KARTON ILOŚĆ	1500 (60x25) szt.
KARTON ROZMIAR	65,5x43x51 cm
PALETA ILOŚĆ	18000 (60x25x12) szt.
PALETA ROZMIAR	170 cm
JĘZYK OPAKOWANIA	ENG
JĘZYK IFU	ENG
TEMPERATURA PZECZOWYWANIA	2C - 30C





DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Core Technology Co., Ltd.
Address: Room 100, C Building, No.29 Life Park Rd., Changping District, Beijing 102206, P.R.China
EC Representative: SUNGO Cert GmbH
Address: Harffstr. 47,40591 Düsseldorf, Germany

Product Name: Influenza A/B+COVID-19/RSV Combo Ag Test
Specification: Multi-Panel
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

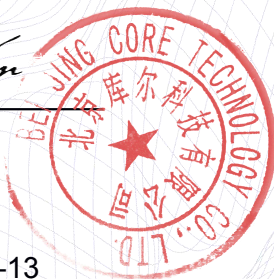
EN 13612:2002/AC:2002	EN ISO 23640:2015	EN ISO 14971:2019
EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO15223-1:2016
EN 62366-1:2015	EN 13641:2002	

Signature: _____

Position: RM

Date: 2022-01-13

Place: Beijing / China



Influenza A/B+COVID-19/RSV Combo Ag Test

* Please carefully read the instructions before use
* For In Vitro Diagnostic and Professional Use only.



Specimen: Nasal swab specimen
Format: Multi-Panel

INTENDED USE

Influenza A/B+COVID-19/RSV Combo Ag Test is an in vitro immunochromatographic assay for the qualitative and differential detection of nucleocapsid protein antigen from influenza A (including the subtype H1N1), influenza B, respiratory syncytial virus and/or SARS-CoV-2 in nasal swab specimens. It is intended to aid in the rapid diagnosis of influenza A, influenza B, respiratory syncytial virus and/or SARS-CoV-2 infections. This test provides only a preliminary test result. Therefore, any reactive specimen with the Influenza A / Influenza B & COVID-19/ RSV Antigen Test must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

Influenza is a highly contagious, acute viral infection of the respiratory tract with symptoms such as headache, chills, dry cough, body aches or fever. It is a communicable disease that is easily transmitted through aerosolized droplets containing live virus from coughing and sneezing. The causative agents of the disease are immunologically diverse single strand RNA viruses known as influenza viruses. Influenza type A viruses are typically more prevalent than influenza type B viruses and are associated with most sensitive influenza epidemics, while influenza type B infections are usually milder. Diagnosis is difficult because the initial symptoms are similar to those caused by other infectious agents. Accurate diagnosis and prompt treatment of patients can have a positive effect on public health. Rapid and accurate diagnosis of influenza viral infection can also help reduce the inappropriate use of antibiotics and gives the physician the opportunity to prescribe appropriate antiviral medications.

Respiratory syncytial virus is an RNA virus belonging to the paramyxoviridae family. The disease is spread by airborne droplets and close contact. It is more common in newborns and infants less than 6 months old. The incubation period is 3 ~ 7 days. Infants and young children have more severe symptoms, including high fever, rhinitis, pharyngitis and laryngitis, followed by bronchiolitis and pneumonia. A few sick children can be complicated with otitis media, pleurisy and myocarditis, etc. Upper respiratory tract infection is the main symptom of infection in adults and older children.

CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. Evidence suggests transmission via fecal-oral route. 7 kinds of HCoV's caused human's respiratory diseases are found by now: HCoV-229E, CoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and COVID-19 which are the serious pathogens for human,s respiratory diseases. Its clinical manifestation are fever, enervate and systemic symptom, with dry cough, difficult breathing etc. and it may aggravate to severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure, severe acid-base metabolic disorders etc and even life threatening rapidly.

PRINCIPLES

The Flu A/B Antigen strip uses influenza A monoclonal antibody (T1), influenza B monoclonal antibody (T2), and goat anti-mouse IgG polyclonal antibodies (C) that are respectively immobilized on a nitrocellulose membrane. It uses colloidal gold to label influenza A monoclonal antibody and influenza B monoclonal antibody. Using nano-colloidal gold technology and applying highly specific antibody-antigen reaction and immunochromatographic analysis technology principle. When testing, the Influenza type A viruses antigen in the sample combined with the colloidal gold-labeled influenza A monoclonal antibody to form a complex, which was then combined with the influenza A monoclonal antibody coated in the test line T1 during chromatography, at this time there is one red line in the T1 area. The Influenza type B viruses antigen in the sample combined with the colloidal gold-labeled influenza B monoclonal antibody to form a complex, which was then combined with the influenza B monoclonal antibody coated in the test line T2 during chromatography, at this time there is one red line in the T2 area. When the samples do not contain Influenza type A and B viruses antigens, there is no red colored lines in the T1 and T2 areas. Regardless of the presence of Influenza type A or B viruses antigens in the sample, a red line will form in the quality control area (C). The red line appears in the quality control area (C) serves as 1. Verification that sufficient volume is added. 2. That proper flow is obtained 3. And as a control for the reagents.

