Clinical Evaluation Report

For

SARS-CoV-2/Flu A+B/RSV Antigen Rapid Test

Ver. No.:	**A/0**
Document No.:	**CE-TF-96-10**
Report Date:	**29/10/2020**
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1 Introduction

This product is intended for in vitro qualitative detection to SARS-CoV-2 antigen, influenza A/B antigen and respiratory syncytial virus antigen in human nasopharyngeal swab or oropharyngeal swab samples.

2 Study purpose

Clinical institutions conduct clinical validation tests on the products (Hereinafter referred to as assessment reagent) to perform a diagnostic sensitivity, specificity study so as to evaluate the clinical performance.

3 Method

For SARS-CoV-2 study, 500 clinical samples (oropharyngeal swab) were selected. There were 100 positive samples and 400 negative samples. The assessment reagent were tested and the results were compared with that of PCR reagent. Homology nasopharyngeal and oropharyngeal swab samples of 135 patients were achieved, including 33 positive cases and 102 negative cases.

For Influenza A study, 189 patients who were suspected of Influenza A are studied. Both nasopharyngeal swab and oropharyngeal swab were collected from same patient.There were 43 positive cases and 146 negative cases. The assessment reagent were tested and the results were compared with that of similar reagent.

For Influenza B study, 186 patients who were suspected of Influenza B are studied. Both nasopharyngeal swab and oropharyngeal swab were collected from same patient.There were 47 positive cases and 139 negative cases. The assessment reagent were tested and the results were compared with that of similar reagent.

For RSV study, 192 patients who were suspected of RSV are studied. Both nasopharyngeal swab and oropharyngeal swab were collected from same patient.There were 51 positive cases and 141 negative cases. The assessment reagent were tested and the results were compared with that of similar reagent.

The diagnostic sensitivity, diagnostic specificity, total coincidence rate and 95% CI were calculated.

4 Analysis

4.1 Statistics Analysis of SARS-CoV-2 Antigen Rapid Test

Table 1 Statistics of assessment reagent results and PCR results on oropharyngeal swab samples

SARS-CoV-2 Antigen Rapid Test	PCR Results		Total
	Positive	Negative	
Positive	95	1	96
Negative	5	399	404
Total	100	400	500

Sensitivity: 95.00% (95%CI: 88.83%-97.85%)

Specificity: 99.75% (95%CI: 98.60%-99.96%)

Total consistent: 98.80% (95%CI: 97.41%-99.45%)

Table 2 Statistical analysis on the consistency of oropharyngeal and nasopharyngeal swabs tested by assessment reagent

Nasopharyngeal swabs	Oropharyngeal swabs		Total
	Positive	Negative	
Positive	31	0	31
Negative	0	104	104
Total	31	104	135

Positive Percent Agreement: 100%

Negative Percent Agreement: 100%

Overall Percent Agreement: 100%

4.2 Statistics Analysis of Influenza A Antigen Rapid Test

Table 3 Statistics analysis of assessment reagent results and comparator method on nasopharyngeal swab samples

Influenza A Antigen Rapid Test	Similar Reagent		Total
	Positive	Negative	
Positive	40	4	44
Negative	3	142	145

Total	43	146	189

Sensitivity: 93.02% (95%CI: 81.39%-97.60%)

Specificity: 97.26% (95%CI: 93.17%-98.93%)

Total consistent: 96.30% (95%CI: 92.55%-98.19%)

Table 4 Statistics analysis of assessment reagent results and comparator method on oropharyngeal swab samples

Influenza A Antigen Rapid Test	Similar Reagent		Total
	Positive	Negative	
Positive	40	4	44
Negative	3	142	145
Total	43	146	189

Sensitivity: 93.02% (95%CI: 81.39%-97.60%)

Specificity: 97.26% (95%CI: 93.17%-98.93%)

Total consistent: 96.30% (95%CI: 92.55%-98.19%)

Table 5 Statistical analysis on the consistency of oropharyngeal and nasopharyngeal swabs tested by assessment reagent

Nasopharyngeal swabs	Oropharyngeal swabs		Total
	Positive	Negative	
Positive	44	0	44
Negative	0	145	145
Total	44	145	189

