COVID-19 / Influenza A+B Antigen Duo

Rapid Antigen Detection Test for SARS-CoV-2 Virus and Influenza A & B Virus in human Anterior Nasal or Nasopharyngeal Secretions

CE REF 1171-25

For Professional In Vitro Diagnostic use only ***Read Instructions before use***

INTENDED USE

TestNOW® - COVID-19 / Influenza A+B Antigen Duo Test is a rapid in vitro immunochromatographic assay for the qualitative detection of both SARS-CoV-2 virus antigen and Influenza A&B antigen present in human anterior nares or nasopharynx. The test is intended for professional and laboratory use as an aid in the rapid and early diagnosis of SARS-CoV-2 virus and/or Influenza A & B infections with Visual Result reading. ***According to CDC's guidance, COVID-19 antigen test has the best sensitivity from day 1 to day 5 after the onset of symptoms. Antigen levels in specimens collected beyond 5-7 days of the onset of symptoms may drop below the limit of detection of the test.***

TestNOW® - COVID-19 / Influenza A+B Antigen Duo Test also detects the following SARS-CoV-2 Variants strains:

1. Alpha Variant (UK/England) (B.1.1.7)
2. South Africa (B.1.351)
3. USA-CA (B.1.1.7)
4. Delta Variant (B.1.617.2)
5. Omicron Variant (B.1.1.529)

TestNOW® - COVID-19 / Influenza A+B Antigen Duo Test detects Nucleocapsid Protein (N-Protein) Antigen, the major conserved structural protein that binds to the SARS-CoV-2 RNA genome. It doesn't detect SARS-CoV-2 surface protein ("Spike"). N-Protein is much more stable than the Spike Protein. Therefore, any mutation in Spike protein of genetic SARS-CoV-2, such as Brazil Variant P.1, Delta Variant B.1.617.2 and Omicron Variant (B.1.1.529) can be detected by **TestNOW® - COVID-19 / Influenza A+B Antigen Duo** Test, as mutations have no interference with the Sensitivity.

SUMMARY

SARS-CoV-2 is single-stranded RNA virus with envelope, the virion is approximately 50–200 nanometers in diameter. It has four structural proteins, known as the spike (S), envelope (E), membrane (M), and nucleocapsid (N) proteins; the N protein holds the RNA genome, and the S, E, and M proteins together create the viral envelope. The incubation period for COVID-19 typically ranges from 2 to 14 days. Those infected with the virus may be asymptomatic or develop common respiratory symptoms, including fever, cough, and fatigue (other symptoms may include muscle pain, diarrhea, sore throat, loss of taste and smell, and abdominal pain). Severe patients may progress to acute respiratory distress syndrome (ARDS), septic shock, diffuse alveolar damage (DAD) and even death.

Influenza (FLU) 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 four types of influenza viruses: A, B, C, and D. Type A viruses are the most prevalent and are associated with most serious epidemics, while Type B infection is generally milder. Type C and D viruses 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.

TestNOW® - COVID-19 / Influenza A+B Antigen Duo Test provides a quick and easy to use test to help in the diagnosis of SARS-CoV-2 and/or Influenza infection to humans.

PRINCIPLE

TestNOW® - COVID-19 / Influenza A+B Antigen Duo Test is a rapid immunochromatographic assay that utilizes specific monoclonal antibodies to detect Nucleocapsid protein of SARS-CoV-2 virus or Nucleoprotein of Influenza A or B virus in anterior nasal swab specimens or nasopharyngeal swab specimens. Anti-virus antibodies are coated on nitrocellulose membrane as the capture zone and conjugated to colloidal gold as the detection probe. When sample extracts from the anterior nasal swab or the nasopharyngeal swab are applied to the test device's sample port, if the extracted specimen contains viral antigens, the antigens will form the antigen-antibody complex with the detection probe. The complex will continue to move on the membrane and can be captured by antibody coated on the capture zone to form a colored band indicating a positive result. Absence of the color band on the test zone indicates a negative result. A built-in control band will always appear when the test is performed properly regardless of the presence or absence of virus antigen in the specimen.