The COVID-19/RSV Antigen strip uses COVID-19 monoclonal antibody (T2), RSV monoclonal antibody(T1) and goat anti-mouse IgG polyclonal antibodies (C) that are respectively immobilized on a nitrocellulose membrane. It uses colloidal gold to label COVID-19 monoclonal antibody, RSV monoclonal antibody. Using nano-colloidal gold technology and applying highly specific antibody-antigen reaction and immunochromatographic analysis technology principle. When testing, the COVID-19 antigen in the sample combined with the colloidal gold-labeled COVID-19 monoclonal antibody to form a complex, which was then combined with the COVID-19 monoclonal antibody coated in the test line T2 during chromatography, at this time there is one red line in the T2 area. The RSV antigen in the sample combined with the colloidal gold-labeled RSV monoclonal antibody to form a complex, which was then combined with the RSV monoclonal antibody coated in the test line T1 during chromatography, at this time there is one red line in the T1 area. When the samples do not contain COVID-19 and RSV antigens, there is no red colored lines in the T1 and T2 areas. Regardless of the presence of Influenza type A or B viruses antigens in the sample, a red line will form in the quality control area (C). The red line appears in the quality control area (C) serves as 1. Verification that sufficient volume is added. 2. That proper flow is obtained 3. And as a control for the reagents.

MATERIALS PROVIDED

Influenza A/B+COVID-19/RSV Combo Ag Test contains the following items to perform the assay:

- 1. Test cassette
- 2. Instruction for use
- 3. Sample collection tube containing processing solution
- 4. Nasal swab
- 5. Tube rack (Optional)

MATERIALS REQUIRED BUT NOT PROVIDED

- 1. Clock or Timer

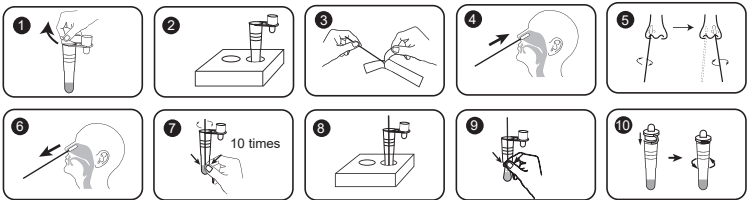
WARNING AND PRECAUTIONS

- 1. Read instruction for use carefully before performing this test. If you Do not follow the instructions, you will get inaccurate results.
- 2. This kit is suitable for qualitative detection of human nasal swab samples.
- 3. For in vitro diagnostic use only.
- 4. Do not use the test cassette beyond the expiration date.
- 5. The test cassette should remain in the sealed pouch until use. Do not use the test cassette if the pouch is damaged or the seal is broken.
- 6. Do not reuse the cassette and swab.
- 7. Do not use turbid contaminated samples for testing.
- 8. Do not mix and interchange different specimens.
- 9. Do not touch the swab head when handling the swab.
- 10. You need to use the swab provided in the kit for sampling.
- 11. The testing process must follow SPECIMEN PREPARATION and TEST PROCEDURE.
- 12. Wear safety mask or other face covering when collecting swabs from children or others.
- 13. After the test, collect and put used product components in a plastic bag. Close the bag and put it in another plastic bag. Dispose of the bag with household garbage. Or collected and processed according to the requirements of the local epidemic prevention department.
- 14. The test samples should be regarded as infectious agents and the operation should be in accordance with the infectious disease laboratory operating rules. After using this kit, the waste should be disposed according to the expected waste management system.
- 15. This kit will show negative results under the following conditions, when the target antigen titer in the sample is below the minimum detection limit of the kit.
- 16. Insufficient sampling or wrong sampling process may lead to wrong results.
- 17. Keep test kit and materials out of the reach of children and pets before and after use.

STORAGE AND STABILITY

Storage: store at 2~30°C.
Shelf life: 24 months.

