SARS-CoV-2/Influenza A+B/RSV Ag Combo Rapid Test Package Insert

REF VISIR-737	English

INTENDED USE

The VivaDiag™ SARS-CoV-2/Influenza A+B/RSV Ag Combo Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV) antigens in nasopharyngeal swab specimens from individuals with suspected SARS- CoV-2/Influenza/RSV infection in conjunction with clinical presentation and the results of other laboratory tests.
The test is for *in vitro* diagnostic use only. 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.

PRINCIPLE

SARS-CoV-2 Rapid Test has one line of anti-SARS-CoV-2 antibody on the detection line (T line) and one line of anti-mouse IgG antibody on the 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 anti-SARS-CoV-2 antibody on the detection line. If the specimen contains SARS-CoV-2 antigen, the detection line will appear red indicating the SARS-CoV-2 antigen is positive. Otherwise, the test result will be negative. The test device also contains a quality control line C which should appear red 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.
Influenza A+B Rapid Test has one line of anti-influenza A antibody on the detection line (A line), one line of anti-influenza B antibody on the detection line (B line) and one line of anti-mouse IgG antibody on each quality control line (C line). When the 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 anti-influenza A antibody and anti-influenza B antibody on the detection line. If the specimen contains influenza A or influenza B antigen, the detection line will appear red indicating the presence of influenza A or influenza B antigen. Otherwise, the test result will be negative. The test device also contains the quality control line C which should appear red 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.
RSV Rapid Test has one line of anti-RSV antibody on the detection line (T line) and one line of anti-mouse IgG antibody on the 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 anti-RSV antibody on the detection line. If the specimen contains RSV antigen, the detection line will appear red indicating the RSV antigen is positive. Otherwise, the test result will be negative. The test device also contains a quality control line C which should appear red 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.

COMPOSITION

Each test kit contains test, sterile swab, extraction solution (in the sealed tube), tube tip, tube stand and package insert.
Materials required but not provided: timer.

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.

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.
- Handle the Negative and Positive Control in the same manner as patient specimens.

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.

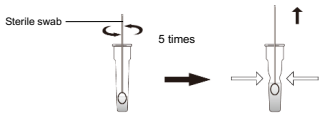
SPECIMEN COLLECTION

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.

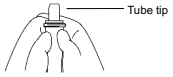
TEST PROCEDURE

Allow the Test Devices and Extraction Solution to equilibrate to 15-30°C prior to testing.
1. Open the extraction solution (in the sealed tube).

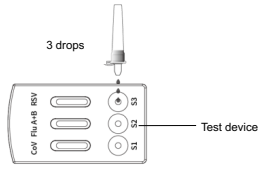
2. Collect specimen refer to Specimen Collection.
3. Insert the swab with collected specimen into the extraction tube filled with extraction solution. Roll the swab 5 times while pressing the head against the bottom and side of the extraction tube.
4. Remove the swab while squeezing the sides of the 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.



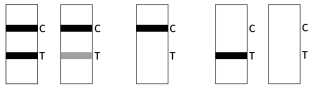
6. Take out a test device from sealed foil pouch and put it on a clean and level surface.
7. Apply 3 drops of the extracted specimen into the each specimen well. Please avoid bubbles during applying.



8. Read the test result at 15 minutes. Don't read the result after 20 minutes.

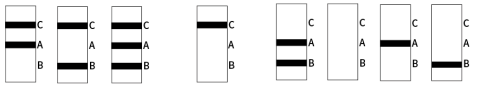
INTERPRETATION OF TEST RESULTS

For SARS-CoV-2:



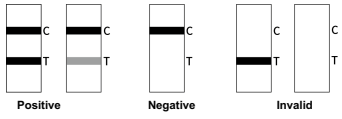
Positive Result:
Both the quality control line C and the detection line T appear.
Negative Result:
Only the quality control line C appears, with no other line appearing on the detection line.
Invalid Result:
Quality control line C fails to appear indicating the test is invalid, no matter if the detection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

For Influenza A+B:



Positive Results:
Positive influenza A antigen:
Both the quality control line C and the influenza A detection line appear, while the influenza B detection line does not appear.
Positive influenza B antigen:
Both the quality control line C and the influenza B detection line appear, while the influenza A detection line does not appear.
Positive influenza A and B antigen:
All 3 lines appear, including the quality control line C and the influenza A and influenza B detection lines.
Negative Result:
Only the quality control line C appears, with no other line appearing on the influenza A and influenza B detection line. It indicates the test result is negative for both influenza A and influenza B antigens.
Invalid Results:
Quality control line C fails to appear indicating the test is invalid, no matter if the influenza A or influenza B detection line appears or not. Collect a new specimen and perform another test with a new test device.

For RSV:



Positive Result:
Both the quality control line C and the detection line T 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.

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.

PERFORMANCE

Clinical Sensitivity/Clinical Specificity
A total of 362 specimens were tested using the VivaDiag™ SARS-CoV-2/Influenza A+B/RSV Ag Combo Rapid Test. These specimens were obtained by nasopharyngeal swab from symptomatic patients. The performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/RSV Ag 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/RSV Ag Combo

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Rapid Test as Compared to PCR Test

VivaDiag™SARS-CoV-2/Influenza A+B/RSV Ag Combo Rapid Test (for SARS-CoV-2)	PCR		
	Positive	Negative	Total
Positive	102	1	103
Negative	4	255	259
Total	106	256	362
Sensitivity	96.23% (102/106, 95%CI, 90.70%~98.52%)		
Specificity	99.61% (255/256, 95%CI, 97.82%~99.93%)		
Accuracy	98.62% (357/362, 95%CI, 96.81%~99.41%)		

Table2: Influenza A Performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/RSV Ag Combo Rapid Test as Compared to PCR Test

VivaDiag™ SARS-CoV-2/Influenza A+B/RSV Ag Combo Rapid Test (for Influenza A)	PCR		
	Positive	Negative	Total
Positive	55	4	59
Negative	3	300	303
Total	58	304	362
Sensitivity	94.83% (55/58, 95%CI, 85.86%~98.23%)		
Specificity	98.68% (300/304, 95%CI, 96.67%~99.49%)		
Accuracy	98.07% (355/362, 95%CI, 96.06%~99.06%)		

Table3: Influenza B Performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/RSV Ag Combo Rapid Test as Compared to PCR Test

VivaDiag™ SARS-CoV-2/Influenza A+B/RSV Ag Combo Rapid Test (for Influenza B)	PCR		
	Positive	Negative	Total
Positive	32	5	37
Negative	1	324	325
Total	33	329	362
Sensitivity	96.97% (32/33, 95%CI, 84.68%~99.46%)		
Specificity	98.48% (324/329, 95%CI, 96.49%~99.35%)		
Accuracy	98.34% (356/362, 95%CI, 96.43%~99.24%)		

Table4: RSV Performance of the VivaDiag™ SARS-CoV-2/Influenza A+B/RSV Ag Combo Rapid Test as Compared to PCR Test

VivaDiag™ SARS-CoV-2/Influenza A+B/RSV Ag Combo Rapid Test (for RSV)	PCR		
	Positive	Negative	Total
Positive	111	2	113
Negative	2	247	249
Total	113	249	362
Sensitivity	98.23% (111/113, 95%CI, 93.78%~99.51%)		
Specificity	99.20% (247/249, 95%CI, 97.12%~99.78%)		
Accuracy	98.90% (358/362, 95%CI, 97.19%~99.57%)		

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				

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CE
IVD

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Effective date: 2023-09-15

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