SG Diagnostics

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Clinical Study on the SG Diagnostics Covid-19 Antigen Rapid Test Kit (Colloidal Gold-Based)

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1. BACKGROUND

The test kit is applicable to detect the antigen of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS- CoV-2) Antigen in human throat swab, Nasal swab samples. This kit is a rapid and convenient immune- chromatographic assay for the qualitative detection of SARS-COV-2 antigen (viral nucleoprotein).

2. SUMMARY OF THE ASSAY

Coronavirus are enveloped RNA viruses that are distributed broadly among humans, birds and other mammals, that cause respiratory, enteric, hepatic, and neurologic diseases. Six Coronavirus species are known to cause human disease. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, sever acute respiratory syndrome, kidney failure and even death.

The pathogen of novel coronavirus pneumonia is the novel coronavirus. WHO has officially named the disease as corona virus diseases 2019 (COVID-19). SG Diagnostics Covid-19 Antigen Rapid Test Kit (Colloidal Gold-Based) is an antigen-capture immunochromatographic assay, detecting presence of COVID-19 viral nucleoprotein antigen in human throat swab, Nasal swab samples. he double antibody sandwich method is adopted in the product, and measurement is conducted in the form of solid-phase immune chromatography. The sample to be tested will diffuse upwards at the charging end under capillary action, and then SARS-COV-2 antigen in the sample will combine with the antibody in the marker pad and form colloidal gold antibody-antigen complex; The complex continues to diffuse to the nitrocellulose membrane with the sample, and then blocked by T-line (test line) packed with antibody, and form colloidal gold labeled antibody- antigen-immune complex packed with antibody. The rest unblocked colloidal gold complex continues to move upwards and combine with C-line (quality control line), indicating that the reaction is completed.

3. CLINICAL TRIAL DESIGN

Following the technical guideline, comparative analysis was performed for the data and results, to evaluate the performance of the test kit. Testing results were freshly collected and analyzed by comparing with qPCR test results. A total of 1194 cases were included, of which 206 (17.25%) were confirmed by qPCR diagnosis as positive and 988 (82.74%) as negative.

4. OVERVIEW OF CLINICAL DATA

The SG Diagnostics Covid-19 Antigen Rapid Test Kit (Colloidal Gold-Based) was validated using clinical samples in Philippines, Italy, Spain and Hungary. The test was validated against secretions extracted from human throat swab or nasal swab consisting of 206 positive and 988 negative swab samples.

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Tests breakdown:

Country	Total test	Positive	Percentage	Negative	Percentage
Hungary	94	49	52%	45	48%
Italy	100	4	4%	96	96%
Spain	200	70	35%	430	65%
Philippines	500*	83	17%	417	83%

* for both symptomatic and asymptomatic, ratio is ~ 9:1

The results are shown below:

Method		RT-qPCR		Total
		Positive	Negative	
SG Diagnostics Covid-19 Antigen Rapid Test Kit	Positive	201	7	208
	Negative	5	981	986
Total		206	988	1194

Sensitivity: 97.57% (95%CI:94.45%~98.96%)
Specificity: 99.29% (95%CI:98.54%~99.66%)
Total agreement: 98.99% (95%CI:98.25%~99.42%)
PPV: 96.63%
NPV: 99.27%