SPECIMEN PREPARATION

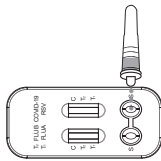


- 1. Remove the foil from the top of the sample collection tube.
- 2. Place the tube in the tube rack or the hole on box backside.
- 3. Remove a nasal swab from the pouch.
- 4. Using the sterile swab provided in the kit, carefully insert the swab into one nostril of the patient.
- 5. The swab tip should be inserted up to 2-4 cm until resistance is met. Roll the swab 5 times in a circular motion around the inside wall ensure that both mucus and cells are collected. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
- 6. Withdraw the swab from the nasal cavity.
- 7. The specimen is now ready for preparation using the extraction buffer provided in the test kit. Insert the swab in collection tube to the bottom, rotate and squeeze the swab 10 times while pressing the head against the bottom and side of the collection tube.
- 8. Leave the swab in the collection tube for 1 minute.
- 9. Rotate and Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab.
- 10. Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube.

Note:

- 1. Please use swab for specimen collection.
- 2. It is highly recommended to collect specimen with wearing a pair of safety gloves to avoid contamination.
- 3. Do not touch the tip (specimen collection area) of the swab.
- 4. Collect sample as soon as after onset of symptoms.
- 5. It is recommended to treat the sample immediately after collection. The sample can be stored at 2°C~8°C for 72 hours, and it needs to be frozen at -20°C for long-term storage, avoiding repeated freezing and thawing.

TEST PROCEDURE



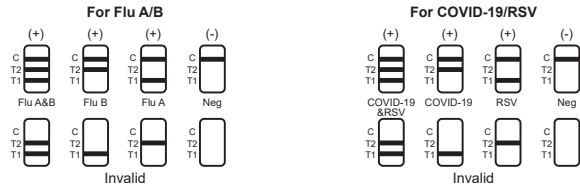
Read the instruction first prior to testing. Bring the pouched test to room temperature prior to testing. Do not open the pouch until ready to begin testing.

- 1. Remove the test from the sealed pouch. Lay it on a flat, clean and dry surface.
- 2. Reverse the sample collection tube, and add 3 drops of test sample by squeezing the collection solution tube into each of the sample well.
- 3. Read results at 15 minutes.

NOTE: The test is intended to be read at 15 minutes. If the test is read before 10 minutes or is read more than 30 minutes after the indicated read time, results may be inaccurate (false negative, false positive, or invalid) and the test should be repeated.

Collect all the package component and sealed in biohazard waste bag: including extraction dropper, swab, test cassette and assay diluent bottle. Discard waste bag accord with local legislation.

INTERPRETATION OF RESULTS



For Flu A/B Antigen Test

- 1. POSITIVE:
 - 1.1 Flu A Positive: The presence of two lines as control line (C) and T1 test line within the result window indicates a positive result for Influenza A viral antigen.
 - 1.2 Flu B Positive: The presence of two lines as control line (C) and T2 test line within the result window indicates a positive result for Influenza B viral antigen.
 - 1.3 Flu A+B Positive: The presence of three lines as control line (C), T1 test line and T2 test line within the result window indicates a positive result for Influenza A and Influenza B viral antigen.
- 2. NEGATIVE: The presence of only control band (C) within the result window indicates a negative result.
- 3. INVALID: If the control band (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test. If the problem persists, please stop using the product and contact with the test distributor.

For COVID-19/RSV Antigen Test

- 1. POSITIVE:
 - 1.1 RSV Positive: The presence of two lines as control line (C) and T1 test line within the result window indicates a positive result for RSV viral antigen.
 - 1.2 COVID-19 Positive: The presence of two lines as control line (C) and T2 test line within the result window indicates a positive result for COVID-19 viral antigen. If tested COVID-19 positive, users should not take any decision of medical relevance without first consulting a medical practitioner.
 - 1.3 COVID-19+RSV Positive: The presence of three lines as control line (C), T1 test line and T2 test line within the result window indicates a positive result for RSV and COVID-19 viral antigen.
- 2. NEGATIVE: The presence of only control band (C) within the result window indicates a negative result.
- 3. INVALID: If the control band (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test. If the problem persists, please stop using the product and contact with the test distributor.

LIMITATION OF THE TEST

This kit is a clinical auxiliary test product. Any sample with a positive test result should be further confirmed by other methods.

PERFORMANCE CHARACTERISTICS

- 1. Limit of Detection (Analytical Sensitivity)
The minimum detection limit is 1.5 x 10⁴ TCID₅₀/test for the Influenza A virus antigen and is 1.5 x 10⁵ TCID₅₀/test for the Influenza B virus antigen.
- 2. Analytical Reactivity
The influenza A strain listed tested positive in the Influenza A & B Ag Test. Although the specific influenza strains causing infection in human can vary, all contain the conserved nucleoproteins targeted by Influenza A+B Ag Test.
Influenza A+B Ag Test can detect all nine influenza B strains.

