



CLINICAL STUDY REPORT OF COVID-19 ANTIGEN SALIVA TEST CASSETTE

Testing Hospital: 安徽医科大学第一附属医院

Applicant: Multibrands International Ltd.

1. Purpose of the test

Through test on certain quantity of representative clinical specimens, and scientific and rational statistic analysis on the test result, evaluate the consistency of the result of COVID-19 Antigen Test Cassette produced by Multibrands Trading (Suzhou) Co., Ltd. and compare with RT-PCR product Shanghai ZJ Bio-Tech Co., Ltd., and evaluate its clinical application capacity.

2. Overall design of the test

The test of parallel contrast is adopted, and RT-PCR similar product which has been launched is taken as comparison device. The COVID-19 Antigen Test Cassette produced by our company and the comparison device will parallel test on the same specimens, and the result will be recorded respectively.

3. Study method

A clinical study is received in which the estimation of the parameters of sensitivity, specificity of the test and Kappa index is observed. However, it is necessary to estimate all the complete parameters for the performance of the diagnostic test (sensitivity, specificity, positive predictive value and negative predictive value) and include the estimated Kappa index. The information should be presented in charts with its analysis and interpretation of the results

3.1 Specimens size and its confirmation basis

To investigate the function of product, a side-by-side comparison was conducted using The COVID-19 Antigen Test Cassette and a commercially available COVID-19 RT-PCR. Testing was performed on 291 clinical specimens previously collected from subjects present for COVID-19 IgG/IgM Testing. Allow the test, the Nasal Swab Specimen to reach room temperature (15-30℃) prior to testing.

3.2 Selection of specimen

The samples were selected from medical institution. To protect the privacy of the specimen suppliers, the providers' name shouldn't appear in the test record.

3.3 The selection of comparison device and confirmation method

RT-PCR product (Novel Corona virus (SARS-CoV-2) Real Time Multiplex RT-PCR Kit) is selected as the comparison method, and the PCR product from Shanghai ZJ Bio-Tech Co.,Ltd. and the infection time information will be a supplementary explanation.



4. Clinical test result

4.1 Positive result

NO.	PCR	COVID-19 Antigen
Positive1#	+	+
Positive2#	+	-
Positive3#	+	+
Positive4#	+	+
Positive5#	+	+
Positive6#	+	+
Positive7#	+	+
Positive8#	+	+
Positive9#	+	+
Positive10#	+	+
Positive11#	+	+
Positive12#	+	+
Positive13#	+	+
Positive14#	+	+
Positive15#	+	+
Positive16#	+	+
Positive17#	+	+
Positive18#	+	+
Positive19#	+	+
Positive20#	+	+
Positive21#	+	+
Positive22#	+	+
Positive23#	+	+