



浙江东方基因生物制品股份有限公司
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Home Use Consumers Self-testing Study Report
Coronavirus Ag Rapid Test Cassette (Swab)
For rapid detection of SARS-CoV-2

1. Background Information

The Coronavirus Ag Rapid Test Cassette (Swab) is intended for use by healthcare professionals or other trained operators who are proficient in performing rapid tests. Equally, healthcare professionals & trained operators can oversee non-trained personnel to undertake the test themselves as long as its carried out in a supervised capacity.

2. Purpose

The purpose of this study was to evaluate product suitability to be used for testing nasal swab sample by the home use consumers (lay persons). And evaluate whether the swab breaks during nasal sampling.

3. Study Design

A total of 1200 subjects (lay persons) with diverse educational and with ages ranging from 18 and 65 years were recruited to perform the test. Each subject would obtain one Coronavirus Ag Rapid Test Cassette (Swab) kit and a questionnaire.

Each subject tested their own nasal swab samples using the kit refer to the kit package insert instructions. Then, healthcare professionals or trained operators would collect nasal swab samples from the subjects and test. Compare the test results of subjects and healthcare professionals or trained operators.

Healthcare professionals can train people to be trained to become trained operators.

According to the package insert, the healthcare professionals guides the personnel to be trained to familiarize themselves with the operation process of the product. After about 0.5 hours of familiarization and learning, the personnel to be trained can be proficient in product testing, and test positive quality control swabs and negative control swabs. The test results are consistent with the expected results and become trained operators.

4. Questionnaire compilation

To record the test and evaluate the test, a questionnaire was drafted. It mainly concentrated on personal information and user test procedure.

- Personal information: It is a record of the subjects.
- Test procedure: This is to evaluate if the package insert can direct lay persons to perform the test correctly.
- Reading results by the lay persons: According to the characteristics of IVDs, the possible results includes: ① Positive result (+); ② Negative result(-); ③ No result(Invalid).

- Whether the swab breaks during nasal sampling.

5. Material

Coronavirus Ag Rapid Test Cassette (Swab) kit

Lot: 2012056

Product specifications:

- 1 Test Cassette
- 1 Extraction Tube with Buffer and Tip
- 1 Sterile Nasal Swab(The molded break point is 4cm from the tip of the swab)
- 1 Package Insert

6. Procedure

The 1200 subjects were recruited from intended use site for the study, including 300 people recruited from the hospital and 900 from the community.

Hospital usage scenarios: Our product kit and questionnaires are provided to the hospital, and then the hospital laboratory technician provided its to the subject for self-testing using nasal swab sample and records the questionnaire. Then, the hospital laboratory technician collects the subject's nasal swab sample for testing and records the result.

Community Recruiters' Usage Scenes: Our products and questionnaires are provided to the subject, who collected their own nasal swab sample and sample preparation and testing by themselves and record the results. Then, our healthcare professionals or trained operators collect the subject's nasal swab sample for testing and record the results.

7. Acceptable Criteria

During the nasal sampling process, the swab did not break.

The agreement rate between home use consumers (lay persons) and healthcare professionals or trained operators is $\geq 95\%$.

8. Results

Table 1: The results of Lay persons vs. Healthcare professionals or Trained operators

		Lay persons		Total
		Positive	Negative	
Healthcare professionals or Trained operators	Positive	156	0	156
	Negative	0	1044	1044
	Total	156*	1044	1200
	Agreement Rate	100%	100%	

*All subjects with positive results are from the hospital usage scenarios, these included 81 asymptomatic infections.

The subjects with diverse educational and age ranges refer to from Table 2 to Table 3.

Table 2: Educational Backgrounds of the Subjects

Educational Backgrounds	Number of Subjects	% of total
Primary school	115	9.6%

Middle school	614	51.2%
High school	148	12.3%
Junior college	160	13.3%
Bachelor and above	161	13.4%
Others	2	0.2%

Table 3: Age distribution of the Subjects

To be clearer about the results, the subject' age ranges were divided into three parts.

Age group	Number of Subjects	% of total
18~35	492	41.0%
36~45	317	26.4%
46~65	391	32.6%

9. Conclusions

A total of 1200 subjects participated this study, during the nasal sampling process, there were no swab breaks. The study results demonstrated 100% agreement between home use consumers (lay persons) and healthcare professionals or Trained operators.

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