Strains	Sources	Subtypes	Concentration
Flu A/Hubei/P R 8/2001	Human	H1N1	1.8x10 ⁴ TCID ₅₀ /test
Flu A/New Kaledonia/20/99	Human	H1N1	1.8x10 ⁴ TCID ₅₀ /test
Flu A/Yamagata/32/89	Human	H1N1	1.8x10 ⁴ TCID ₅₀ /test
Flu A/Beijing/262/95	Human	H1N1	1.8x10 ⁴ TCID ₅₀ /test
Flu A/Singapore/1/ 57	Human	H2N2	3.0x10 ⁴ TCID ₅₀ /test
Flu A/Hubei/3/2005	Human	H3N2	3.0x10 ⁴ TCID ₅₀ /test
Flu A/Akita/1/94	Human	H3N2	3.0x10 ⁴ TCID ₅₀ /test
Flu A/Kita Kyus yu/159/93	Human	H3N2	3.0x10 ⁴ TCID ₅₀ /test
Flu A/Lowa/15/30	Swine	H1N1	3.0x10 ⁴ TCID ₅₀ /test
Flu A/Hongkong/168/93	Swine	H1N1	3.0x10 ⁴ TCID ₅₀ /test
Flu A/Anhui/24/2004	Swine	H5N1	6.0x10 ⁴ TCID ₅₀ /test
Flu A/Hubei/134/2000	Swine	H9N2	6.0x10 ⁵ TCID ₅₀ /test
Flu A/Hubei/251/2001	Swine	H9N2	6.0x10 ⁵ TCID ₅₀ /test
Flu A/Yuyao/1/2006	Chicken	H5N1	6.0x10 ⁴ TCID ₅₀ /test
Flu A/Yuyao/2/2006	Chicken	H5N1	6.0x10 ⁴ TCID ₅₀ /test
Flu A/Jiangsu/2/2004	Chicken	H5N1	6.0x10 ⁴ TCID ₅₀ /test
Flu A/Hubei/216/83	Duck	H7N8	3.0x10 ⁵ TCID ₅₀ /test
Flu A/Hubei/118/2003	Duck	H9N2	1.5x10 ⁵ TCID ₅₀ /test
Flu A/Hubei/155/2003	Duck	H9N2	6.0x10 ⁵ TCID ₅₀ /test
Flu A/Hubei/137/1982	Duck	H10N4	3.0x10 ⁵ TCID ₅₀ /test
Flu A/Singapore/3/97	Duck	H5N3	6.0x10 ⁴ TCID ₅₀ /test
Flu A/Henan/1/2004	Tree sparrow	H5N1	6.0x10 ⁵ TCID ₅₀ /test
Flu A/Henan/2/2004	Tree sparrow	H5N1	3.0x10 ⁵ TCID ₅₀ /test
Flu A/Henan/4/2004	Tree sparrow	H5N1	6.0x10 ⁴ TCID ₅₀ /test
Flu A/Wisconsin/66	Turkey	H9N2	6.0x10 ⁴ TCID ₅₀ /test
Flu A/England/1/63	Turkey	H7N3	6.0x10 ⁴ TCID ₅₀ /test
Flu A/Singapore/1/57	Bird	H5N1	6.0x10 ⁴ TCID ₅₀ /test
Flu A/Hunan/71/2/2004	Bird	H5N1	6.0x10 ⁴ TCID ₅₀ /test
Flu A/Shanxi/50/2006	Bird	H5N1	6.0x10 ⁴ TCID ₅₀ /test
Flu A/Shanxi/42/2006	Bird	HSN1	6.0x10 ⁴ TCID ₅₀ /test
Flu A/Fujian/320/2004	Bird	H5N1	3.0x10 ⁵ TCID ₅₀ /test

3. Analytical Specificity And Cross-reactivity

The Influenza A+B Ag Test was evaluated with a total of 30 bacterial and viral isolates. Bacterial isolates were evaluated at a concentration between 10⁷ and 10⁹ org/mL. Viral isolates were evaluated at a concentration of at least 10⁴-10⁸ TCID₅₀/mL. Adenovirus 18 and Parainfluenza virus 3 were tested at 10⁴ TCID₅₀/mL. None of the organisms or viruses listed below gave a positive result in the Influenza A+B Ag Rapid Test.

