Report

SELF-TEST EVALUATION
MP BIOMEDICALS Germany GmbH

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SUMMARY

In this report, the user-acceptability, feasibility and test outcome of self testing by laymen were evaluated using the Rapid SARS-CoV-2 Antigen Test Card from MP Biomedicals. The evaluation included observation, participant questionnaires and reference testing by healthcare professionals. A total of 100 persons participated. The concordance of results between laymen self-testing vs professional testing was 99%. The majority of participants considered the test very easy or easy to perform, and found the instructions to be very easy or easy to interpret. All participants were considered capable of independent home testing.

INTRODUCTION

The fall of 2019, several patients with severe respiratory infections were admitted to hospitals in Wuhan in the Hubei province in China. The causative agent was shown to be a new coronavirus, SARS-CoV-2. Its global impact has so far been great, with nearly 115 million cases and about 2,6 million deaths. The complex features of this viral disease makes it difficult to control. To reduce the number of cases, it is necessary to identify and isolate infected persons as fast as possible.

Diagnosis is made by detecting the virus in respiratory secretions by RT-PCR. During the last months, antigen detecting rapid diagnostics tests (Ag-RDTs) for COVID-19 have also become commercially available. These tests are usually lateral flow immunoassays (LFIA). Ag-RDT are inexpensive and relatively easy to use. Some countries allow self-testing with Ag-RDT, most recently Germany. In order to reduce the risk of faulty results and adverse outcomes when conducting self-testing by laymen, these tests should come with clear instructions and user-friendly test-kit components.

The objective of this report was to evaluate the user-acceptability and if the test results of Ag-RDT were comparable between a layman and a healthcare professional.

MATERIALS AND METHODS

Settings

This was a manufacturer-independent prospective evaluation. It was performed in Uppsala and Örebro, Sweden, during February - March 2021. Principals were physicians working at Uppsala and Örebro University Hospitals. Individuals eligible for inclusion were asymptomatic persons aged 14 years or older. Participants were required to understand the written instructions in English or Swedish. Language proficiency was judged based on participants' information and assessment by the principal physicians. Participants were excluded if any of the swab specimens could not be collected, or if the participants had previous experience with self-testing. Participants were enrolled until the required number of 100 was reached.

Index test Ag-RDT

The Ag-RDT evaluated was the Rapid SARS-CoV-2 Antigen Test Card from MP Biomedicals Germany GmbH (MP Biomedicals). The test is commercially available for naso- and oropharyngeal as well as anterior nasal sampling. The swabs included in the test kit were flocked nylon swabs.

Evaluation procedures

Focus was on the following:

1. Ability of laypersons to conduct self-sampling correctly.
2. Ability of laypersons to analyze and interpret the results correctly.
3. Percentage of agreement between the results obtained when the tests were conducted by a layperson and a healthcare professional.

After providing informed consent, the participants received a written and illustrated instruction for self-sampling and self-testing in English, adapted from the manufacturer's instructions for use (IFU). The same IFU in Swedish was also available. Participants performed the procedures without time restrictions. The procedures were observed by a principal physician without answering questions or providing corrections. Deviations from the instructions were recorded in a healthcare professional questionnaire. (See questionnaire in appendix below). The participants were allowed a second attempt if desired.

Nasal self-sampling (both nostrils) and testing was conducted by the layperson. The result of the self-testing was interpreted by the layman first and thereafter by the physician.The visual read-out of the Ag-RDT test band was categorized as negative, positive or invalid.

Self-sampling

Each participant was provided with an adapted IFU document and a timer. In brief, sampling instructions were as follows:

Clear, clean and dry a flat surface.

Check the test kit contents. Make sure that nothing is damaged or broken.

Timer at hand.

Blow your nose several times before collecting specimen.

Wash hands.

Rotate the lid of the sample extraction buffer bottle. Caution: Open it away from your face and be careful not to spill any of the liquid.

Squeeze all extraction buffer out of the bottle into the extraction tube. Caution: Avoid touching the bottle against the tube.

Find the swab in the sealed wrapper in front of you. Identify the soft, fabric tip of the swab.

Peel open the swab packaging and gently take out the swab. Caution: Never touch the soft, fabric tip of the swab with your hands.

Carefully insert swab into one nostril. The swab tip should be inserted no less than 2.5 cm (1 inch) from the edge of the nostril. Roll swab 3-4 times along the mucosa inside the nostril. Leave the swab in the nostril for several seconds. Using the same swab, repeat this process for the other nostril.

Withdraw swab from the nasal cavity. Caution: This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.

Place swab into the extraction tube. Roll swab three to five (3-5) times. Leave swab in the extraction buffer for 1 minute.

Pinch the extraction tube with fingers and remove the solution from the swab as much as possible.

Install the nozzle cap onto the sample extraction tube tightly.

Self-testing

Each participant was provided with an adapted IFU document. In brief, the testing instructions were as follows:

Bring the kit components to room temperature before testing.

Open the pouch and remove the card. Place the card on a flat and level surface. Caution: Once opened, the test card must be used immediately.