Positive Percent Agreement: 100%

Negative Percent Agreement: 100%

Overall Percent Agreement: 100%

4.3 Statistics Analysis of Influenza B Antigen Rapid Test

Table 6 Statistics analysis of assessment reagent results and comparator method on nasopharyngeal swab samples

Influenza B Antigen Rapid Test	Similar Reagent		Total
	Positive	Negative	

Positive	44	3	47
Negative	3	136	139
Total	47	139	186

Sensitivity: 93.62% (95%CI: 82.84%-97.81%)

Specificity: 97.84% (95%CI:93.85%-99.26%)

Total consistent: 96.77% (95%CI: 93.14%-98.51%)

Table 7 Statistics analysis of assessment reagent results and comparator method on oropharyngeal swab samples

Influenza B Antigen Rapid Test	Similar Reagent		Total
	Positive	Negative	
Positive	44	3	47
Negative	3	136	139
Total	47	139	186

Sensitivity: 93.62% (95%CI: 82.84%-97.81%)

Specificity: 97.84% (95%CI:93.85%-99.26%)

Total consistent: 96.77% (95%CI: 93.14%-98.51%)

Table 8 Statistical analysis on the consistency of oropharyngeal and nasopharyngeal swabs tested by assessment reagent

Nasopharyngeal swabs	Oropharyngeal swabs		Total
	Positive	Negative	
Positive	47	0	47
Negative	0	139	139
Total	47	139	186

Positive Percent Agreement: 100%

Negative Percent Agreement: 100%

Overall Percent Agreement: 100%

4.4 Statistics Analysis of RSV Antigen Rapid Test

Table 9 Statistics analysis of assessment reagent results and comparator method on nasopharyngeal swab samples

RSV Antigen Rapid Test	Similar Reagent		Total
	Positive	Negative	
Positive	48	3	51
Negative	3	138	141
Total	51	141	192

Sensitivity: 94.12% (95%CI: 84.08%-97.98%)

Specificity: 97.87% (95%CI:93.93%-99.27%)

Total consistent: 96.88% (95%CI: 93.35%-98.56%)

Table 10 Statistics analysis of assessment reagent results and comparator method on oropharyngeal swab samples

RSV Antigen Rapid Test	Similar Reagent		Total
	Positive	Negative	
Positive	48	3	51
Negative	3	138	141
Total	51	141	192

Sensitivity: 94.12% (95%CI: 84.08%-97.98%)

Specificity: 97.87% (95%CI:93.93%-99.27%)

Total consistent: 96.88% (95%CI: 93.35%-98.56%)

Table 11 Statistical analysis on the consistency of oropharyngeal and nasopharyngeal swabs tested by assessment reagent

Nasopharyngeal swabs	Oropharyngeal swabs		Total
	Positive	Negative	
Positive	51	0	51
Negative	0	141	141
Total	51	141	192

Positive Percent Agreement: 100%

Negative Percent Agreement: 100%

Overall Percent Agreement: 100%

5 Conclusion

(1) Clinical results of assessment reagents SARS-CoV-2 Antigen Rapid Test:

The diagnostic sensitivity is 95.00%, the diagnostic specificity is 99.75%, and the overall coincidence rate is 98.80%. The test results of two sample types (nasopharyngeal swab and oropharyngeal swab) were consistent indicating that the two sample types can be used for detection.

(2) Clinical results of assessment reagents Influenza A Antigen Rapid Test:

The diagnostic sensitivity is 93.02%, the diagnostic specificity is 97.26%, and the overall coincidence rate is 96.30%. The test results of two sample types (nasopharyngeal swab and oropharyngeal swab) were consistent indicating that the two sample types can be used for detection.

(3) Clinical results of assessment reagents Influenza B Antigen Rapid Test:

The diagnostic sensitivity is 93.62%, the diagnostic specificity is 97.84%, and the overall coincidence rate is 96.77%. The test results of two sample types (nasopharyngeal swab and oropharyngeal swab) were consistent indicating that the two sample types can be used for detection.

(4) Clinical results of assessment reagents RSV Antigen Rapid Test:

The diagnostic sensitivity is 94.12%, the diagnostic specificity is 97.87%, and the overall coincidence rate is 96.88%. The test results of two sample types (nasopharyngeal swab and oropharyngeal swab) were consistent indicating that the two sample types can be used for detection.