MATERIALS PROVIDED

1. Test Device (25 Devices): Each individually packed test card houses a Covid-19 Antigen strip incorporated with a pair of anti-SARS-CoV-2 specific mouse monoclonal antibodies, and an Influenza A&B antigen strip incorporated with two pairs of monoclonal antibodies specific to Influenza A and Influenza B virus respectively.
2. Extraction Buffer Tube (26 pieces): Buffer solution contains salt and detergent.
3. Nozzle (26 pieces).
4. Sterile Anterior Nasal / Nasopharyngeal Swab (26 pieces).
5. Instructions for Use (1 copy).

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Specimen collection container
2. Timer or Clock
3. Tube Stand
4. Personal Protection Equipment

STORAGE

1. Store the test device at 4°- 30°C in the original pouch. Do Not Freeze.

2. Kit contents are stable until the expiration date printed on the outer box based on the proper storage conditions.
3. The test device must be kept in the sealed pouch until use.

PRECAUTIONS

Read the package insert carefully prior to testing the kit and follow the instructions to obtain accurate results.

1. For in vitro diagnostic use.
2. Instructions for Use must be read and followed carefully for accurate results.
3. Do not use the kit contents beyond the expiration date printed on the outside of the box.
4. Do not interchange or mix different lots of components of **TestNOW® - COVID-19 / Influenza A+B Antigen Duo** Test.
5. Do not insert the test device directly into the sampling area (mouth, nasal).
6. Disregard test results beyond specified time (20 minutes).
7. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
8. Use of protective tools are recommended when handling patient samples.
9. Dispose of containers and used contents in accordance with Federal, State and Local requirements.
10. Do not reuse kit components.
11. The test device must remain sealed in the protective foil pouch until use.
12. Inadequate or inappropriate specimen collection, storage, and transport may yield inaccurate test results.
13. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
14. If infection with a novel SARS-CoV-2 virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent SARS-CoV-2 viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

