SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus /SP Combo Rapid Test Package Insert

REF VIRI-7107	English

INTENDED USE

The VivaDiag™ SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus/SP Combo Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2, Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), Adenovirus antigens, Mycoplasma pneumoniae antigens, Human Metapneumovirus antigens, Human Parainfluenza Virus type Ⅰ/Ⅱ/Ⅲ antigens and Rhinovirus antigens in nasopharyngeal swab specimens from individuals with suspected SARS-CoV-2 / Influenza / RSV / Adenovirus / Mycoplasma pneumoniae / Human Metapneumovirus / Human Parainfluenza Virus /Rhinovirus/SP infection in conjunction with clinical presentation and the results of other laboratory tests. For professional use only. It is intended for clinical laboratories and healthcare professional use only for point-of-care testing. Not for at-home testing. For *in vitro* diagnostic use only.

PRINCIPLE

COVID-19 is an acute respiratory infectious disease. People are generally 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 main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Influenza (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Laboratory identification of human influenza virus infections is commonly performed using direct antigen detection, virus isolation in cell culture, or detection of influenza-specific RNA by reverse transcriptase-polymerase chain reaction (RT-PCR).

Human PIVs (HPIVs) are currently divided into 5 serotypes—HPIV-1, HPIV-2, HPIV-3, HPIV-4a, and HPIV-4b—in 2 different genera: Respirovirus (HPIV-1 and HPIV-3) and Rubulavirus (HPIV-2 and HPIV-4). HPIV is closely related to Hendra virus, Nipah virus, and metapneumoviruses. HPIVs primarily affect young children, in whom the pathogenic spectrum includes upper and lower respiratory tract infections. They are responsible for 30-40% of all acute respiratory tract infections in infants and children. These conditions include common cold with fever, laryngotracheobronchitis (croup), bronchiolitis, and pneumonia. HPIVs are an important cause of outbreaks in daycare facilities, pediatric wards nursing homes and other institutional settings. HPIVs are also a cause of community-acquired respiratory tract infections of variable severity in adults.

Respiratory Syncytial Virus (RSV), which causes infection of the lungs and breathing passages, is a major cause of respiratory illness in young children. In adults, it may only produce symptoms of a common cold, such as a stuffy or runny nose, sore throat, mild headache, cough, fever, and a general feeling of being ill.Most children with RSV infection, both those who were hospitalized and those who were treated as outpatients, had no coexisting medical conditions or characteristics that significantly identified them as being at greater risk for severe RSV disease, except for being under 2 years of age.

Adenoviruses most commonly cause respiratory illness; however, depending on the infecting serotype, they may also cause various other illnesses, such as gastroenteritis, conjunctivitis, cystitis, and rash illness. Symptoms of respiratory illness caused by Adenovirus infection range from the common cold syndrome to pneumonia, croup, and bronchitis. Patients with compromised immune systems are especially susceptible to severe complications of Adenovirus infection. Adenovirus is transmitted by direct contact, fecal-oral transmission, and occasionally waterborne transmission. Some types are capable of establishing persistent asymptomatic infections in tonsils, adenoids, and intestines of infected hosts, and shedding can occur for months or years.

Mycoplasma pneumoniae can cause acute respiratory infections, such as atypical pneumonia. With clinical symptoms such as headache, fever, dry cough, sore throat, and muscle pain. All age groups will beinfected, but the infection rate is higher among middle-aged and young people, as well as children under4 years old. 30% of all infected individuals will have whole lung infections. Mycoplasma pneumoniae can also cause non respiratory diseases, such as meningitis, encephalitis, pancreatitis, etc.

hMPV infection is a typical respiratory infection in infants. It is similar to respiratory syncytial (RS) virus infection and differentiation from each other is difficult. The incubation period lasts for 3 to 9 days, with the majority falling within the range of 3 to 6 days. It may present symptoms associated with either upper respiratory tract infections or lower respiratory tract infections.The principal manifestations are cough, fever, nasal congestion, rhinorrhea, and pharyngeal pain, etc.

Rhinovirus Ag Rapid Test has one line of Rhinovirus VP3 protein antibody on the detection line (T1 line), VP1 protein antibody on the detection line (T2 line),and one quality control line (C line). When extracted specimen is added to the specimen well, it will react with the labeled antibody to form a complex, the mixture then migrates through the membrane by capillary action and interacts with the coated Rhinovirus antibody on the detection line. If the specimen contains Rhinovirus antigen, the detection line will appear color indicating the Rhinovirus antigen is positive. Otherwise, the test result will be negative. The test device also contains a quality control line C which should appear color for all valid tests. If the quality control line C does not appear, the test result will be invalid even if the detection line appears.

