**COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab)**

*For in vitro diagnostic use only. For self-testing.*

**Carefully read the instructions before performing the test.**

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| **PREPARATION** |

Keep a clock, timer or stopwatch at hand. (*material requested but not provided*)

1.Allow all kit components to reach room temperature (15-30°C) prior to testing.

2.Open the kit and look for the following:

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| **Material Provided** | **Test cassette** | **Extraction tube with buffer and tip** | **Sterile swab** | **Workstation** | **Package insert** | **Waste Bag** |
| **GCFC-T502a-H1** | 1 | 1 | 1 | / | 1 | 1 |
| **GCFC-T502a-H2** | 2 | 2 | 2 | / | 1 | 2 |
| **GCFC-T502a-H4** | 4 | 4 | 4 | / | 1 | 4 |
| **GCFC-T502a-H5** | 5 | 5 | 5 | / | 1 | 5 |
| **GCFC-T502a-H7** | 7 | 7 | 7 | 1 | 1 | 7 |

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| **Material Provided** | **Test cassette** | **Extraction tube with buffer** | **tip** | **Sterile swab** | **Workstation** | **Package insert** | **Waste Bag** |
| **GCFC-T502a-H20** | 20 | 20 | 20 | 20 | 2 | 1 | 20 |

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| **BEFORE TESTING** |
| 1. Read instructions carefully before use.
2. Look at the expiration date of the kit box. Do not use it if the expiration date has passed.
3. Do not use the test if there is visible damage of the foil packaging.
4. Wash or sanitize your hands before performing the test.
5. Allow the test device, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.
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| **SPECIMEN COLLECTION** |

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|  | **Step 1**Open the swab package where indicated.Pull the swab out by grasping the plastic end.Do not touch the absorbent swab tip. |
|  | **Step 2**Insert the swab into one nostril.The swab tip should be inserted up to 2-4 cm until resistance is met. |  | **Step 3**Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. |
|  | **Step 4**Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities. |  | **Step 5**Withdraw the swab from the nasal cavity. |

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| **TEST PROCEDURE** |

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|  | **Step 6**Insert the extraction tube into the hole on the kit box as marked. Make sure that the tube is standing upright and reaches the bottom of the box. (***1 Test / 2 Tests / 4 Tests / 5 Tests***) |  | Insert the extraction tube into the workstation provided in the kit. Make sure that the tube is standing upright and reaches the bottom of the workstation. (***7 Tests / 20 Tests***) |
|  | **Step 7**Tear off the sealing film on the extraction tube gently to avoid spilling out the liquid. |  | **Step 8**Insert the swab into the extraction tube which contains the extraction buffer (approximately 0.3 mL). |
|  | **Step 9**Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube. |  | **Step 10**Leave the swab in the extraction tube for 1 minute. |
|  | **Step 11**Squeeze the tube several times from the outside to immerse the swab. Remove the swab. |  | **Step 12**Insert the tip into the extraction tube. |
|  | **Step 13**Remove the test device from the pouch and lay it on a flat clean surface. Add 4 drops of the solution into the sample well of the test device by gently squeezing the tube. |  | **Step 14**Start timer and wait 15 minutes. Do not read the test result after 20 minutes. |

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| **RESULT INTERPRETATION** |

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| **POSITIVE** |
| 图片1 | 图片1 | 图片1 | 图片1 |
| **1. COVID-19 Positive:**The presence of two lines as control line (C) and CoV test line within the result window indicates a positive result for SARS-CoV-2 antigen． | **2. Flu A Positive:**The presence of two lines as control line (C) and A test line within the result window indicates a positive result for Influenza A viral antigen. | **3. Flu B Positive:**The presence of two lines as control line (C) and B test line within the result window indicates a positive result for Influenza B viral antigen. | **4. Flu A+B Positive:**The presence of three lines as control line (C), A test line and B test line within the result window indicates a positive. |
| 图片1 | 图片1 | 图片1 |
| **5. COVID-19+Flu A Positive:**The presence of three lines as control line (C), CoV test line and A test line within the result window indicates a positive result for SARS-CoV-2 and Influenza A viral antigen. | **6. COVID-19+Flu B Positive:**The presence of three lines as control line (C), CoV test line and B test line within the result window indicates a positive result for SARS-CoV-2 and Influenza B viral antigen. | **7. COVID-19+Flu A+Flu B Positive：**The presence of Four lines as control line (C), CoV test line，A test and B test line within the result window indicates a positive result for SARS-CoV-2, Influenza A and Influenza B viral antigen. |