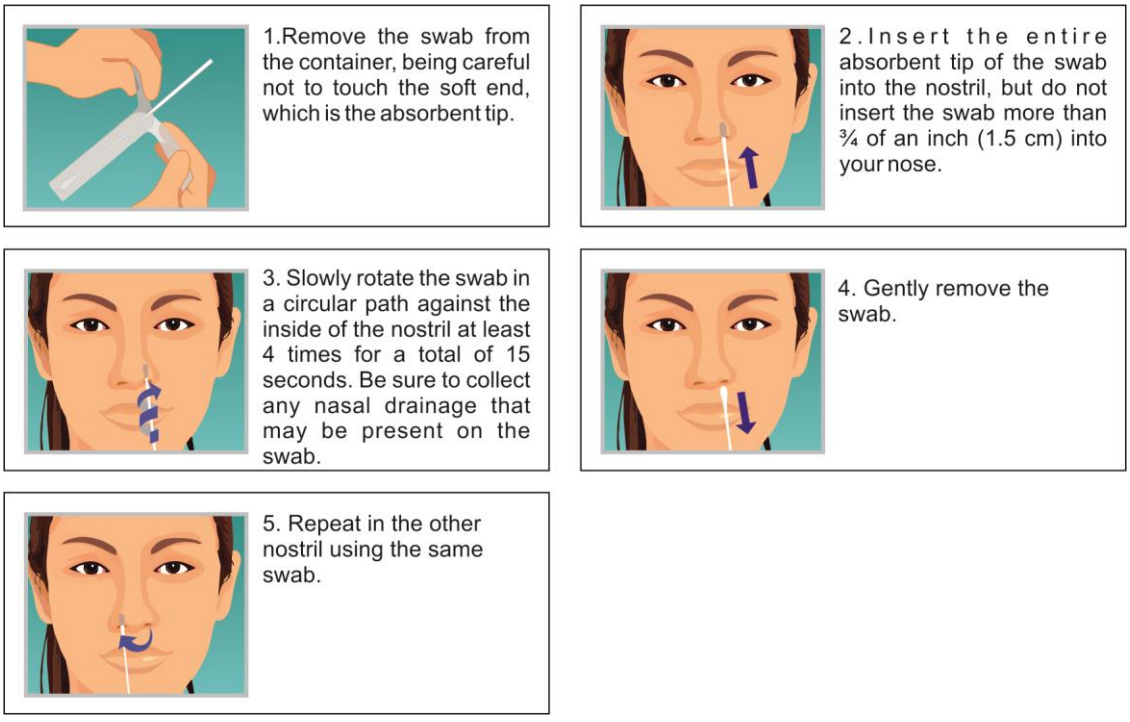
LIMITATIONS

1. The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 and/or Influenza A&B viral antigen from the anterior nasal or nasopharyngeal swab.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. ***According to CDC's guidance, COVID-19 antigen test has the best sensitivity from day 1 to day 5 after the onset of symptoms. Antigen levels in specimens collected beyond 5-7 days of the onset of symptoms may drop below the limit of detection of the test.***
4. Failure to follow the Test Procedure and interpretations of Test Results may adversely affect test performance and/or invalidate the Test Results.
5. Test Results must be evaluated in conjunction with other clinical data available to the physician.
6. Negative test results do not rule out other potential non-SARS-CoV-2 viral infections. Negative results should be confirmed by molecular diagnosis if COVID-19 or Influenza disease is suspected.
7. Positive test results do not rule out co-infections with other pathogens.
8. Monoclonal antibodies may fail to detect, or detect with less sensitivity, on the viruses that have undergone minor amino acid changes in the target epitope region.

SPECIMEN COLLECTION

Proper specimen collection, storage, and transport are critical to the performance of this test. Specimens should be tested as soon as possible after collection. The training in specimen collection is highly recommended because of the importance of specimen quality. For optimal test performance, use the swabs supplied in the kit. It is important to obtain as much secretion as possible. Secretion specimens can be collected by either of the following two swabbing options:

1. ANTERIOR NASAL SWABBING



2. NASOPHARYNGEAL SWABBING

Remove the swab from the container, being careful not to touch the soft end, which is the absorbent tip.

Carefully insert the sterile swab into the nostril that presents the most secretions under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times then remove it from the nasopharynx.

PROCEDURE

All specimens and assay procedures must be handled at room temperature.

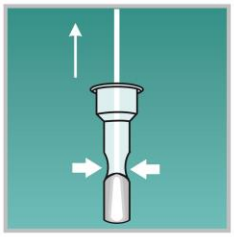
- Check the expiration date on each component's package or outer box before use. Do not use any test material beyond the labelled expiration date.
- Bring the kit components to room temperature before testing.
- Open the pouch and remove the test device. Once opened, the test device must be used immediately.
- Label the test device with sample identification (ID).

PROCEDURE

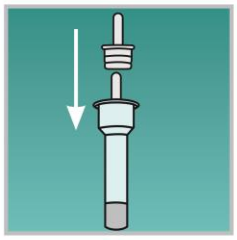
1. Peel off aluminum foil seal from the top of the Extraction Tube containing extraction buffer.

2. Insert the swab with sample into the extraction buffer tube. Stir the swab and squeeze the tube alternatively for five (5) times.

3. Leave the swab in the extraction buffer for 1 minute.



4. Remove the swab while squeezing the sides of tube to extract the liquid from the swab. Dispose of the used swab in accordance with your biohazard waste disposal protocol.



5. Insert the noozle cap and press tightly onto the tube.

6. Invert the extraction tube and gently squeeze (3) drops of extracted sample into each of the Test Device's sample ports (S).

CAUTION: Please slowly add one drop at a time, ensuring the previous drop is completely absorbed before adding the next.

Read result at 15 minutes.
Some positive results may appear earlier.

CAUTION:

Do not read result after 20 minutes.
It may give false results.