Bacterial Panel:

Acinetobacter calcoaceticus	Bacteroides fragilis	Neisseria gonorrhoeae	Neisseria meningitidis
Pseudomonas aeruginosa	Staphylococcus aureus	Streptococcus pneumoniae	Streptococcus sanguis
Proteus vulgaris	Streptococcus sp. Gp.B	Streptococcus sp.Gp.C	Streptococcus sp. Gp.G
Mycobacterium tuberculosis	Mycoplasma orale		

Viral Panel:

Human Adenovirus B	Human Rhinovirus 2	Human Adenovirus C	Human Rhinovirus 14
Adenovirus type 10	Human Rhinovirus 16	Adenovirus type 18	Measles
Human Coronavirus OC43	Mumps	Human Cocksackievirus A9	Sendai virus
Coxsackievirus B5	Parainfluenza virus 2	Human herpesvirus 2	Parainfl uenza virus 3

5. Interfering Substances

Whole blood, and several over-the-counter (OTC) products and common chemicals were evaluated and did not interfere with the Influenza A+B Ag Test at the levels tested: whole blood (1%); three OTC mouthwashes (25%); three OTC throat drops (25%); three OTC nasal sprays (10%); 4-Acetamidophenol (10mg/mL); Acetylsalicylic Acid(20mg/mL); Chlorpheniramine(5mg/mL); Dextromethorphan(10mg/mL); Diphenhydramine (5mg/mL); Ephedrine(20mg/mL); Guaiacol glyceryl ether(20mg/mL); Oxymetazoline(10mg/mL); Phenylephrine(100mg/mL); and Pseudoephedrine(20mg/mL).

For COVID-19/RSV Antigen Test :

1. Limit of Detection (Analytical Sensitivity)

The LoD of COVID-19 Ag Test LOD in nasal swab matrix was confirmed as 22.5 TCID₅₀/mL.

The LoD of RSV A type in nasal swab matrix was confirmed as 1X10⁴ TCID₅₀/mL;

The LoD of RSV B type in nasal swab matrix was confirmed as 1.2X10⁴ TCID₅₀/mL.

2. Analytic Specificity

Results demonstrated that COVID-19/RSV Antigen Test has no significant cross-reactivity with the seromarkers listed following :

	Potential Cross-Reactant	Concentration
Virus	Adenovirus	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human metapneumovirus (hMPV)	1.0 x 10 ⁵ TCID ₅₀ /mL
	Rhinovirus	1.0 x 10 ⁵ PFU/mL
	Enterovirus/Coxsackievirus B4	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human coronavirus OC43	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human coronavirus 229E	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human coronavirus NL63	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 1	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 2	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 3	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 4	1.0 x 10 ⁵ TCID ₅₀ /mL
	Influenza A	1.0 x 10 ⁵ TCID ₅₀ /mL
	Influenza B	1.0 x 10 ⁵ TCID ₅₀ /mL
Bacteria	MERS-CoV	1.0 x 10 ⁵ TCID ₅₀ /mL
	Bordetella pertussis	1.0 x 10 ⁵ cells/mL
	Chlamydia pneumoniae	1.0 x 10 ⁵ IFU/mL
	Haemophilus influenzae	1.0 x 10 ⁵ cells/mL
	Legionella pneumophila	1.0 x 10 ⁵ cells/mL
	Mycoplasma pneumoniae	1.0 x 10 ⁵ U/mL
	Streptococcus pneumoniae	1.0 x 10 ⁵ cells/mL
	Streptococcus pyogenes (group A)	1.0 x 10 ⁵ cells/mL
	Mycobacterium tuberculosis	1.0 x 10 ⁵ cells/mL
	Staphylococcus aureus	1.0 x 10 ⁵ org/mL
Yeast	Staphylococcus epidermidis	1.0 x 10 ⁵ org/mL
	Pooled human nasal wash	N/A
	Candida albicans	1.0 x 10 ⁵ cells/mL

3. Interference

The following substances and conditions were found not to interfere with the test. List of potentially interfering compounds and concentrations tested are as follows:

Substance	Active Ingredient	Concentration
Endogenous	Mucin	2% w/v
	Whole Blood	1% v/v
OTC Nasal Drops	Phenylephrine	15% v/v
OTC Nasal Gel	Sodium Chloride (i.e. NeilMed)	5% v/v
OTC Nasal Spray 1	Cromolyn	15% v/v
OTC Nasal Spray 2	Oxymetazoline	15% v/v
OTC Nasal Spray 3	Fluconazole	5% w/v
Throat Lozenge	Benzocaine, Menthol	0.15% w/v
OTC Homeopathic Nasal Spray 1	Galphimia glauca, Sabadilla,	20% v/v
OTC Homeopathic Nasal Spray 2	Zincum gluconum (i.e., Zicam)	5% w/v
OTC Homeopathic Nasal Spray 3	Alkaloi	10% v/v
OTC Homeopathic Nasal Spray 4	Fluticasone Propionate	5% v/v
Sore Throat Phenol Spray	Phenol	15% v/v
Anti-viral Drug	Tamiflu (Osetamivir Phosphate)	0.5% w/v
Antibiotic, Nasal Ointment	Mupirocin	0.25% w/v
Antibacterial, Systemic	Tobramycin	0.0004% w/v

