

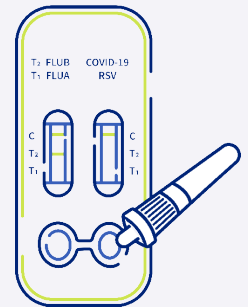
Core tests® ComboResp Lateral Flow Test

Covid-19, Influenza A, Influenza B, RSV



Prepare yourself for the winter season with the Core tests® ComboResp

Qualitative and differential detection of nucleocapsid protein antigen from Influenza A (including the subtype H1N1), Influenza B, RSV and/or Covid-19 in nasal swab specimens from symptomatic and asymptomatic patients. Aids in the rapid diagnosis of Influenza A, Influenza B, Respiratory Syncytial Virus, and/or SARS-CoV-2 infections in the healthcare setting management, general population screening, workplace screening, etc. Intended for professional use.



Rapid
Results in 10 minutes



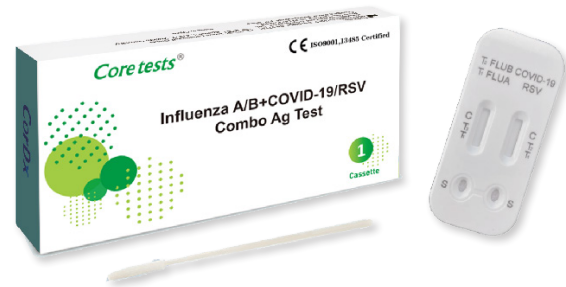
Reliable
CTDA Approved
CE-IVD Marked



Convenient
1 Swab, 1 Test Card, 4 Results

Limit of Detection

Covid-19	LoD 200 TCID ₅₀ /mL
Influenza A	LoD 1.5×10 ⁴ TCID ₅₀ /mL
Influenza B	LoD 1.5×10 ⁵ TCID ₅₀ /mL
RSV	LoD 1×10 ⁴ TCID ₅₀ /mL



Ordering Information

Product Number	Product	Pack Contents
STB292-01	Single Test Pack	1 Test Cassette 1 Sample Collection Tube with Processing Solution 1 Sampling Swab 1 Instructions for Use
STB292-25	25 Test Pack	25 Test Cassettes 25 Sample Collection Tubes with Processing Solution 25 Sampling Swabs 1 Instructions for Use



Contact

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Diagnostic Sensitivity and Specificity

For the Flu A+B antigen tests, a study using total 600 nasal swab samples was conducted.

Table 1 - Comparison of Influenza A Ag Test		Results of Clinical Diagnosis		Total Results
		Positive	Negative	
Results of Influenza A Ag Test	Positive	118	2	120
	Negative	1	479	480
Total Results		119	481	600

Sensitivity of 99.2% (118/119), Specificity of 99.6% (479/481), Total Agreement of 99.5% (597/600).

Table 2 - Comparison of Influenza B Ag Test		Results of Clinical Diagnosis		Total Results
		Positive	Negative	
Results of Influenza B Ag Test	Positive	109	1	110
	Negative	1	489	490
Total Results		110	490	600

Sensitivity of 99.1% (109/110), Specificity of 99.8% (489/490), Total Agreement of 99.7% (598/600).

For the Covid-19 antigen test, a study using a total 260 nasal swab samples was conducted. Test results were compared with nucleic acid detection test.

Across 110 positive samples, 40% of samples with Ct > 25, 40% of samples with 25 ≤ Ct ≤ 30 and 20% of samples with Ct > 30. The test results of diagnostic sensitivity of samples with Ct ≤ 25: 44/44, 100.00% (95%CI: 91.96% to 100.00%).

Table 3 - Comparison of Covid-19 Ag Test		Results of Clinical Diagnosis		Total Results
		Positive	Negative	
Results of Covid-19 Ag Test	Positive	78	0	78
	Negative	32	150	182
Total Results		110	150	260

Sensitivity of 70.91% (78/110), Specificity of 100.00% (150/150), Total Agreement of 87.69% (228/260).

For the RSV antigen test, a study using a total 415 nasal swab samples was conducted. Test results were compared with nucleic acid detection test.

Table 4 - Comparison of RSV Ag Test		Results of Clinical Diagnosis		Total Results
		Positive	Negative	
Results of RSV Ag Test	Positive	112	2	114
	Negative	3	298	201
Total Results		115	300	415

Sensitivity of 97.4% (112/115), Specificity of 99.3% (298/300), Total Agreement of 98.8% (410/415).



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