INTERPRETATION OF RESULTS

Positive result

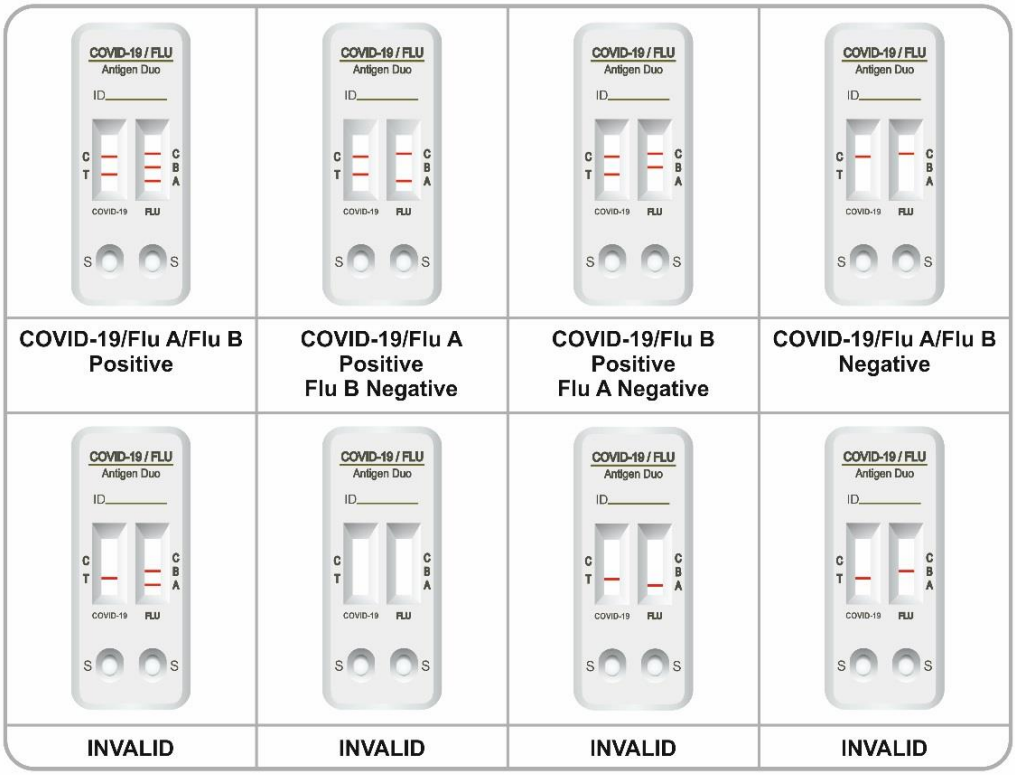
At 15 minutes, in addition to the distinct red-purple color line on the C Line region, the appearance of any shade of a red color band on the T, A or B, line region indicates a positive result for the presence of viral antigen as illustrated in the picture. A positive result does not rule out co-infections with other pathogens.

Negative result

At 15 minutes, the appearance of ONLY the red- purple control band on C Line region indicates viral antigen was not detected. A negative result indicates that the viral antigen or the antigen level is below the detection limit.
A negative result does not exclude viral infection and should be confirmed by molecular diagnostic method if the disease is suspected.

Invalid result

If at 15 minutes, the red-purple control band does not appear on the C Line region, regardless of if a test band appears, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new test device.



QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good laboratory practice recommends the daily use of control materials to validate the reliability of the device. Control materials, which are not provided with this test kit, may be commercially available.

PERFORMANCE CHARACTERISTICS:

COVID-19 Antigen

Clinical Evaluation

The clinical evaluation was conducted in different countries. The anterior nasal and nasopharyngeal swab samples were confirmed by RT-PCR. Total one hundred and fifty-three (153) positive samples including fifty-three (53) anterior nasal samples and one hundred (100) nasopharyngeal samples; and Total three hundred and forty-five (345) negative samples including eighty-five (85) anterior nasal samples and two hundred and sixty (260) nasopharyngeal samples were tested. The results are summarized below.

Anterior Nasal Swab Samples:

TestNOW® - COVID-19 Antigen Test Results	**RT-PCR Results**		Total
	Positive (+)	Negative (-)	
Anterior Nasal Positive (+)	52	1	53
Anterior Nasal Negative (-)	0	85	85
Total	52	86	138

Clinical Sensitivity = 52 / 53 × 100% = 98.1% (CI 95%: 89.93% to 99.95%)
Positive Predictive Value (PPV) = 52 / 52 = 100% (No CI data available from MedCalc statistical software)
Clinical Specificity = 85 / 85 × 100% = 100% (CI 95%: 95.75% to 100.00%)
Negative Predictive Value (NPV) = 85 / (85 + 1) = 98.8% (CI 95%: 92.42% to 99.83%)

Nasopharyngeal Swab Samples:

