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Clinical Evaluation Report of LumiQuick QuickProfile™ COVID-19 Antigen Test Card

Purpose

To evaluate the clinical diagnosis ability and the in-use effectiveness of the QuickProfile™ COVID-19 Antigen Test Card

Background and Scope

To expand the clinical validation of QuickProfile™ COVID-19 Antigen Test Card for more accurate representative clinical data, LumiQuick is collaborating with hospitals, laboratories and business partners in different countries to conduct testing on clinical positive and negative samples. Because SARS-CoV-2 virus has many variants in different countries and region, the study will help to validate the application of QuickProfile™ COVID-19 Antigen Test Card on diagnosis of COVID-19 disease for global demands.

The evaluation includes both Nasopharyngeal and Anterior Nasal samples to validate the product can provide the flexibility of the sampling method for better and easier testing of SARS-CoV-2 virus in human nasal samples.

Materials

Test Reagent: QuickProfile™ COVID-19 Antigen Test Card, Catalog# 71110

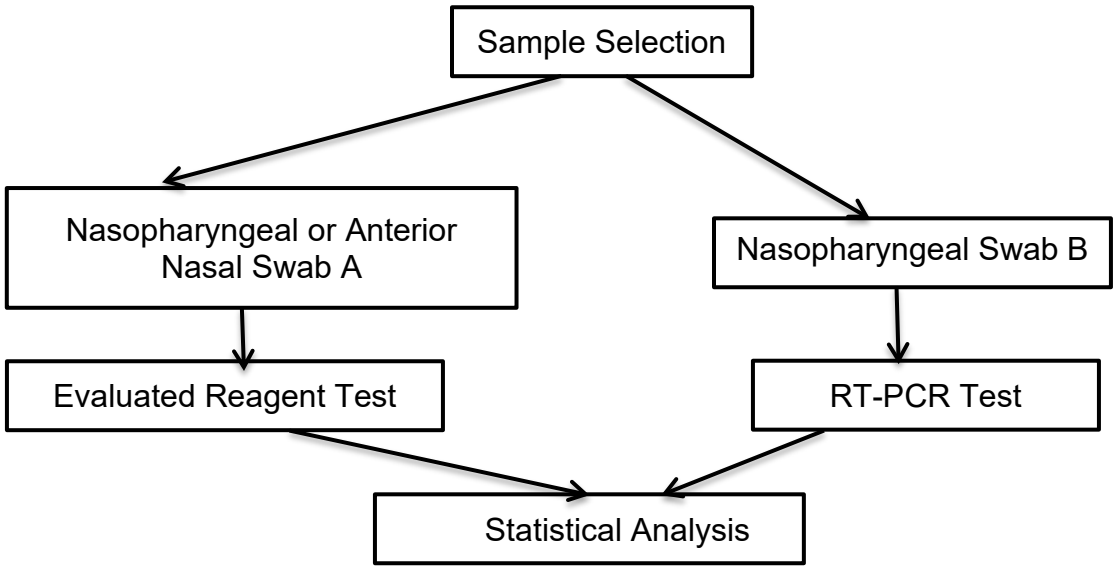
Manufacturer: LumiQuick Diagnostics, Inc. USA (LQ)

Reference Reagent: SARS-CoV-2 RT-PCR Test.

Experiment Design

1. Overall Experiment Design and Plan

In this clinical trial, blind data analysis was adopted and the QuickProfile™ COVID-19 Antigen Test Card manufactured by LumiQuick Diagnostics, Inc. was used to compare and study the detection results of the samples with the RT-PCR method. The proposed test process is as follows:



2. Clinical Trial Sites

Due to the limitation of clinical samples each trial site can provide, the studies can be performed at multiple sites.

3. Sample Collection

Collect samples separately according to the instructions for use for the test.

Different sample types can come from different patients.

3.1 Sample type: nasopharyngeal and anterior nasal samples

3.2 Sample requirements: the majority of samples will be disease onset within 1-7 days or asymptomatic; sample quantity shown in the table below:

		Nasal Samples
Positive	LQ	≥100 (a small number of samples with Ct value ≥ 30 are needed)
Negative	LQ	≥100

3.3 Sample collection procedures

Anterior nasal samples

1. Carefully insert the swab into the nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril.
2. Swab along the mucosa inside the nostril to ensure that both mucus and cells are collected.