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| **NEGATIVE** | **INVALID** |
|  | The presence of ***only*** **control line**(C) within the result window indicates a negative result. |  | If the **control line** (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. |

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| **SAFELY DISPOSE OF YOUR TEST KIT** |
| Once your test is complete, put all of the used test kit contents in the waste bag provided. Put in your general household waste. |

**INTENDED Purpose**

The COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) is an in vitro immunochromatographic assay for the qualitative and differential detection of nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals who are both symptomatic within the first seven days and asymptomatic, influenza A and influenza B in nasal swab specimens directly from individuals who are symptomatic within the first seven days. It is intended to aid in the rapid diagnosis of SARS-CoV-2, influenza A and/or influenza B infections. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) must be confirmed with alternative testing method(s) and clinical findings.

It is intended for Self-testing use and not for near patient use.

**SUMMARY AND EXPLANATION**

Influenza is an acute and highly contagious viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single-strand RNA virus known as influenza viruses. There are three types of influenza viruses: A, B and C. Type A viruses are the most prevalent and are associated with most serious epidemics, and Type B infection can also cause seasonal epidemics that typically only affect humans. Type C virus have never been associated with a large epidemic of human disease. Both type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season and particular epidemic area. The disease is easily transmitted through coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks normally occur each year during fall and winter seasons.

The novel coronaviruses belong to the beta coronaviruses genus. COVID-19 is an acute respiratory infectious disease. Entire human population is susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The symptoms of COVID-19 are similar to those of other viral respiratory disease and include fever or chills, cough, shortness of breath or difficulty of breathing, fatigue, muscle or body aches, headache, the new loss of taste or smell, sore throat, congested or runny nose, nausea or vomiting or diarrhea, etc. As the early symptoms of COVID-19 are similar to those of seasonal Influenza A or B, a rapid detection test to specifically diagnose symptomatic patients is needed.

**PRINCIPLE OF THE TEST**

The COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) is an immunochromatographic membrane assay that uses monoclonal antibodies for the simultaneous qualitative and differential detection of detect SARS-CoV-2, influenza type A and/or influenza type B nucleoprotein antigens in nasal swab samples. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with detector antibodies (monoclonal antibodies against SARS-CoV-2, influenza A and B respectively); the reaction membrane contains the secondary antibodies against SARS-CoV-2, influenza A and B respectively. The whole strip is fixed inside a plastic device.

 When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-CoV-2 conjugate and the virus will be captured by the specific anti-SARS-CoV-2 monoclonal antibodies coated on the CoV region (CoV). If influenza A presents in the sample, a complex formed between the anti-influenza A conjugate and the virus will be captured by the specific anti-influenza A monoclonal antibodies coated on the A region (A). If the sample contains influenza B, a complex formed between the anti-influenza B conjugate and the virus will be captured by the specific anti-influenza B monoclonal antibodies coated on the B region (B).

To serve as a procedural control, a red line will always appear in the control region(C) indicating that proper volume of sample has been added and membrane wicking has occurred.

**WARNINGS AND PRECAUTIONS**

1. The test cassette should remain in the sealed pouch until use.
2. Do not use kit past its expiration date.
3. Swabs, tubes and test cassettes are for single use only.
4. Do not interchange or mix components from different kit lots.
5. Testing should only be performed using the swabs provided within the kit.
6. Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens.
7. Specimens must be processed as indicated in the SPECIMEN COLLECTION and SAMPLE PREPARATION PROCEDURE sections of this Product Insert. Failure to follow the instructions for use can result in inaccurate results.
8. To obtain accurate results, do not use visually bloody or overly viscous samples.
9. Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient swabs used Test Strips and used extraction buffer vials may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local regulatory requirements.
10. Humidity and temperature can adversely affect results.
11. Used testing materials should be discarded in accordance with local regulations.
12. Notice that any serious incident shall be reported to manufacturer and competent authority of the Member State in which user and/or patient is established.
13. Do not bite the seal film of the extraction tube. Avoid the extraction buffer contacting your skin. The extraction buffer contains preservatives which may cause an allergic reaction in some people. lf the solution contacts the skin or eye, wash with lots of water. lf skin irritation occurs get medical attention.
14. Keep away from children to reduce the risk of accidental drinking of buffer liquid or swallowing of small parts.
15. Children under 18 years of age Self-test and report with adult supervision. The adult may conduct the test if necessary. Children under 12 years of age should be tested by an adult. Do not conduct the test if you do not feel confident testing a child. Do not continue the test if the children feel pain.