TestNOW® - COVID-19 Antigen Test Results	**RT-PCR Results**		Total
	Positive (+)	Negative (-)	
Nasopharyngeal Positive (+)	95	5	100
Nasopharyngeal Negative (-)	2	258	260
Total	97	263	360

Clinical Sensitivity = 95 / 100 × 100% = 95.0% (CI 95%: 88.72% to 98.36%)
Positive Predictive Value (PPV) = 95 / (95 +2) = 97.9% (CI 95%: 92.27% to 99.47%)
Clinical Specificity = 258 / 260 × 100% = 99.2% (CI 95%: 97.25% to 99.91%)
Negative Predictive Value (NPV) = 258 / (258 + 5) = 98.1% (CI 95%: 95.64% to 99.18%)

Positive Sample agreement by PCR Cycle Threshold Value (Ct, Value):

Ct. Value	No. of Samples	Positive (+)	Negative (-)	Agreement
≤ 30	108	107	1	99.1%
≥ 30	45	40	5	88.9%

Analytical Sensitivity

The Limit of Detection (LoD) for the **TestNOW® - COVID-19 Antigen** Test was established in an analytical sensitivity study performed with three Recombinant Nucleocapsid (N) Proteins. The LoD was confirmed by testing a total of 20 replicates at the target concentration to demonstrate detection at least 95% of the time. A total of 20 replicates at the target concentration of each analyte listed in the table showed 100% positive results.

No.	SARS-CoV-2 Nucleocapsid (N) Proteins	Limit of Detection (LoD)
1	Recombinant N Protein 1	< 1 ng/mL
2	Recombinant N Protein 2	< 1 ng/mL
3	Recombinant N Protein 3	< 1 ng/mL

Limit of Detection (LoD) on Various SARS-CoV-2 Strains:

Three SARS-CoV-2 strains were diluted to various concentration to test the analytical sensitivity of **TestNOW® - COVID-19 Antigen** Test. Twenty replicate tests were conducted on each concentration. The agreement was 100%. The LoD is summarized as below.

No.	SARS-CoV-2 Strains	Sources	Limit of Detection (LoD)
1	USA-WA 1/2020	ZeptoMetrix Corporation, USA	3.80 x10^2 $TCID_{50}$/mL
2	Italy-1NMI 1	ZeptoMetrix Corporation, USA	3.16 x10^2 $TCID_{50}$/mL
3	Hong Kong/VM20001061/2020	ZeptoMetrix Corporation, USA	9.55 x10^2 $TCID_{50}$/mL
4	England (B.1.1.7)/204820464/2020	ZeptoMetrix Corporation, USA	4.57 x 10^2 $TCID_{50}$/mL
5	South Africa (B.1.351)/KRISP-K005325/2020	ZeptoMetrix Corporation, USA	3.16 x 10^2 $TCID_{50}$/mL
6	USA-CA (B.1.1.7)/USA/CA_CDC_5574/2020	ZeptoMetrix Corporation, USA	1.26 x 10^2 $TCID_{50}$/mL
7	Recombinant N Protein Antigen SARS-CoV-2, FPZ-0689 Delta B 1.617.1	Fapon Biotech, China	1 ng/mL
8	Recombinant N Protein Antigen SARS-CoV-2, FPZ-0694 Delta B 1.617.2	Fapon Biotech, China	1 ng/mL
9	SARS-CoV-2 Variant B.1.1.529 (Omicron) NP Recombinant Protein	Fapon Biotech, China	20 pg/ml

Cross Reactivity

The cross reactivity of the **TestNOW® - COVID-19 Antigen** Test was evaluated with a total of 6 bacteria, 18 viruses. None of the microorganisms tested in the following table gave a positive result at the defined concentration. The specificity of non-cross reactivity is 100%.