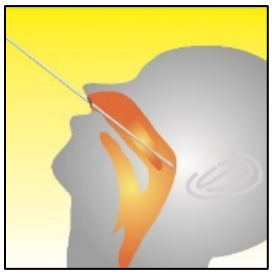
Rotate the swab several times.

3. Withdraw the swab from the nasal cavity.

Note: The samples collected with the RT-PCR viral extraction buffer cannot be used for testing with LQ test reagents.

Nasopharyngeal swab specimens:

1. Carefully insert the sterile swab into the nostril that presents the most secretions under visual inspection.
2. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx.
3. Rotate the swab several times then remove it from the nasopharynx.



3.4 Sample Selection and Exclusion Criteria

1. Inclusion Criteria:
   a. No limitation on gender and age.
   b. The information of the samples can be completely traced.
2. Exclusion Criteria:
   a. Insufficient sample size.
   b. Improper storage of samples.
   c. Others deemed reasonable by the principal investigator.
3. Rejection Criteria:

a. Incomplete case history or failure to meet the inclusion criteria.

b. The normal test cannot be completed due to equipment or operation factors (the sample is contaminated during operation and the sample size is insufficient).

c. Samples deemed inappropriate by the principal investigator.

4. Experiment and Data Entry

1. Prepare samples according to the instructions for use for the test
2. Carry out the tests in a timely manner
3. Report the results of both RT-PCR, QuickProfile™ COVID-19 Antigen Test Card and other available sample information

5. Statistical Analysis Methods

The sensitivity, specificity, accuracy and confidence interval were calculated by comparing the detection results of Evaluated Reagent with RT-PCR (see Table 1).

Table 1 Comparison of test results for the Evaluated Reagent and RT-PCR

RT-PCR Confirmed samples	Sample Number	QuickProfile™ COVID-19 Antigen Test Card Results		Agreement %
		Positive	Negative	
Positive	A	B	C	B/A
Negative	D	E	F	F/D
Total	A+D	B+E	C+F	

Clinical sensitivity = B/A x 100%

Clinical specificity = F/D x 100%

Positive predictive value (PPV) = B/(B+E) x 100%

Negative predictive value (NPV) = F/(C+F) x 100%

CI 95% = $p \pm 1.96 \times [p(1-p) / n]^{1/2}$

P = calculated value, n = total sample number in the group

6. Result Statistical Summary

6.1 Spectrum Dx Laboratory, Santa Margarita, California, USA

Sample type: Nasopharyngeal swab

RT-PCR Test: Allplex™2019-nCoV Assay, Seegene

Study complete date: March 5th, 2021

RT-PCR Confirmed samples	Sample Number	QuickProfile™ COVID-19 Antigen Test Card Results		Agreement
		Positive	Negative	
Asymptomatic positive	33	31	2	93.9%
Symptomatic positive	16	15	1	93.8%
Negative	36	0	36	100%
Total	85	46	39	93.9%

6.2 Montefiore, The University Hospital for Albert Einstein College of Medicine, New York City, New York, USA

Sample type: Nasopharyngeal swab

RT-PCR Test: RealStar®SARS-CoV-2, Altona Diagnostics

Study complete date: February 2nd, 2021

RT-PCR Confirmed samples	Sample Number	QuickProfile™ COVID-19 Antigen Test Card Results		Agreement
		Positive	Negative	
Symptomatic positive	51	49	2	96.1%
Negative	51	0	51	100%
Total	102	49	53	98%

6.3 Center for Applied Proteomics and Molecular Medicine, CLIA Certified Lab, George Mason University, Virginia, USA

Sample type: Anterior nasal swab

RT-PCR Test: COVID-19 Multiplex PCR Assay, ThermoFisher Scientific

Study complete date: January 15th, 2021

RT-PCR Confirmed samples	Sample Number	QuickProfile™ COVID-19 Antigen Test Card Results		Agreement
		Positive	Negative	
Asymptomatic positive	1	1	0	100%
Symptomatic positive	1	1	0	100%
Negative	35	0	35	100%
Total	37	2	35	100%

6.4 Ankara Dr. Nafiz Korez Sincan State Hospital, Ankara, Turkey

Sample type: Anterior nasal swab

RT-PCR Test: Diagnovital HS SARS-CoV-2 RT PCR, RTA Laboratories

Study complete date: February 24th, 2021

RT-PCR Confirmed samples	Sample Number	QuickProfile™ COVID-19 Antigen Test Card Results		Agreement
		Positive	Negative	
Symptomatic positive	51	50	1	98%
Negative	50	0	50	100%
Total	51	50	1	98%

6.5 Xiamen Boson Biotech, Ltd., Xiamen, Fujian, China

Sample type: Nasopharyngeal swab

RT-PCR Test: 2019-nCoV Nucleic Acid Detection Kit, Beijing Kinghawk Pharmaceutical Co., Ltd.