DIAGNOSTIC SENSITIVITY AND SPECIFICITY

For Flu A+B Antigen Test:

A study using total 600 nasal swab samples was conducted. The diagnostic sensitivity and specificity of the influenza A Ag test and the influenza B Ag test results are given as below:

Table 1 - Comparison of influenza A Ag test

		Results of Clinical diagnosis		Total Results
		Positive	Negative	
Results of Influenza A Ag test	Positive	118	2	120
	Negative	1	479	480
Total Results		119	481	600

Sensitivity of 99.2% (118/119), Specificity of 99.6% (479/481), A total agreement of 99.5% (597/600).

Table 2 - Comparison of influenza B Ag test

		Results of Clinical diagnosis		Total Results
		Positive	Negative	
Influenza B Ag test	Positive	109	1	110
	Negative	1	489	490
Total Results		110	490	600

Sensitivity of 99.1% (109/110), Specificity of 99.8% (489/490), A total agreement of 99.7% (598/600).

For COVID-19/RSV Antigen Test:

A study using a total 415 nasal swab samples was conducted.Test results were compared with nucleic acid detection test. The diagnostic sensitivity and specificity of the test results are shown in Table 3:

Table 3 - Comparison of COVID-19 Ag Test

		Results of Clinical diagnosis		Total Results
		Positive	Negative	
Results of COVID-19 Ag Test	Positive	152	2	154
	Negative	3	285	261
Total Results		155	260	415

Results gave sensitivity is 98.1% (152/155), specificity is 99.2%(258/260), and a total agreement of 98.8% (410/415).

Table 4 - Comparison of RSV Ag Test










		Results of Clinical diagnosis		Total Results
		Positive	Negative	
Results of RSV Ag Test	Positive	112	2	114
	Negative	3	298	301
Total Results		115	300	415

Results gave sensitivity is 97.4% (112/115), specificity is 99.3% (298/300), and a total agreement of 98.8% (410/415).

PRECAUTIONS

- This kit is used for one-time in vitro testing. The same kit cannot be reused.
- This kit is suitable for qualitative detection of human nasal swab samples.
- The experimental environment should be protected from wind, and experiments should not be performed in an excessively high temperature, high humidity, or excessively dry environment.
- The test samples should be regarded as infectious agents and the operation should be in accordance with the infectious disease laboratory operating rules. After using this kit, the waste should be disposed according to the expected waste management system.
- Do not use after the expiration date.
- Before using this kit, you must read instructions carefully and strictly control the reaction time. If you do not follow the instructions, you will get inaccurate results.
- The results of samples are closely related to the methods of sample collection. Incorrect sample collection may result in negative results.
- Do not use turbid contaminated samples for testing.
- This kit will show negative results under the following conditions,when the target antigen titer in the sample is below the minimum detection limit of the kit.

INDEX OF SYMBOLS

	Do not re-use		Batch code
	Store at 2~30 C		Use-by date
	Manufacturer		CE Mark
	In vitro diagnostic medical device		Consult instructions for use
	Authorized representative in the European Union		

MANUFACTURER CONTACT INFORMATION

 Core Technology Co., Ltd.
Room 100, C Building, No.29 Life Park Rd., Changping District, Beijing 102206, P.R.China

 SUNGO Cert GmbH
Harffstr. 47, 40591 Düsseldorf, Germany

File No. CORE-CE-Flu A+B COVID+RSV-05; IFU-C
Ver. 1.1 Eff. Date: Jan.11,2022

Formularz dla podmiotów / Form for organizations

A. Identyfikacja właściwego organu / Identification of the Competent Authority	
1.001 Kod / Code PL/CA01	
1.002 Nazwa w języku miejscowym - po polsku / Name in local language - in Polish Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych	
1.003 Nazwa po angielsku / Name in English The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	
1.004 Kod kraju / Country code PL	1.005 Kod pocztowy i miasto / Postal code and city
1.006 Ulica, nr / Street, no.	1.007 Telefon / Phone +48 22 4921100

Proszę wypełniać tylko pola z białym tłem / Please fill in fields with a white background only