Invert the extraction tube and add 3 drops (about 75 µL) of test specimen into the specimen well (S) by gently squeezing the extraction tube. Caution: The formation of air bubbles in the specimen well (S) must be avoided.

Read the results after 15-20 minutes. Caution: Results after 20 minutes may not be accurate.

Dispose of the used device according to your local regulations and biohazard waste disposal protocol.

Self-interpretation of results

Each participant was provided with an adapted IFU document. In brief, the self-interpretation instructions were as follows:

Positive: If two colored bands appear with one colored band in the Control Zone (C) and another in the Test Zone (T) within 15-20 minutes, the test result is positive.

Caution: No matter how faint the colored band is in the Test Zone (T), the result should be considered as positive.

Negative: If one colored band appears in the Control Zone (C) and no colored band appears in the Test Zone (T) within 15-20 minutes, the test result is negative.

Invalid: If no coloured line appears in the control area (C) within 15-20 minutes, the test is invalid. Repeat the test with a new test card.

Reference Ag-RDT

As a reference, testing was performed on the participant by a principal physician, according to the manufacturer's IFU. For the reference Ag-RDT, the test kit and components came from the same supplier (MP Biomedicals Germany GmbH) and were identical to the one used by the participant. After interpretation, the results were documented separately. A comparison was done after testing questionnaires were completed, in order to calculate the result agreement.

Additional data collection, user acceptability and feasibility

Participants filled out a paper-based questionnaire (see questionnaire in appendix below). Questions included were age, sex, education and language proficiency.

User acceptability and feasibility of self-sampling and self-testing were determined by participants on a scale from 1 (very easy) to 5 (very difficult). Additionally, personal factors making the procedure more difficult (e.g., visual impairment) and suggestions for improvement were recorded.

Statistical analysis

Test results by participants and healthcare professionals were compared in order to calculate the result agreements. Observation results were reviewed in order to determine if the self-sampling, self-testing and interpretation was conducted correctly. If deficiency was observed, an analysis was made to enable suggestions on improvement. Descriptive statistics were used for participant characteristics, user acceptability and feasibility assessment.

RESULTS

Participants

The participants had a median age of 40 years (range 17-75 years) and 65 were males and 35 females. The educational levels were as follows: 1 person had finished elementary school, 52 persons high school and 47 persons had completed higher education (university level). The level in English varied: very good (*n*=30), good (*n*=39), acceptable (*n*=27), bad (*n*=3) and very bad (*n*=1 person) . No participant had any prior self-testing experience, but two had experience from working in a laboratory setting.

Ag-RDT self-testing versus professional testing

The test agreement between self-testing vs professional testing was 99%. All participants and professionals had negative results apart from one participant having an invalid test (no migrating liquid in the cassette). When the test was repeated by the participant the results was negative, in concordance with the professional test.

In the observer questionnaires, seven remarks were made concerning sampling from only one nostril (*n*=4) and applying the sample incorrectly or excessively to the specimen well (*n*=3). The four participants sampling from one nostril corrected the error by themselves without interference from the observer. The remaining three, completed the self-testing successfully on a second attempt.

Feasibility of self-testing

All participants were considered capable of independent home testing in the healthcare professional questionnaire. In the participant questionnaires, 52 considered the test very easy to perform, 42 easy to perform and 6 acceptable. None considered the test to be difficult or very difficult to perform. Forty-eight considered the instructions very easy to interpret, 42 easy, 6 acceptable and 4 difficult. Thirty-six persons thought most people would have a very easy time learning to use the rapid test, 46 easy, 17 acceptable and 1 difficult. None thought it would be very difficult.

CONCLUSION

In this report, the user-acceptability, feasibility and test outcome of self testing by laymen were evaluated using the Rapid SARS-CoV-2 Antigen Test Card from MP Biomedicals. The evaluation included observation, participant questionnaires and reference testing by healthcare professionals. A total of 100 persons participated. The concordance of results between laymen self-testing vs professional testing was 99%. The majority of participants considered the test very easy or easy to perform, and found the instructions to be very easy or easy to interpret. Physicians determined that all participants were considered capable of independent home testing.

APPENDIX

Participant Questionnaire

We are very thankful for your participation in this evaluation. While waiting for the result of the antigen test ("rapid test"), please answer the following questions. We will evaluate your data pseudonymously, without being able to draw any conclusions about your person.

1. Age:
2. Sex:
3. Do you have any laboratory working experience, or experience in conducting rapid tests? _____ ❑YES ❑NO

Test evaluation scale from 1 to 5, only one mark per question

4. How easy/difficult did you find it to perform the rapid antigen test?
   ❑1 ❑2 ❑3 ❑4 ❑5
   (1= very easy) (5=very difficult)

5. How understandable did you find the instructions?
   ❑1 ❑2 ❑3 ❑4 ❑5
   (1=very easy) (5=very difficult)

6. How easy/difficult do you think most people can learn to use the rapid antigen test?
   ❑1 ❑2 ❑3 ❑4 ❑5
   (1= very easy) (5=very difficult)

7. Was there a personal reason that made it difficult for you to perform the test? (e.g. visual impairment, disturbance of fine motor skills)?