**STORAGE AND STABILITY**

1. The kit can be stored at room temperature or refrigerated (2-30°C).
2. Do not freeze any of the test kit components.
3. Do not use test device and reagents after expiration date.
4. Test cassettes that have been outside of the sealed pouch for more than 1 hour should be discarded.

**SPECIMEN TRANSPORT AND STORAGE**

1. Do not return the nasal (nares) swab to the original paper packaging.
2. Specimen should be tested immediately after collection. If immediate testing of specimen is not possible, insert the swab into an unused general-purpose plastic tube. Ensure the swab fits within the plastic tube and secure a tight seal. The specimen should be disposed and recollected for retesting if it has not been tested for more than 1 hour at 15-30˚C or for more than 2 hours at 2-8˚C.
3. It is recommended that the extract of swab samples be tested as soon as possible after specimen collection and preparation. If the sample cannot be tested immediately, the extracted swab sample solution is stored at room temperature (15-30°C) for no more than 0.5 hour.

**QUALITY CONTROL**

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

**LIMITATIONS**

1. The COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) is for in vitro diagnostic use and should only be used for the qualitative detection of influenza A, B and/or SARS-CoV-2 in nasal swab specimens.
2. The etiology of respiratory infection caused by microorganisms other than influenza A, B or SARS-CoV-2 will not be established with this test.
3. The COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) is capable of detecting both viable and non-viable influenza and SARS-CoV-2 particles. The performance of the COVID-19/Flu A&B Ag Rapid Test Cassette (Swab) depends on the amount of virus (antigen) in the specimen and may not correlate with cell culture performed on the same specimen.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at anytime rule out the presence of influenza A, B or SARS-CoV-2 viral antigens in specimen, as they may be present below the minimum detection level of the test. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Inadequate or inappropriate specimen collection, storage, and transport may yield false negative test result.
6. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
7. Although this test has been shown to detect cultured avian influenza viruses, including avian influenza A subtype H5N1 virus, the performance characteristics of this test with specimens from humans infected with H5N1 or other avian influenza viruses are unknown.
8. Positive and negative predictive values are highly dependent on prevalence. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low. Positive test results do not rule out co-infections with other pathogens, such as parainfluenza virus.
9. For COVID-19, the amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 7 of illness are more likely to be negative compared to a RT-PCR assay.
10. For COVID-19, positive test results do not differentiate between SARS-CoV and SARS-CoV-2. Negative results should be treated as presumptive and confirmed with an authorized molecular assay, if necessary, for clinical management, including infection control.

**PERFORMANCE CHARACTERISTICS**

**1. Clinical Study**

**COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) Results for Nasal Swab COVID-19**

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| --- | --- | --- | --- | --- |
| **SARS-CoV-2** | **RT-PCR** | **Overall Sensitivity (95% CI)** | **Overall Specificity (95% CI)** | **Overall Accuracy****(95% CI)** |
| **Positive** | **Negative** | **Total** |
| COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) | Positive | 126 | 4 | 130 | 89.36%(83.06%- 93.92%) | 99.57%(98.90%- 99.88%) | 98.22%(97.23%- 98.92%) |
| Negative | 15 | 922 | 937 |
| Total | 141 | 926 | 1067 |

Positive agreement of the COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) is higher with specimens of Ct values ≤30 with a sensitivity of 99.05% (95% CI:94.81% to 99.98%) and lower with specimens of Ct values >30 with a sensitivity of 61.1% (95% CI: 43.46% to 76.86%) for SARS-CoV-2. As suggested in references 1-3, patients with Ct values >30 are no longer contagious. 1, 2, 3

**COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) Results for Nasal Swab Influenza A**

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| **Influenza A** | **RT-PCR** | **Overall Sensitivity (95% CI)** | **Overall Specificity (95% CI)** | **Overall Accuracy****(95% CI)** |
| **Positive** | **Negative** | **Total** |
| COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) | Positive | 126 | 5 | 131 | 88.73%(82.35- 93.42%) | 99.04%(97.77- 99.69%) | 96.83%(95.19- 98.03%) |
| Negative | 16 | 515 | 531 |
| Total | 142 | 520 | 662 |

**COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) Results for Nasal Swab Influenza B**

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| **Influenza B** | **RT-PCR** | **Overall Sensitivity (95% CI)** | **Overall Specificity (95% CI)** | **Overall Accuracy****(95% CI)** |
| **Positive** | **Negative** | **Total** |
| COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) | Positive | 124 | 7 | 131 | 87.32%(80.71- 92.31%) | 98.65%(97.25- 99.46%) | 96.22%(94.48- 97.54%) |
| Negative | 18 | 513 | 531 |
| Total | 142 | 520 | 662 |

1 CDC. Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (Interim Guidance). (2020).

2 CDC. Duration of Isolation of Precautions for Adults with COVID-19. (2020).

3 Bullard, et al. Predicting Infectious Severe Acute Respiratory Syndrome Coronavirus 2 From Diagnostic Samples. Clin Infect Dis. 2020 Dec 17;71(10):2663-2666. doi: 10.1093/cid/ciaa638.

**2. Usability**

1) In the contrived test, reading results of laypersons in comparison with professionals showed a coincidence rate ranged from 97% to 100%. It demonstrated that vast majority and even inexperienced users can interpret the test correctly.

2) In comparison with RT-PCT test, for self-testing and professional-testing COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab), it demonstrated sensitivity of 93.55% and specificity of greater than 99.99%, with accuracy of 98.95% for detection of COVID-19. It demonstrated sensitivity of 90.00% and specificity of greater than 99.99%, with accuracy of 98.43% for detection of Influenza A. It demonstrated sensitivity of 90.00% and specificity of greater than 99.99%, with accuracy of 98.43% for detection of Influenza B.

**3. Analytical Sensitivity (Limit of Detection)**

1) The Limit of Detection (LoD) was established using limiting dilutions of the inactivated Influenza A, Influenza B and SARS CoV-2 viruses in negative nasal matrix. 60 replicates were prepared and tested to confirm the LoD by demonstrating ≥95% positivity.

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| **Virus Strains** | **LoD** | **No. Positive/Total** | **Positive Agreement** |
| SARS CoV-2 | 1.15 x 102 TCID50 /mL | 60/60 | 100% |
| Influenza A (H1N1) | 3.0 x 105 TCID50 /mL | 60/60 | 100% |
| Influenza B (Yamagate lineage) | 3.0 x 106 TCID50 /mL | 60/60 | 100% |

2) Detection limits (LoD) were established by 1st WHO International Standard for SARS-CoV-2 antigen. 60 replicates were prepared and tested to confirm the LoD by demonstrating ≥95% positivity.

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| **Virus Strains** | **LoD** | **No. Positive/Total** | **Positive Agreement** |
| 1st WHO International Standard for SARS-CoV-2 antigen | 50IU /mL | 60/60 | 100% |

**4. Analytical Reactivity / Inclusivity**

The SARS-Cov-2, influenza A and B strain listed tested positive in the COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab). Although the specific SARS-Cov-2 and influenza strains causing infection in human can vary, all contain the conserved nucleoproteins targeted by COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab).