S pneumoniae is a common cause of bacterial meningitis, bacteremia, and otitis media. S pneumoniae infection is also an important cause of sinusitis, septic arthritis, osteomyelitis, peritonitis, and endocarditis. Worldwide in 2000, 14.5 million estimated episodes of invasive pneumococcal disease were reported in children younger than 5 years, which correlates to more than 800,000 estimated deaths (11% of all deaths in this age group).

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
- Do not open the sealed pouch unless ready to conduct the assay.
- Do not use expired devices.
- Bring all reagents to room temperature (15°C-30°C) before use.
- Do not use the components in any other type of test kit as a substitute for the components in this kit.
- Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
- Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.

COMPOSITION

Materials provided

1. Test Device in foil pouch
2. Buffer
3. Sterile Swab
4. Tube Tip
5. Tube Stand
6. Package Insert

Materials required but not provided

1. Timer
2. Pipette and pipette tip
3. Personal protective equipment, such as protective gloves, medical masks, lab coats, etc.
4. Appropriate biohazardous waste containers and disinfectants.

STORAGE AND STABILITY

- Store the test kit in a cool, dry place between 36-86°F (2-30°C). Keep away from light. Exposure to temperature and / or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze. Use the test kit at temperatures between 59-86°F (15-30°C).
- Use the test kit between 10-90% humidity.
- Do not use the test kit beyond the expiration date (printed on the foil pouch and box).

Note:

All expiration dates are printed in Year-Month-Day format. 2022-06-18 indicates June 18, 2022.

SPECIMEN COLLECTION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Specimen Collection:

Use the nasopharyngeal swab supplied in the kit. It is important to obtain as much secretion as possible. Therefore, to collect a nasopharyngeal swab sample, 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, and then remove it from the nasopharynx.

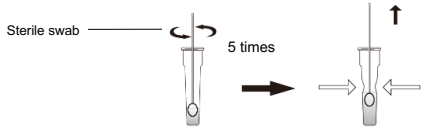
Nasopharyngeal swab

TEST PROCEDURE

Please read the instructions carefully before testing. Allow equipment, buffers, and samples to equilibrate to room temperature (15°C to 30°C) prior to testing.

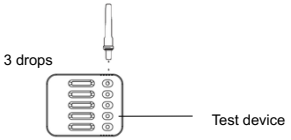
1. Open the extraction solution (in the sealed tube).

2. Collect specimen refer to Specimen Collection.
3. Insert the swab with collected specimen into the extraction tube filled with extraction solution. Roll the swab 5 times while pressing the head against the bottom and side of the extraction tube.
4. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Try to release as much liquid as possible. Dispose the used swab as a biohazard waste.



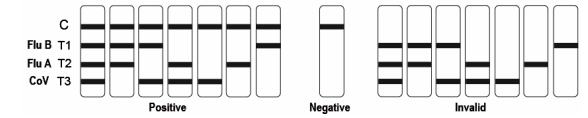
5. Put on the tube tip.

6. Take out a test device from sealed foil pouch and put it on a clean and level surface.
7. Apply 3 drops of the extracted specimen into the each specimen well. Please avoid bubbles during applying.
8. Read the test result at **15 minutes.** Don't read the result after 20 minutes.



INTERPRETATION OF TEST RESULTS

For SARS-CoV-2/Influenza A+B:



Positive Result:

Positive SARS-CoV-2, influenza A and B antigen:

All 4 lines appear, including the quality control line C , detection line T1(influenza B) , detection line T2(influenza A) and detection line T3(SARS-CoV-2).

Positive the corresponding testing:

The quality control line C and the corresponding line in the detection line(T1, T2, T3) appear.

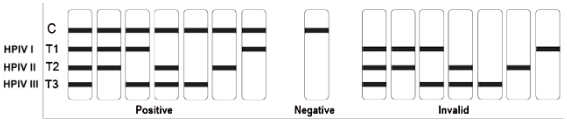
Negative Result:

Only the quality control line C appears, with no other line appearing on the detection line.

Invalid Result:

Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not. Collect a new specimen and perform another test with a new test device.

For HPIV:



Positive Result:

Positive HPIV Ⅰ, HPIV Ⅱ and HPIV Ⅲ antigen:

All 4 lines appear, including the quality control line C , detection line T1(HPIV I) , detection line T2(HPIV II) and detection line T3(HPIV III).

