Diagnostic Kit for SARS-CoV-2 Rapid Ag Test Kit (Colloidal Gold)
Clinical Evaluation Report

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Institution for Positive Samples: Bakırköy Dr. Sadi Konuk Research And Training Hospital

Statistical Company: Vitrosens Biotechnology Co. Ltd.

Responsible: Furkan Tunç

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VITROSENS BIOTECHNOLOGY **Vitrosens Biyoteknoloji Ltd. Şti. Adress:** Şerifali Mh. Şehit. Sk No:17, 34775 Ümraniye/İSTANBUL
Tel: +90 542 275 0260 **E-mail:** info@vitrosens.com **Web:** www.vitrosens.com

RapidFor™ Diagnostic Kit for SARS-CoV-2 Ag
Clinical Report

1. Clinical Evaluation Purpose

Testing the oropharyngeal and nasopharyngeal swab 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™ SARS-CoV-2 Rapid Antigen Detection Kit (Colloidal Gold), developed by Vitrosens Biotechnology Co., Ltd. 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: RapidFor™ SARS-CoV-2 Rapid Antigen Kit (Colloidal Gold)（VSCD02）

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

3. Experiment Design

3.1 Sample 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".

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

600 PCR positive specimens and 525 PCR negative specimens according to Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit by Bioeksen were investigated with RapidFor™ Coronavirus (SARS-CoV-2) Rapid Antigen Kit (Colloidal Gold)

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 statistical interpretation.

	qPCR			
RapidFor™ Coronavirus (SARS-CoV-2) Rapid Antigen Kit(Colloidal Gold)		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.

4. Clinical Evaluation

（1） With 600 positive samples, 584 samples were detected as positive; With 525 negative samples, 520 samples were detected as negative.

（2） **Sensitivity: 97.3%** (584/600), 95%Cl (95.82, 98.51).

（3） **Specificity: 99.0%** (520/525), 95%Cl (97.81, 99.69).

	RT-PCR Positive	RT-PCR Negative	Total
Detected Positive	584	5	589
Detected Negative	16	520	536
Total	600	525	1125

SARS-Cov-2 Rapid Ag Test Kit (Colloidal Gold)	Comparative RT-PCR method (Positive according to Ct value)	
	Positive	Negative
Positive	289	284
Negative	0	16
Total	289	300
Positive	100%	94.6%

5. Discussion and Conclusion

5.1 Discussion

In this clinical trial with fresh samples, 1125 samples were taken from RT-PCR positive or negative patients, and the samples were eluted using the sample extraction solution matched with this reagent. Among them, 600 cases of "case group" samples and 525 samples of "control group" were determined by nucleic acid detection. Among them, 584 positive samples and 520 negative samples were detected by the assessment reagent. The positive coincidence rate of the assessment reagent was 97.3%, and the negative coincidence rate was 99%.

5.2 Conclusion

In summary, the detection results of Diagnostic Kit for RapidFor™ SARS-CoV-2 Rapid Antigen Kit (Collaidal Gold) developed by Vitrosens Biotechnology Co, Ltd. 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.