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| **Strains** | **Sources** | **Subtypes** | **Concentration** |
| Influenza A/Hubei/PR 8/2001 | Human | H1N1 | 3.6×105 TCID50/mL |
| Influenza A/New Kaledonia/20/99 | Human | H1N1 | 3.6×105 TCID50/mL |
| Influenza A/Yamagata/32/89 | Human | H1N1 | 3.6×105 TCID50/mL |
| Influenza A/Beijing/262/95 | Human | H1N1 | 3.6×105 TCID50/mL |
| Influenza A/Singapore/1/57 | Human | H2N2 | 6.0×105 TCID50/mL |
| Influenza A/Hubei/3/2005 | Human | H3N2 | 6.0×105 TCID50/mL |
| Influenza A/Akita/1/94 | Human | H3N2 | 6.0×105 TCID50/mL |
| Influenza A/Kita Kyusyu/159/93 | Human | H3N2 | 6.0×105 TCID50/mL |
| Influenza A/Iowa/15/30 | Swine | H1N1 | 6.0×105 TCID50/mL |
| Influenza A/Hongkong/168/93 | Swine | H1N1 | 6.0×105 TCID50/mL |
| Influenza A/Anhui/24/2004 | Swine | H5N1 | 1.2×106 TCID50/mL |
| Influenza A/Hubei/134/2000 | Swine | H9N2 | 1.2×107 TCID50/mL |
| Influenza A/Hubei/251/2001 | Swine | H9N2 | 1.2×107 TCID50/mL |
| Influenza A/Yuyao/1/2006 | Chicken | H5N1 | 1.2×106 TCID50/ml |
| Influenza A/Yuyao/2/2006 | Chicken | H5N1 | 1.2×106 TCID50/mL |
| Influenza A/Jiangsu/2/2004 | Chicken | H5N1 | 1.2×106 TCID50/mL |
| Influenza A/Hubei/216/83 | Duck | H7N8 | 6.0×106 TCID50/mL |
| Influenza A/Hubei/118/2003 | Duck | H9N2 | 3.0×106 TC ID50/mL |
| Influenza A/Hubei/155/2003 | Duck | H9N2 | 1.2×107 TCID50/mL |
| Influenza A/Hubei/137/1982 | Duck | H10N4 | 6.0×106 TCID50/mL |
| Influenza A/Singapore/3/97 | Duck | H5N3 | 1.2×106 TCID50/mL |
| Influenza A/Henan/1/2004 | Tree sparrow | H5N1 | 1.3×107 TCID50/mL |
| Influenza A/Henan/2/2004 | Tree sparrow | H5N1 | 6.0×106 TCID50/mL |
| Influenza A/Henan/4/2004 | Tree sparrow | H5N1 | 1.2×106 TCID50/mL |
| Influenza A/Wisconsin/66 | Turkey | H9N2 | 1.2×106 TCID50/mL |
| Influenza A/England/1/63 | Turkey | H7N3 | 1.2×106 TCID50/mL |
| Influenza A/Singapore/1/57 | Bird | H5N1 | 1.2×106 TCID50/mL |
| Influenza A/Hunan/71/2004 | Bird | H5N1 | 1.2×106 TCID50/mL |
| Influenza A/Shanxi/50/2006 | Bird | H5N1 | 1.2×106 TCID50/mL |
| Influenza A/Shanxi/42/2006 | Bird | H5N1 | 1.2×106 TCID50/mL |
| Influenza A/Fujian/320/2004 | Bird | H5N1 | 6.0×106 TCID50/mL |
| Influenza B | Human | Yamagata Lineage | 3.0×106 TCID50/mL |
| Influenza B | Human | Victoria lineage | 9.0×105 TCID50/mL |
| SARS-CoV-2 | Human | Alpha（B.1.1.7） | 2.0×105 TCID50/mL |
| SARS-CoV-2 | Human | Delta（B.1.617.2） | 4.0×104 TCID50/mL |
| SARS-CoV-2 | Human | Omicron（B.1.1.529） | 3.0×104 TCID50/mL |
| SARS-CoV-2 | Human | Omicron（[XBB.1.16](https://baike.baidu.com/item/XBB.1.16/62898272?structureClickId=62898272&structureId=78a8591e7011aaf8a9bb2328&structureItemId=2cbe27efdb566e36757d4d61&lemmaFrom=starMapContent_star&fromModule=starMap_content&lemmaIdFrom=55621597)) | 2.0×105 TCID50/mL |
| SARS-CoV-2 | Human | Omicron（[BA.2.12.1](https://baike.baidu.com/item/BA.2.12.1/60766124?structureClickId=60766124&structureId=78a8591e7011aaf8a9bb2328&structureItemId=82c735fa3ca1f3295af71918&lemmaFrom=starMapContent_star&fromModule=starMap_content&lemmaIdFrom=55621597)) | 3.6×104 TCID50/mL |
| SARS-CoV-2 | Human | Omicron（[BA.5.1.3](https://baike.baidu.com/item/BA.5.1.3/61812327?structureClickId=61812327&structureId=78a8591e7011aaf8a9bb2328&structureItemId=3b693b6b6a260e3bedde4617&lemmaFrom=starMapContent_star&fromModule=starMap_content&lemmaIdFrom=55621597)) | 1.0×105 TCID50/mL |

**5. Analytical Specificity (Cross-reactivity)**

The cross-reactivity of COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) was evaluated by testing a panel of respiratory pathogens that could potentially cross-react with the analyte detection reagents in the test device. Testing showed no evidence of cross-reactivity at the concentrations tested except for SARS-coronavirus.

