Diagnostic Kit for SARS-CoV-2 Saliva Ag Test Kit (VCSD05, CMA-039)
Clinical Evaluation Report

Clinical Trial Start Date: 16.11.2020

Clinical Trial Finish Date: 10.01.2021

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1. Clinical Evaluation Purpose

Testing the saliva samples from patients with pneumonia and positive nucleic acid test results (suspected of SARS-CoV-2 infection). Patients with other diseases or negative persons with negative nucleic acid test results by using Diagnostic Kit: RapidFor™ Coronavirus (SARS-CoV-2) Saliva Antigen Detection Kit (Collaidal Gold),developed by Vitrosens Biotechnology. The test results compared with the nucleic acid test result blindly. The trial purpose is to verify the consistency of the test results of the tested reagents with the nucleic acid test results.

2. Tested Reagents

2.1 Product name: ™ Coronavirus (SARS-CoV-2) Saliva Antigen Kit Catalog Number: VSCD05, CMA-039

2.2 Comparison reagent: Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit by Bioeksen

3. Experiment Design

3.1Sample selection
In order to examine the sensitivity and specificity of the product from a clinical perspective, this clinical trial selected (1) patients diagnosed with pneumonia with positive nucleic acid test results (suspected of SARS-CoV-2 infection) as the "case group"; (2)patients with other diseases or normal persons with negative nucleic acid test results as the "control group". The sample matrix was selected as saliva.

In this trial, the results of nucleic acid detection of SARS-CoV-2 were selected as a control. The blind method and the comparative test design were used. The tested reagent was used to blindly test the test samples, and the complete and real clinical trial data were recorded. After submitting the data to the person in charge of statistics, the person in charge made statistics according to the statistical method in the clinical trial plan, and evaluated the coincidence rate and consistency of the tested reagent and the nucleic acid detection result based on the statistical results.

3.2 Sample size

194 PCR positive saliva specimens and 243 PCR negative saliva specimens according to Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit by Bioeksen were investigated with RapidFor™ Coronavirus (SARS-CoV-2) Saliva Antigen Kit(VSCD05).

3.3 Statistical interpretation

Please refer to 2x2 Contingency Table in EP12-A2 （User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline— Second Edition，2008） for statisticalinterpretation.

	qPCR			
Saliva Antigen Kit(VSCD05)		Positive	Negative	Total
	Positive	A True positive	B False positive	A+B
	Negative	C False negative	D True negative	C+D
	Total	A+C	B+D	A+B+C+D

Please refer to computing method in EP12-A2 （User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline— Second Edition， 2008）to calculate negative coincidence rate,

positive coincidence rate, and 95% confidence interval for negative coincidence rate and 95% confidence interval for positive coincidence rate.

Statistical interpretation

Clinical Evaluation

(1) With194 positive samples, 185 samples were detected as positive; With 243 negative samples, 241 samples were detected as negative.

(2) Sensitivity: 95.3% (185/194), 95%Cl (92.31, 97.42).

(3) Specificity: 99.1% (241/243),95%Cl (93.56, 98.93).

	RT-PCR Positive	RT-PCR Negative	Total
Detected Positive	185	2	187
Detected Negative	9	241	250
Total	194	243	437

5. Discussion and Conclusion

5.1 Discussion

In this clinical trial with fresh samples, 437 samples were taken from RT-PCR positive or negative patients. Among them, 194 cases of "case group" samples and 243 samples of "control group" were determined by nucleic acid detection. example. Among them, 185 positive samples and 241 negative samples were detected by the assessment reagent. The positive coincidence rate of the assessment reagent was 95.3%, and the negative coincidence rate was 99.1%.

5.2 Conclusion

In summary, the detection results of Diagnostic Kit for RapidFor™ Coronavirus (SARS-CoV-2) Saliva Antigen Kit(VSCD05) developed by Vitrosens Biotechnology and the nucleic acid detection results are in good agreement, and the SARS-CoV-2 antigen detection function can meet the needs of clinical application.