Bacteria panel	Test con. CFU/mL	Bacteria panel	Test con. CFU/mL
Escherichia coli, Clinical Isolate	7.92 x 10^8	Staphylococcus aureus, MRSA;COL	1.84 x 10^8
Haemophilus influenzae, Type B Egypt	5.43 x 10^7	Staphylococcus epidermidis, MRSE, RP62A	9.27 x 10^8
Pseudomonas aeruginosa, Clinical Isolate	8.44 x 10^8	Streptococcus pneumoniae, Z022 19F	4.16 x 10^5
Viral panel	**Test con. $TCID_{50}$/mL**	**Viral panel**	**Test con. $TCID_{50}$/mL**
Coronavirus (HCoV-OC43)	1.65 x 10^5	Parainfluenza virus Type 2	1.05 x 10^5
Coronavirus (HCoV-NL63)	1.41 x 10^4	Parainfluenza virus Type 3	8.51 x 10^7
Coronavirus (HCoV-229E)	4.17 x 10^4	Parainfluenza virus Type 4A	1.51 x 10^5
MERS-Cov Virus Florida / USA-2_Saudi Arabia_2014	3.55 x 10^4	Human Metapneumovirus 16 Type A1	1.26 x 10^5
Rhinovirus A2	3.89 x 10^3	Adeno virus type 4	5.01 x 10^4
Influenza A virus H1N1 Brisbane/59/07	7.24 x 10^4	Respiratory syncytial virus Type A	1.26 x 10^5
Influenza A virus H3N2 Brisbane/10/07	4.17 x 10^4	Respiratory syncytial virus Type B	1.26 x 10^5
Influenza B virus Florida/02/06	1.26 x 10^5	Enterovirus Type 68	3.80 x 10^5
Parainfluenza virus Type 1	5.01 x 10^4	Enterovirus Type 71	1.65 x 10^5

Interference

Exogenous (Nasal spray product, common chemicals) and endogenous substances listed in the table were evaluated by spiking into extraction buffer with or without 1 x LOD SARS-CoV-2 virus and tested by six replicates. The results showed 100% positive on samples spiked with 1 x LOD and 100% negative without virus. These substances did not interfere with the **TestNOW® - COVID-19 Antigen** Test at the levels tested below.

Interference substances	Testing Concentration	Interference substances	Testing Concentration
Aspirin	20 mg/ml	Oxymetazoline HCl	10 mg/ml
Dextromethorphan	10 mg/ml	Phenylephrine HCl	10 mg/ml
Diphenhydramine HCl	5 mg/ml	Saline nasal sprays	10%
Hemoglobin	20 mg/ml	Whole blood	5%
Mucin	0.04%	Ibuprofen	20 mg/ml

Hook Effect

TestNOW® - COVID-19 Antigen Test Device showed no Hook effect at highest concentration that can be tested with:

No.	Type	Strain	$TCID_{50}$/mL	Positive	Negative	Agreement

1	Virus	SARS-CoV-2, USA-WA 1/2020	$3.8x10^5$	2	0	100%
2	Virus	SARS-CoV-2, Italy-INMI-1	$3.16x10^5$	2	0	100%
3	Virus	SARS-CoV-2, HK/VM20001061/2020 1/2020	$9.55x10^5$	2	0	100%

Influenza A+B

Analytical Sensitivity

The limit of detection (LOD) for the **TestNOW® - Influenza A+B Antigen** Test was evaluated by using six (6) strains of influenza A and three (3) strains of influenza B.

Influenza Viral Strain	LOD ($TCID_{50}$/mL)
A/H1N1/Brisbane/59/07	7.24 x10
A/H3N2/Brisbane/10/07	4.17x10
A/H3N2/Victoria/361/11	$1.9x10^2$
A/H3N2/Wisconsin/67/05	7.05x10
A/H3N2/HK/8/68	$1.26x10^2$
A/H1N1/Singapore/63/04	$5x10^2$
B/Florida/02/06	$1.26x10^2$
B/Lee/40	$6.3x10^2$
B/Malaysia/2506/04	$1.9x10^2$

Reactivity

The reactivity study evaluates the ability to detect Influenza strains representing temporal and geographical diversity. The reactivity/inclusivity was evaluated with 5 Influenza A and 2 Influenza B strains. Influenza A strains included Influenza A/H1 strains, Influenza A/H3 strains and other types. Influenza B strains including that from both the Victoria lineage and Panama lineage.