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| **Pathogens** | **Concentration Tested** |
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| Adenovirus 1 | 3.09×105TCID50/mL |
| Adenovirus 2 | 2.8×105TCID50/mL |
| Adenovirus 3 | 5×105.5 TCID50/mL |
| Adenovirus 4 | 1×105 PFU/mL |
| Adenovirus 5 | 1×105 PFU/mL |
| Adenovirus 7 | 2.8×105 TCID50/mL |
| Adenovirus 55 | 1×105 PFU/mL |
| EV-A71 | 3.55×105TCID50/mL |
| EV-B69 | 1×105 PFU/mL |
| EV-C95 | 1×105 PFU/mL |
| EV-D70 | 1×105 PFU/mL |
| Human Metapneumovirus (hMPV) | 3.55×105TCID50/mL |
| Novel influenza A H1N1 virus (2009) | 1×106 PFU/mL |
| Respiratory syncytial virus Type A | 5.5×105 PFU/mL |
| Respiratory syncytial virus Type B | 2.8×105 TCID50/mL |
| Rhinovirus | 1.41×105TCID50/mL |
| Seasonal influenza A H1N1 virus | 1×105 PFU/mL |
| Influenza A H3N2 virus | 3.55×105TCID50/mL |
| Influenza A H5N1 virus | 1×106 PFU/mL |
| Influenza B Yamagata | 1.8×105 CEID50/mL |
| Influenza B Victoria | 1.7×105 CEID50/mL |
| Mumps virus | 1×105 PFU/mL |
| Varicella zoster virus | 1×106 PFU/mL |
| Bordetella pertussis | 7.5×106 CFU/mL |
| Candida albicans | 9.5×106 CFU/mL |
| Chlamydia pneumoniae | 7.5 x 106 IFU/mL |
| Haemophilus influenzae | 5.2×106 CFU/mL |
| Human coronavirus 229E | 1.41×105TCID50/mL |
| Human coronavirus OC43 | 1.05×105TCID50/mL |
| Human coronavirus NL63 | 1.17×105TCID50/mL |
| Human coronavirus HKU1 | 1×106 PFU/mL |
| MERS-coronavirus | 1.05×105TCID50/mL |
| Legionella pneumophila | 1.91×106 CFU/mL |
| Mycobacterium tuberculosis | 2.3×106CFU/mL |
| Mycoplasma pneumoniae | 2.7×106 CCU/mL |
| Parainfluenza virus 1 | 1.6×105TCID50/mL |
| Parainfluenza virus 2 | 1.6×105TCID50/mL |
| Parainfluenza virus 3 | 1.6×105TCID50/mL |
| Parainfluenza virus 4 | 1.15×105TCID50/mL |
| Streptococcus pyogenes | 3.6×106 CFU/mL |
| Streptococcus agalactiae  | 7.9×107 CFU/mL |
| Streptococcus pneumoniae | 4.2×106 CFU/mL |
| Staphylococcus aureus | 3.2×108 CFU/mL |
| Staphylococcus epidermidis | 2.1×108 CFU/mL |
| Pooled human nasal wash | N/A |
| SARS-coronavirus | 1.58 × 104 TCID50/mL |
| Measles virus | 8.9×105 TCID50/mL |

**6. High Dose Hook Effect**

No high dose hook effect was observed with up to 4.6×105 TCID50/mL of inactivated SARS-CoV-2, up to 3×108 TCID50/mL of Influenza A virus, or up to 3×108 TCID50/mL of Influenza B virus with the COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab).

**7. Precision**

**Repeatability**

The repeatability of the COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) was evaluated with three lots of the device by three operators in one day. Each operator tests each specimen in 20 replicates using a lot of the device. The testing was performed following the package insert. The results are indicated that the repeatability of the products is fine.

**Reproducibility**

Three lots of COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) were performed at two runs per day in 5 different days at three different sites by six operators. A total of 30 determinations by each operator at each specimen. The testing was performed following the package insert. The results are indicated that the reproducibility of the products is fine.