B. Identyfikacja zgłoszenia lub powiadomienia / Identification of notification	
1.008 Data wpływu / Date of notification	1.009 Numer referencyjny / Reference number
1.010 Rodzaj zgłoszenia lub powiadomienia / Notification type	
<input checked="" type="checkbox"/> 1. Pierwsze dla wyrobu / First for device <input type="checkbox"/> 2. Zmiana danych podmiotu / Change of entity details <input type="checkbox"/> 3. Zmiana danych wyrobu / Change of device details	
1.011 W przypadku zmiany dotyczącej podmiotu proszę wskazać dane ulegające zmianie In case of change of entity details please indicate the data being changed	
1.012 Status podmiotu dokonującego niniejszego zgłoszenia lub powiadomienia / Status of the organization making this notification	
<input type="checkbox"/> W - Wytwórca (Producent) / Manufacturer <input type="checkbox"/> A - Autoryzowany przedstawiciel (Upoważniony przedstawiciel) / Authorized representative <input checked="" type="checkbox"/> I - Importer / Importer <input type="checkbox"/> D - Dystrybutor / Distributor <input type="checkbox"/> Z - Podmiot zestawiający system lub zestaw zabiegowy / Organization assembling system or procedure pack <input type="checkbox"/> S - Podmiot sterylizujący wyrób medyczny, system lub zestaw zabiegowy / Organization sterilizing medical device, system or procedure pack <input type="checkbox"/> O - Świadczeniodawca wykonujący ocenę działania (badanie działania) / Organization carrying out performance evaluation <input type="checkbox"/> L - Laboratorium wytwarzające na swój użytek wyrób IVD / Laboratory produced in home IVD device <input type="checkbox"/> DL - Podmiot wykonujący działalność leczniczą / Entity performing medical activity <input type="checkbox"/> IZ - Instytucja zdrowia publicznego / Health institution <input type="checkbox"/> P - Podmiot, który używa wyrobów do działalności gospodarczej lub zawodowej / Entity that uses products for business or professional activity	

C. Identyfikacja wytwórcy (producenta) / Identification of the manufacturer	
1.013 Numer referencyjny / Reference number	1.014 Kod kraju / Country code CN
1.015 Nazwa wytwórcy (producenta), pełna / Name of the manufacturer, in full Core Technology Co., Ltd.	
1.016 Nazwa wytwórcy (producenta), skrócona / Name of the manufacturer, abbreviated	
1.017 Miasto / City Beijing	1.018 Kod pocztowy / Postal code 102206
1.019 Ulica, nr / Street, no. No.29 Life Park Rd.	1.020 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.021 Imię i nazwisko / Full name Conor Callanan	1.022 Telefon / Phone +86-10-69390616
1.023 E-mail info@coretests.com	1.024 Faks / Fax

D. Identyfikacja autoryzowanego przedstawiciela (upoważnionego przedstawiciela) / Identification of the authorized representative	
1.025 Numer referencyjny / Reference number	1.026 Kod kraju / Country code DE
1.027 Nazwa autoryzowanego przedstawiciela (upoważnionego przedstawiciela), pełna / Name of the authorized representative, in full SUNGO Cert GmbH	
1.028 Nazwa autoryzowanego przedstawiciela (upoważnionego przedstawiciela), skrócona / Name of the authorized representative, abbreviated	
1.029 Miasto / City Düsseldorf	1.030 Kod pocztowy / Postal code 40591
1.031 Ulica, nr / Street, no. Harffstr. 47	1.032 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.033 Imię i nazwisko / Full name Ninggang Luo	1.034 Telefon / Phone +44 (0) 7868234015
1.035 E-mail info@sungoglobal.com	1.036 Faks / Fax

E. Identyfikacja ... / Identification of the ...		1.037 <input checked="" type="checkbox"/> I - ... importera / ... importer <input type="checkbox"/> D - ... dystrybutora / ... distributor
1.038 Numer referencyjny / Reference number	1.039 Kod kraju / Country code PL	
1.040 Nazwa importera lub dystrybutora, pełna / Name of the importer or distributor, in full BISAF spółka z ograniczoną odpowiedzialnością		
1.041 Nazwa importera lub dystrybutora, skrócona / Name of the importer or distributor, abbreviated		
1.042 Miasto / City Wrocław	1.043 Kod pocztowy / Postal code 54-530	
1.044 Ulica, nr / Street, no. Rdestowa 5	1.045 Skrytka pocztowa / PO Box	
Osoba do kontaktu / Contact person		
1.046 Imię i nazwisko / Full name Tomasz Lisek	1.047 Telefon / Phone +48725808180	
1.048 E-mail 24h@bisaf.pl	1.049 Faks / Fax	