Positive the corresponding testing:

The quality control line C and the corresponding line in the detection line(T1, T2, T3) appear.

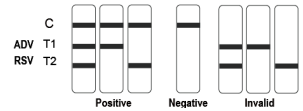
Negative Result:

Only the quality control line C appears, with no other line appearing on the detection line.

Invalid Result:

Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not. Collect a new specimen and perform another test with a new test device.

For RSV/Adenovirus:



Positive Result:

Positive Respiratory Syncytial Virus (RSV) / Adenovirus antigens(ADV):

All 3 lines appear, including the quality control line C , detection line T1(Adenovirus) , detection lines T2(Syncytial Virus) .

Positive the corresponding testing:

The quality control line C and the corresponding line in the detection line(T1, T2) appears.

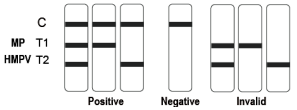
Negative Result:

Only the quality control line C appears, with no other line appearing on the detection line.

Invalid Result:

Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not. Collect a new specimen and perform another test with a new test device.

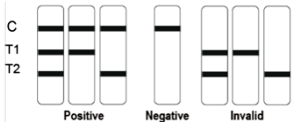
For MP / HMPV :



Positive Result:

Positive Respiratory MP/ HMPV:
All 3 lines appear, including the quality control line C , detection line T1(MP) , detection lines T2(HMPV) .
Positive the corresponding testing:
The quality control line C and the corresponding line in the detection line(T1, T2) appears.
Negative Result:
Only the quality control line C appears, with no other line appearing on the detection line.
Invalid Result:
Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not. Collect a new specimen and perform another test with a new test device.

For RhV (T1)/SP (T2):



Positive Result:
Positive RhV and SP:
All 3 lines appear, including the quality control line C , detection line T1(RhV) , detection lines T2(SP) .
Positive the corresponding testing:
The quality control line C and the corresponding line in the detection line(T1, T2) appears.

Negative Result:
Only the quality control line C appears, with no other line appearing on the detection line.
Invalid Result:
Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not. Collect a new specimen and perform another test with a new test device.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is the internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- This test is for *in vitro* diagnostic use only and cannot be re-used.
- The used test should be treated as potentially infectious materials and should be disposed of properly.
- The test kit should be kept away from direct sunlight, moisture and heat.
- Please check if the test kit has any damage and check the expiry date before use.
- The sample volume will affect the accuracy of the test result. Inaccurate sample volume may cause a false positive or negative result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Positive and negative predictive values are highly dependent on prevalence. The local prevalence should be taken into consideration when interpreting diagnostic test results.
- Please be very careful when collecting nasopharyngeal swab specimen from children.
- Components from different batches are not allowed to be used in combination.

PERFORMANCE

1. Accuracy

Clinical Sensitivity/Clinical Specificity

A total of 790 specimens were tested using the VivaDiag™ SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus/SP Combo Rapid Test. These specimens were obtained by nasopharyngeal swab from symptomatic patients. The performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus/SP Combo Rapid Test was compared to a commercialized molecular assay.

Table 1 - SARS-CoV-2 Performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus/SP Combo Rapid Test as Compared to PCR Test

VivaDiag™ Combo Rapid Test (for SARS-CoV-2)	PCR		
	Positive	Negative	Total
Positive	103	3	106
Negative	3	681	684
Total	106	684	790
Sensitivity	97.17% (103/106, 95%CI, 92.01%~99.03%)		
Specificity	99.56% (681/684, 95%CI, 98.72%~99.85%)		
Accuracy	99.24% (784/790, 95%CI, 98.35%~99.65%)		

Table 2 - Influenza A Performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus/SP Combo Rapid Test as Compared to PCR Test

VivaDiag™ Combo Rapid Test (for Influenza A)	PCR		
	Positive	Negative	Total
Positive	55	5	60
Negative	3	727	730
Total	58	732	790
Sensitivity	94.83% (55/58, 95%CI, 85.86%~98.23%)		
Specificity	99.31% (727/732, 95%CI, 98.41%~99.71%)		
Accuracy	98.98% (782/790, 95%CI, 98.01%~99.49%)		

Table 3 - Influenza B Performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus/SP Combo Rapid Test as Compared to PCR Test