**8. Interfering Substances studies**

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab). No interference was seen with the listed substances when tested at the concentration presented in the table below.

|  |  |
| --- | --- |
| **Substances (Active Ingredient)** | **Concentration Tested** |
| Human blood (EDTA anticoagulated) | 20% (v/v) |
| Mucin | 5 mg/mL |
| Oseltamivir phosphate | 5 mg/mL |
| Ribavirin | 5 mg/mL |
| Levofloxacin | 5 mg/mL |
| Azithromycin | 5 mg/mL |
| Meropenem | 5 mg/mL |
| Tobramycin | 2 mg/mL |
| 4-Acetamidophenol | 10 mg/mL |
| Acetylsalicylic Acid | 20 mg/mL |
| Chlorpheniramine | 5 mg/mL |
| Dextromethorphan | 10 mg/mL |
| Diphenhydramine | 5 mg/mL |
| Ephedrine | 20 mg/mL |
| Guaiacol glyceryl ether | 20 mg/mL |
| Phenylpropanolamine | 20 mg/mL |
| Phenylephrine | 0.5 mg/mL |
| Oxymetazoline | 0.1 mg/mL |
| 0.9% sodium chloride | 20% (v/v) |
| A natural soothing ALKALOL | 20% (v/v) |
| Beclomethasone | 0.2 mg/mL |
| Hexadecadrol | 1mg/ml |
| Flunisolide | 0.15mg/ml |
| Triamcinolone  | 0.22 mg/mL |
| Budesonide | 0.256 mg/mL |
| Mometasone | 0.2 mg/mL |
| Fluticasone | 0.1 μg/mL |
| Fluticasone propionate | 0.2 mg/mL |
| Recombinant human interferon α 2a  | 10 U/mL |
| Zanamivir  | 0.5 mg/mL |
| Lopinavir  | 1 μg/mL |

**QUESTIONS AND ANSWERS**

**What Is COVID-19?**

COVID-19 is a disease caused by the SARS-CoV-2 virus.

**What Is Influenza?**

Influenza (flu) is a disease caused by influenza viruses. There are two main types of influenza viruses: types A

and B. Both type A and B influenza viruses regularly spread in people and are responsible for seasonal flu each year.

**What Is The COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab)?**

The COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) is a type of test called an antigen test. This antigen test is designed to detect proteins from three types of viruses: two viruses that cause influenza (type A and type B) and the virus that causes COVID-19 in human anterior nasal swab specimens.

**Why Was My Specimen Tested?**

Testing of your specimen(s) will help find out if you may have COVID-19 and/or influenza.

**What Are the Known and Potential Risk and Benefits of The Test?**

Potential risks include:

1. Possible discomfort or other complications that can happen during specimen collection.

2. Possible incorrect test result (see below for more information).

Potential benefits include:

1. The results, along with other information, can help your healthcare provider make informed

recommendations about your care.

2. The results of this test may help limit the spread of COVID-19 and/or influenza to your family

and those you come in contact with.

**What Does A Positive Test Result For COVID-19 Mean?**

If you have a positive test result for COVID-19 with the COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab), it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. You should follow your local healthcare guidance to reduce the potential transmission of disease. There is a chance that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19. Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms. Your healthcare provider may recommend a confirmatory test, depending on your clinical history and risk factors.

**What Does A Positive Test Result for Influenza A And/or B Viruses Mean?**

If you have a positive test result for the presence of influenza A and/or influenza B viruses, it is very likely that you have the flu. If you have a positive result for an influenza virus, your healthcare provider will determine the best way to care for you based on the test results along with other factors in your medical history. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results, medical history, and your symptoms.

**What Are the Differences Between Antigen Tests and Other Covid-19 Tests?**

There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional

molecular test would help with your care, and when you should discontinue home isolation.

**WHAT SHOULD I DO AFTER TESTING?**

You should not take any decision of medical relevance without consulting the appropriate healthcare professional, information on disease effects and prevalence.

Emergency medical help line in major Europe countries is:

Germany: 112

France: 15

Spain: 061

UK: 111 or 999

Italy: 118

Emergency medical help lines for other countries or regions can be obtained by contacting your local public health department.

**Where can I find the Safety and Performance Summary?**

You can find it at https://ec.europa.eu/tools/eudamed.

You can request the SSP by emailing sales@orientgene.com.

**INDEX OF SYMBOLS**



 

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