ichroma™ COVID-19 Ag Interim Report on Clinical Evaluation

I. Purpose

This study was conducted to evaluate the clinical sensitivity & clinical specificity using definite diagnosis reagent and ichroma™ COVID-19 Ag. Also this study is aimed to Evaluation of correlation between RT-PCR and Immunoassay (Antigen and Antibody) for Coronavirus Disease 2019 (COVID-19)

II. Materials

- Test Cartridge: 1 lot of ichroma™ COVID-19 Ag
- Test Analyzer: ichroma™ II
- Definite diagnosis Reagent (Coronavirus Disease 2019 real-time reverse transcription PCR)
  : Allpex™ 2019-nCoV Assay (Manufacturer: Seegene Inc.)
- Definite diagnosis Analyzer: CFX96™ real-time PCR System (Manufacturer: Bio-rad)
- Number of Samples: 186 ea

III. Test Method

Among the remaining samples to be discarded after a regular test, which have been requested at Uzbekistan and Korea, samples with positive and negative coronavirus infection-19, positive and negative influenza, and positive and negative for other respiratory diseases are anonymized and used. Samples can be used within 14 days when stored in a refrigerator (2~8℃) and within 1 year when stored in a frozen (-20℃).

Anonymous residual samples are randomly assigned and delivered to clinical trial research personnel. The person in charge of clinical trial research measures using each measurement method and writes a case report. The person in charge of the clinical trial performs the test using each test method, then prepares a case report and delivers it to the person in charge of the clinical trial.

The clinical trial director uses the principles of the immunological measurement method produced by the researcher, and the lateral flow-based fluorescence immunoassay (FIA). The values of ichroma™ COVID-19 Ag produced using the existing confirmed method of Seegene's Coronavirus Infectious Disease-19 real-time reverse transcription polymerase chain reaction (Coronavirus Disease 2019 real-time reverse transcription PCR) results to compare and evaluate. The medical devices used in the clinical trial are as follows. The tests were conducted according to established standard test procedure using ichroma™ COVID-19 Ag. All samples were tested using Test Cartridge, Definite diagnosis Reagent.

IV. Result

*** Coronavirus Disease 2019 real-time reverse transcription PCR & ichroma™ COVID-19 Ag**

		RT-PCR		Total
		Positive	Negative	
ichroma™ COVID-19 Ag	Positive	94	2	96
	Negative	10	80	90
Total		104	82	186

*Clinical Sensitivity (%) = 90.4 % (95% CI: 83.2% ~ 94.7%)

*Clinical Specificity (%) = 97.6 % (95% CI: 91.5% ~ 99.3%)