Clinical Study for
SARS-CoV-2 & Flu AB & RSV &
Adenovirus Antigen Combo Rapid Test

By:	Printed Name	Signature	Date
	Fangli Tong	Fangli Tong	2022.01.29

I. Instruction

The SARS-CoV-2 & Flu A/B & RSV & Adenovirus Antigen Combo Rapid Test is a rapid test for the qualitative and differential detection of SARS-CoV-2, Influenza virus type A and type B nucleoprotein antigens, respiratory syncytial virus(RSV) and respiratory adenovirus antigens in nasal swab or nasopharyngeal swab.

II. Study Objective

To perform a clinical sensitivity, specificity study.

III. Clinical Study Site and Study Period

Sample collection sites in China	Testing sites in China
Site 1: Shenzhen CDC No. 8 Longyuan Road, Nanshan District, Shenzhen, P.R. China	Site 1: Shenzhen CDC No. 8 Longyuan Road, Nanshan District, Shenzhen, P.R. China
Site 2: Adicon No.208 Zhenzhong Road, West Lake District, Hangzhou, Zhejiang, P.R. China	Site 2: Adicon No.208 Zhenzhong Road, West Lake District, Hangzhou, Zhejiang, P.R. China

IV. Study Procedure

Material：

Nasal/Nasopharyngeal swab samples from infected patients and non-infected patients.

SARS-CoV-2 & Flu AB & RSV & Adenovirus Antigen Combo Rapid Test: Lot#: CFRAC1060002 Extraction Solution, Lot#: 210520022

Comparison Test:

(1) RT-PCR, Novel Coronavirus (2019-nCoV) Nucleia Acid Diagnostic Kit (PCR-Fluorescence Probing), CE Marked, manufactured by Sansure BioTech Inc. Promotor SARS-COV-2 RT-PCR Test Kit, CE Marked, manufactured by ACON Biotech(Hangzhou)Co., Ltd.

(2) SD BIOLINE Influenza Antigen, CE Marked product, manufactured by Standard Diagnostics, Inc.

(3) Genesis Respiratory syncytial virus Antigen Rapid Diagnostic Test Kit, CE Marked product, manufactured by Hangzhou Genesis Biodetection & Biocontrol Co., Ltd.

(4) Genesis Adenovirus Antigen Rapid Test Kit, CE Marked product, manufactured by Hangzhou Genesis Biodetection & Biocontrol Co., Ltd.

Method：

1) Collected at least 100 SARS-CoV-2 positive nasal/nasopharyngeal specimens, at least 30 Influenza A positive nasal/nasopharyngeal specimens, at least 30 Influenza B positive nasal/nasopharyngeal specimens, at least 30 RSV nasal/nasopharyngeal specimens, at least 30 adenovirus nasal/nasopharyngeal specimens. All specimens are from symptomatic individuals who were SARS-CoV-2 or Influenza A or Influenza B or RSV or adenovirus positive with comparison test.
2) Collected at least 100 negative clinical specimens from symptomatic individuals.
3) Test the specimens with SARS-CoV-2 & Flu AB & RSV & Adenovirus Antigen Combo Rapid Test follow the package insert.

V. Acceptance Criteria：

1) For SARS-CoV-2
   Sensitivity: ≥85%; Specificity: ≥95%
2) For Influenza A/B
   Sensitivity: ≥80%; Specificity: ≥95%
3) For RSV
   Sensitivity: ≥85%; Specificity: ≥95%
4) For Adenovirus
   Sensitivity: ≥85%; Specificity: ≥95%

VI. Test Result：

1. Nasal Swab Sample:

(1) For SARS-CoV-2

Candidate method		RT-PCR		
		Negative	Positive	Total
SARS-CoV-2 Test Results	Negative	403	4	407
	Positive	2	99	101
	Total	405	103	508

Relative Sensitivity: 96.12% (95% CI: 90.12%-98.80%)
Relative Specificity: 99.51% (95% CI: 98.10%-99.99%)
Accuracy: 98.82% (95% CI: 97.38%-99.52%)

(2) For Influenza A

Candidate method		Comparato		
		Negative	Positive	Total
Flu A Test Results	Negative	461	0	461
	Positive	2	45	47
	Total	463	45	508

Relative Sensitivity: 100.00% (95% CI: 90.62%-100.00%)
Relative Specificity: 99.57% (95% CI: 98.33%-99.99%)
Accuracy: 99.61% (95% CI: 98.48%-99.99%)

(3) For Influenza B

Candidate method		Comparato		
		Negative	Positive	Total
Flu B Test Results	Negative	457	1	458
	Positive	2	48	50
	Total	459	49	508

Relative Sensitivity: 97.96% (95% CI: 88.31%-99.99%)
Relative Specificity: 99.56% (95% CI: 98.32%-99.99%)
Accuracy: 99.41% (95% CI: 98.19%-99.88%)

(4) For Respiratory Syncytial Virus

Candidate method		Comparato		
		Negative	Positive	Total
RSV Test Results	Negative	470	0	470
	Positive	3	35	38
	Total	473	35	508

Relative Sensitivity: 100.00% (95% CI: 88.24%-100.00%)
Relative Specificity: 99.37% (95% CI: 98.06%-99.88%)
Accuracy: 99.41% (95% CI: 98.19%-99.88%)