Study complete date: February 10th, 2021

RT-PCR Confirmed samples	Sample Number	QuickProfile™ COVID-19 Antigen Test Card Results		Agreement
		Positive	Negative	
Symptomatic positive	0	0	0	
Negative	209	2	207	99%
Total	209	2	207	99%

6.6 Summary of all site results

RT-PCR Confirmed samples	Sample Number	QuickProfile™ COVID-19 Antigen Test Card Results		Agreement
		Positive	Negative	
Asymptomatic positive	34	32	2	94.1%
Symptomatic positive	119	115	4	96.6%
Negative	381	2	379	99.5%
Total	534	149	385	

Clinical sensitive = (32 +115)/(34+119)=147/153= 96.1% (CI 95%: 94.5% - 97.7%)

PPV = (32+115)/(32+115+2) = 147/149=98.7% (CI95%: 97.8% - 99.6%)

Clinical specificity = 3379/381 = 99.5% (CI 95% 99.1% - 99.9%)

NPV = 379/(2+4+379) = 98.4% (CI 95% 97.8% - 99.0%)

6.7 Summary of results based on sample types

RT-PCR Confirmed samples	Sample Number	QuickProfile™ COVID-19 Antigen Test Card Results		Agreement
		Positive	Negative	
Nasopharyngeal Positive	100	95	5	95.0%
Anterio Nasal Positive	53	52	1	98.1%
Nasopharyngeal Negative	296	2	294	99.3%
Anterio nasal Negative	85	0	85	100%
Total	534	149	385	

3.8 Summary of clinical sensitivity by days after symptom onset

Days after onset of symptoms	Sample Number	QuickProfile™ COVID-19 Antigen Test Card Results		Agreement
		Positive	Negative	
Asymptomatic or Symptomatic ≤ 7 days	115	110	5	95.7%
Symptomatic ≥ 8 days	38	37	1	97.4%
Total	153	147	6	96.1%

6.9 Summary of clinical sensitivity by RT-PCR Ct Value

RT-PCR Ct Value	Sample Number	QuickProfile™ COVID-19 Antigen Test Card Results		Agreement
		Positive	Negative	
≤ 30	108	107	1	99.1%
≥ 30	45	40	5	88.9%
Total	153	147	6	96.1%

7. Conclusion

7.1 There are a total of one hundred and fifty-three (153) RT-PCR confirmed SARS-CoV-2 samples and three hundred and forty-five (345) RT-PCR confirmed SARS-CoV-2 negative samples tested independently at multiple sites. The overall sensitivity, positive predictive value (PPV), specificity, negative predictive value (NPV) are summarized below:

Clinical sensitivity = (32 +115)/(34+119)=147/153= 96.1% (CI 95%: 94.5% - 97.7%)
PPV = (32+115)/(32+115+2) = 147/149=98.7% (CI95%: 97.8% - 99.6%)
Clinical specificity = 379/381 = 99.5% (CI 95% 99.1% - 99.9%)
NPV = 379/(2+4+379) = 98.4% (CI 95% 97.8% - 99.0%)

7.2 The results from one hundred and fifteen (115) samples either are asymptomatic or 1-7 days after the onset of the symptoms showed 95.7% sensitivity. This group is the most important group for the early detection of SARS-CoV-2 virus infection.

7.3 Both sampling methods, nasopharyngeal and anterior nasal swabs, can be used for QuickProfile™ COVID-19 Antigen Test Card. Anterior nasal swab sample is easier for the collection. It provides the convenience for the point-of-care or home test application.

7.4 The results based on RT-PCR Ct value showed the sensitivity for samples with Ct value less than 30 is 99.1%. The sensitivity for the samples with Ct value equal or higher than 30 is 88.9%.