Type/Subtype	Virus Strain	Result	
		Flu A	Flu B
Influenza A/H3N2	Perth/16/2009	P	N
Influenza A/H1N1	Solomon Islands/03/2006	P	N
Influenza A/H1N1	New Caledonia/20/99	P	N
Influenza A	Swine NY/01/2009	P	N
Influenza A	Swine Canada/6294/09	P	N
Influenza B	Brisbane/33/2008(Victoria lineage)	N	P
Influenza B	Panama/45/90	N	P

Cross Reactivity

The cross reactivity of the **TestNOW® - Influenza A+B Antigen** Test was evaluated with a total of 6 bacteria and 18 viruses. None of the microorganisms tested in the following table gave a positive result at the defined concentration.

Bacteria panel	Test concentration CFU/mL
Escherichia coli, Clinical Isolate	7.92×10^8
Haemophilus influenzae, Type B Egypt	5.43×10^7
Pseudomonas aeruginosa, Clinical Isolate	8.44×10^8
Staphylococcus aureus, MRSA;COL	1.84×10^8
Staphylococcus epidermidis, MRSE, RP62A	9.27×10^8
Streptococcus pneumoniae, Z022 19F	4.16×10^7
Viral panel	**Test concentration $TCID_{50}$/mL**
SARS-COV-2 (Hongkong/VM20001061/2020)	$3.16 X10^4$
SARS-Cov-2 (Italy-INMI1)	$9.55X10^4$
SARS-CoV-2 Variant B.1.1.7 (USA/CA-CDC-5/2)	1.26×10^5
SARS-CoV-2 Variant B.1.351 (South Africa/KRISP)	3.16×10^5
SARS-CoV-2 Variant Brazil P.1 Japan/TY7-503/2021	1.26×10^5
SARS-CoV-2 Variant Delta B.1.617.2 (UDA/PHC658/2021)	5.01×10^4
SARS-CoV-2 Variant Kappa B.1.617.1 (USA/CA-Stanford-15_502/2021)	3.39×10^6
SARS-CoV-2 Variant Zeta P2-2021 (USA/NY-Wadsworth-2106055-01/2021)	1.26×10^5
SARS-Cov-2 (USA-WA1/2020)	$1.15 X10^5$
Corona virus (HCoV-OC43)	1.65×10^5
Corona virus (HCoV-NL63)	1.41×10^4

Corona virus (HCoV-229E)	4.17×10^4
Rhinovirus A2	3.89×10^3
Parainfluenza virus Type 1	5.01×10^4
Parainfluenza virus Type 2	1.05×10^5
Parainfluenza virus Type 3	8.51×10^7
Parainfluenza virus Type 4A	1.51×10^5
Human Metapneumovirus 16 Type A1	1.26×10^5
Adeno virus type 4	5.01×10^4
Respiratory syncytial virus Type A	1.26×10^5
Respiratory syncytial virus Type B	1.26×10^5
Enterovirus Type 68	1.51×10^5
Enterovirus Type 71	3.80×10^5
MERS-Cov Virus Florida / USA-2_Saudi Arabia_2014	3.55×10^4

Interference

Exogenous (Nasal spray product, common chemicals) and endogenous substances listed in the table below were evaluated by spiking into extraction buffer with or without 1 x LOD Influenza A virus (strain: Brisbane/59/07) and Influenza B virus (strain: Florida/02/06). The results showed 100% positive on samples spiked with 1 x LOD and 100% negative without virus. These substances did not interfere with the **TestNOW® - Influenza A+B Antigen** Test at the levels tested below.

Interference substances	Testing Concentration	Interference substances	Testing Concentration
Aspirin	20 mg/ml	Oxymetazoline HCl	10 mg/ml
Dextromethorphan	10 mg/ml	Phenylephrine HCl	10 mg/ml
Diphenhydramine HCl	5 mg/ml	Saline nasal sprays	10%
Hemoglobin	20 mg/ml	Whole blood	5%
Mucin	0.04%	Ibuprofen	20 mg/ml

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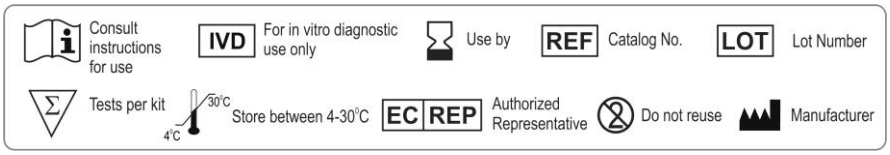
SHELF LIFE: 18 Months

INDEX OF CE SYMBOLS



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