(5) For Adenovirus

Candidate method		Comparato		
		Negative	Positive	Total
Adenovirus Test Results	Negative	465	1	466
	Positive	3	39	42
	Total	468	40	508

Relative Sensitivity: 97.50% (95% CI: 85.96%-99.99%)
Relative Specificity: 99.36% (95% CI: 98.04%-99.87%)
Accuracy: 99.21% (95% CI: 97.92%-99.77%)

2. Nasopharyngeal Swab Sample:

(1) For SARS-CoV-2

Candidate method		RT-PCR		
		Negative	Positive	Total
SARS-COV-2 Test Results	Negative	401	4	405
	Positive	2	97	99
	Total	403	101	504

Relative Sensitivity: 96.04% (95% CI: 89.93%-98.77%)

Relative Specificity: 99.50% (95% CI: 98.09%-99.99%)
Accuracy: 98.81% (95% CI: 97.36%-99.52%)

(2) For Influenza A

Candidate method		Comparato		
		Negative	Positive	Total
Flu A Test Results	Negative	471	0	471
	Positive	3	30	33
	Total	474	30	504

Relative Sensitivity: 100.00% (95% CI: 86.53%-100.00%)
Relative Specificity: 99.37% (95% CI: 98.07%-99.88%)
Accuracy: 99.40% (95% CI: 98.18%-99.88%)

(3) For Influenza B

Candidate method		Comparato		
		Negative	Positive	Total
Flu B Test Results	Negative	471	1	472
	Positive	2	30	32
	Total	473	31	504

Relative Sensitivity: 96.77% (95% CI: 82.42%-99.99%)
Relative Specificity: 99.58% (95% CI: 98.37%-99.99%)
Accuracy: 99.40% (95% CI: 98.18%-99.88%)

(4) For Respiratory Syncytial Virus

Candidate method		Comparato		
		Negative	Positive	Total
RSV Test Results	Negative	471	0	471
	Positive	3	30	33
	Total	474	30	504

Relative Sensitivity: 100.00% (95% CI: 86.53%-100.00%)
Relative Specificity: 99.37% (95% CI: 98.07%-99.88%)
Accuracy: 99.40% (95% CI: 98.18%-99.88%)

(5) For Adenovirus

Candidate method		Comparator		
		Negative	Positive	Total
Adenovirus Test Results	Negative	469	1	470
	Positive	3	31	34
	Total	472	32	504

Relative Sensitivity: 96.88% (95% CI: 82.89%-99.99%)
Relative Specificity: 99.36% (95% CI: 98.06%-99.87%)
Accuracy: 99.21% (95% CI: 97.90%-99.77%)

VII. Conclusion:

Nasal specimens: for SARS-CoV-2, the SARS-CoV-2 & Flu AB & RSV & Adenovirus Antigen Combo Rapid Test has sensitivity of 96.12%, specificity of 99.51%, and accuracy of 98.82% when comparing with RT-PCR. For Influenza A, the SARS-CoV-2 & Flu AB & RSV & Adenovirus Antigen Combo Rapid Test has sensitivity of 100.00%, specificity of 99.57%, and accuracy of 99.61% when comparing with Rapid Test Method. For Influenza B, the SARS-CoV-2 & Flu AB & RSV & Adenovirus Antigen Combo Rapid Test has sensitivity of 97.96%, specificity of 99.56%, and accuracy of 99.41 % when comparing with Rapid Test Method. For Respiratory Syncytial Virus, the SARS-CoV-2 & Flu AB & RSV & Adenovirus Antigen Combo Rapid Test has sensitivity of 100.00%, specificity of 99.37%, and accuracy of 99.41 % when comparing with Rapid Test Method. For Adenovirus, the SARS-CoV-2 & Flu AB & RSV & Adenovirus Antigen Combo Rapid Test has sensitivity of 97.50%, specificity of 99.36%, and accuracy of 99.21% when comparing with Rapid Test Method.

Nasopharyngeal specimens: for SARS-CoV-2, the SARS-CoV-2 & Flu AB & RSV & Adenovirus Antigen Combo Rapid Test has sensitivity of 96.04%, specificity of 99.50%, and accuracy of 98.81% when comparing with RT-PCR. For Influenza A, the SARS-CoV-2 & Flu AB & RSV & Adenovirus Antigen Combo Rapid Test has sensitivity of 100.00%, specificity of 99.37%, and accuracy of 99.40% when comparing with Rapid Test Method. For Influenza B, the SARS-CoV-2 & Flu AB & RSV & Adenovirus Antigen Combo Rapid Test has sensitivity of 96.77%, specificity of 99.58%, and accuracy of 99.40% when comparing with Rapid Test Method. For Respiratory Syncytial Virus, the SARS-CoV-2 & Flu AB & RSV & Adenovirus Antigen Combo Rapid Test has sensitivity of 100.00%, specificity of 99.37%, and accuracy of 99.40 % when comparing with Rapid Test Method. For Adenovirus, the SARS-CoV-2 & Flu AB & RSV & Adenovirus Antigen Combo Rapid Test has sensitivity of 96.88%, specificity of 99.36%, and accuracy of 99.21% when comparing with Rapid Test Method.