VivaDiag™ Combo Rapid Test (for Influenza B)	PCR		
	Positive	Negative	Total
Positive	31	4	35
Negative	2	753	755
Total	33	757	790
Sensitivity	93.94% (31/33, 95%CI, 80.39%~98.32%)		
Specificity	99.47% (753/757, 95%CI, 98.65%~99.79%)		
Accuracy	99.24% (784/790, 95%CI, 98.35%~99.65%)		

Table 4 - RSV Performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus/SP Combo Rapid Test as Compared to PCR Test

VivaDiag™ Combo Rapid Test (for RSV)	PCR		
	Positive	Negative	Total
Positive	110	4	114
Negative	3	673	676
Total	113	677	790
Sensitivity	97.35% (110/113, 95%CI, 92.48%~99.09%)		
Specificity	99.41% (673/677, 95%CI, 98.49%~99.77%)		
Accuracy	99.11% (783/790, 95%CI, 98.18%~99.57%)		

Table 5 - Adenovirus Performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus/SP Combo Rapid Test as Compared to PCR Test

VivaDiag™ Combo Rapid Test (for Adenovirus)	PCR		
	Positive	Negative	Total
Positive	67	6	73
Negative	1	716	717
Total	68	722	790
Sensitivity	98.53% (67/68, 95%CI, 92.13%~99.74%)		
Specificity	99.17% (716/722, 95%CI, 98.20%~99.62%)		
Accuracy	99.11% (783/790, 95%CI, 98.18%~99.51%)		

Table 6 - M.pneumoniae Performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus/SP Combo Rapid Test as Compared to PCR Test

VivaDiag™ Combo Rapid Test (for M.pneumoniae)	PCR		
	Positive	Negative	Total
Positive	112	2	114
Negative	3	673	676
Total	115	675	790
Sensitivity	97.39% (112/115, 95%CI, 92.61%~99.11%)		
Specificity	99.70% (673/675, 95%CI, 98.93%~99.92%)		
Accuracy	99.36% (785/790, 95%CI, 98.53%~99.73%)		

Table 7 - HMPV Performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus/SP Combo Rapid Test as Compared to PCR Test

VivaDiag™ Combo Rapid Test (HMPV)	PCR		
	Positive	Negative	Total
Positive	100	4	104
Negative	5	681	686
Total	105	685	790
Sensitivity	95.24% (100/105, 95%CI, 89.33%~97.95%)		
Specificity	99.42% (681/685, 95%CI, 98.51%~99.77%)		
Accuracy	98.86% (781/790, 95%CI, 97.85%~99.40%)		

Table 8 - HPIV Performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus/SP Combo Rapid Test as Compared to PCR Test

VivaDiag™ Combo Rapid Test (HPIV)	PCR		
	Positive	Negative	Total
Positive	82	4	86
Negative	3	701	704
Total	85	705	790
Sensitivity	96.47% (82/85, 95%CI, 90.13%~98.79%)		
Specificity	99.43% (701/705, 95%CI, 98.55%~99.78%)		
Accuracy	99.11% (783/790, 95%CI, 98.18%~99.57%)		

Table 9 - RhV Performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus/SP Combo Rapid Test as Compared to PCR Test

VivaDiag™ Combo Rapid Test (RhV)	PCR		
	Positive	Negative	Total
Positive	110	2	112
Negative	5	673	678
Total	115	675	790
Sensitivity	95.65% (110/115, 95%CI, 90.22%~98.13%)		
Specificity	99.70% (673/675, 95%CI, 98.93%~99.92%)		
Accuracy	99.11% (783/790, 95%CI, 98.18%~99.57%)		

Table 10 - SP Performance of the VivaDiag™ SARS-CoV-2/InfluenzaA+B/HPIV2/HPIV1+3/ RSV/Adenovirus/MP/HMPV/SP Combo Rapid Test as Compared to PCR Test

VivaDiag™ Combo Rapid Test (SP)	PCR		
	Positive	Negative	Total
Positive	110	2	112
Negative	5	1073	1078
Total	115	1075	1190
Sensitivity	95.65% (110/115, 95%CI, 90.22%~98.13%)		
Specificity	99.81% (1073/1075, 95%CI, 99.32%~99.95%)		
Accuracy	99.41% (1183/1190, 95%CI, 98.79%~99.71%)		

INDEX OF SYMBOLS

	Consult instructions for use		Use by	Σ	Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only	LOT	Lot number	REF	Catalog number
2°C 30°C	Storage temperature limitations		Manufacturer		Do not reuse
EC REP	Authorized Representative				

IMPORTÉR A DISTRIBUTOR PRO ČR:
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CE IVD