F. Identyfikacja ... / Identification of the organization ...	
<input type="checkbox"/> Z - ... podmiotu zestawiającego system lub zestaw zabiegowy / ... assembling system or procedure pack <input type="checkbox"/> S - ... podmiotu sterylizującego wyrób medyczny, system lub zestaw zabiegowy / ... sterilizing medical device, system or procedure pack <input type="checkbox"/> O - ... świadczeniodawcy wykonującego ocenę działania (badanie działania) / ... carrying out performance evaluation <input type="checkbox"/> L - ... laboratorium wytwarzające na swój użytek wyrób IVD / Laboratory produced in home IVD device <input type="checkbox"/> DL - ... podmiot wykonujący działalność leczniczą / Entity performing medical activity <input type="checkbox"/> IZ - ... instytucja zdrowia publicznego / Health institution <input type="checkbox"/> P - ... podmiot, który używa wyrobów do działalności gospodarczej lub zawodowej / Entity that uses products for business or professional	
1.050	1.051 Numer referencyjny / Reference number
1.052 Kod kraju / Country code	
1.053 Nazwa podmiotu, pełna / Name of the organization, in full	
1.054 Nazwa podmiotu, skrócona / Name of the organization, abbreviated	
1.055 Miasto / City	1.056 Kod pocztowy / Postal code
1.057 Ulica, nr / Street, no.	1.058 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.059 Imię i nazwisko / Full name	1.060 Telefon / Phone
1.061 E-mail	1.062 Faks / Fax
G. Identyfikacja pełnomocnika działającego w imieniu podmiotu dokonującego zgłoszenia lub powiadomienia Identification of the person acting as proxy for the organization making this notification Wypełnia pełnomocnik ustanowiony na mocy art. 33 KPA lub art. 38 ust. 1 ustawy o CEIDG i Punkcie Informacji dla Przedsiębiorcy To be filled in by person acting as proxy in accordance with art. 33 of the Polish Code of Administrative Procedure or art. 45 par. 1 of CEIDG Act	
1.063 Imię i nazwisko / Full name	
1.064 Miasto / City	1.065 Kod pocztowy / Postal code
1.066 Ulica, nr / Street, no.	1.067 Skrytka pocztowa / PO Box
1.068 Telefon / Phone	1.069 Faks / Fax
H. Liczba wyrobów objętych tym zgłoszeniem lub powiadomieniem / Number of devices covered by this notification Proszę podać właściwe liczby lub zero, jeśli nie dołączono danego typu formularza Please provide proper numbers or zero if there are no attached forms of given type	
1.070 Liczba dołączonych Załączników nr 2 / Number of attached forms no. 2	0
1.071 Liczba dołączonych Załączników nr 3 / Number of attached forms no. 3	0
1.072 Liczba wyrobów wymienionych w dołączonych Załącznikach nr 4 / Number of devices listed in attached forms no. 4	1

Potwierdzam, że powyższe informacje są poprawne według mojej najlepszej wiedzy.
 I affirm that the information given above is correct to the best of my knowledge.

Miasto / City Wrocław

Data / Date 2024-04-16

Nazwisko / Name Tomasz Lisek

Podpis / Signature TOMASZ LISEK

BISAF Spółka z o.o.

ul. Rdestowa 5, 54-530 Wrocław
 NIP 8943153454, Regon 385955440
 KRS 0000838986

Wykaz wyrobów objętych powiadomieniem

List of devices covered by this notification

Proszę wypełniać tylko pola z białym tłem / Please fill in fields with a white background only

A. Identyfikacja powiadomienia / Identification of notification		
4.001 Numer kolejny Załącznika nr 4 w obrębie tego powiadomienia	4.002 Numer referencyjny Załącznika nr 1 / Reference number of form no. 1	
1 Ordinal number of form no. 4 within this notification		

B. Wykaz wyrobów / List of devices				
4.003 Nr referencyjny / Ref. no	4.004 Nazwa handlowa wyrobu / Trade name of device 1), 2)	4.005 Kod Basic UDI-DI, jeżeli został nadany / Basic UDI-DI code, if applicable	4.006 Nazwa rodzajowa wyrobu / Generic device name 3)	4.007 Numer identyfikacyjny jednostki notyfikowanej, jeżeli dotyczy / Identification number of the notified body, if applicable
	Influenza A/B+COVID-19/RSV Combo Ag Test		Szybki test antygenowy combo w kierunku grypy A+B+COVID-19/RSV dla profesjonalistów	

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