   _____

8. Do you have a suggestion for improvement to simplify the test?

   _____

9. School / education
   What is your highest general school qualification?
   _____

10. What is your level of English?

    ❑ Very bad ❑ bad ❑ acceptable ❑good ❑very good

Healthcare Professional Questionnaire

Part A – Self sampling of the anterior nose

Observation form

Observer: _____
ID:_____
Date: _____

Important: No verbal or non-verbal assistance/correction should be given
Exception: Actively encourage hand disinfection

1. Checked test components? ❑YES ❑NO
2. Participant blew their nose? ❑YES ❑NO
3. Extraction buffer added to extraction tube? ❑YES ❑NO
4. Swab opened correctly? ❑YES ❑NO
5. Touching the tip? ❑YES ❑NO
6. Depth of swab in nostril approx. 2.5 cm? ❑YES ❑NO
7. At least 3x rotation? ❑YES ❑NO
8. Rubbed against nose walls? ❑YES ❑NO
9. Both nostrils? ❑YES ❑NO
   Other:

Part B – Self Testing & Interpretation

Important: No verbal or non-verbal assistance/correction should be given
Exception: Actively encourage hand disinfection
Test result is requested from the participant at the end

1. Inserted swab correctly into extraction tube? ❑YES ❑NO
2. Rotated the swab at least 3 times? ❑YES ❑NO
3. Left swab in extraction buffer 1 minute? ❑YES ❑NO
4. Squeezed the extraction tube? ❑YES ❑NO
5. Pressed cap onto tube? ❑YES ❑NO
6. Removed test card from pouch? ❑YES ❑NO
7. Correct amount of drops (2-3)? ❑YES ❑NO
8. Drops put into correct field on test cassette (specimen well, not result window)? ❑YES ❑NO
9. Read test result after 15 min (max 20 min)? ❑YES ❑NO
10. Interpreted test result correctly? ❑YES ❑NO
11. Second try? If yes, why? ❑YES ❑NO
12. Other deviations? If yes, which? ❑YES ❑NO
13. Linguistic comprehension problems of the instructions? ❑YES ❑NO
14. Content-related comprehension problems of the instructions? ❑YES ❑NO

Test Result:

How does the **PARTICIPANT** interpret the test result?

❑negative ❑positive ❑invalid ❑does not know
comment:

How does the **PHYSICIAN** interpret the test result?

❑negative ❑positive ❑invalid ❑does not know
comment:

Application:
Do you consider the participant to be capable of independent home testing?
❑YES ❑NO

other:

Table1 : Participant results per age, sex, self-test interpretation and physician determination.

Nr.	Age	Sex	Self-Test Interpretation		Physician Determination		
			Participant	Physician	Sampling Ability	Interpretation Ability	Self-testing Ability
1	32	M	Negative	Negative	Capable	Capable	Capable
2	30	F	Negative	Negative	Capable	Capable	Capable
3	40	M	Negative	Negative	Capable	Capable	Capable
4	33	F	Negative	Negative	Capable	Capable	Capable
5	37	M	Negative	Negative	Capable	Capable	Capable
6	32	F	Negative	Negative	Capable	Capable	Capable
7	24	F	Negative	Negative	Capable	Capable	Capable
8	64	M	Negative	Negative	Capable	Capable	Capable
9	60	F	Negative	Negative	Capable	Capable	Capable
10	75	M	Negative	Negative	Capable	Capable	Capable
11	49	M	Negative	Negative	Capable	Capable	Capable
12	35	M	Negative	Negative	Capable	Capable	Capable
13	34	M	Negative	Negative	Capable	Capable	Capable
14	39	M	Negative	Negative	Capable	Capable	Capable
15	29	F	Negative	Negative	Capable	Capable	Capable
16	32	F	Negative	Negative	Capable	Capable	Capable
17	50	M	Negative	Negative	Capable	Capable	Capable
18	51	F	Negative	Negative	Capable	Capable	Capable
19	54	M	Negative	Negative	Capable	Capable	Capable
20	56	M	Negative	Negative	Capable	Capable	Capable
21	27	F	Negative	Negative	Capable	Capable	Capable
22	28	M	Negative	Negative	Capable	Capable	Capable
23	43	F	Negative	Negative	Capable	Capable	Capable
24	53	M	Negative	Negative	Capable	Capable	Capable
25	44	M	Negative	Negative	Capable	Capable	Capable
26	48	M	Negative	Negative	Capable	Capable	Capable
27	23	M	Negative	Negative	Capable	Capable	Capable
28	26	F	Negative	Negative	Capable	Capable	Capable
29	47	F	Negative	Negative	Capable	Capable	Capable
30	56	M	Negative	Negative	Capable	Capable	Capable
31	46	M	Negative	Negative	Capable	Capable	Capable
32	41	F	Negative	Negative	Capable	Capable	Capable
33	28	M	Negative	Negative	Capable	Capable	Capable
34	56	M	Negative	Negative	Capable	Capable	Capable
35	47	F	Negative	Negative	Capable	Capable	Capable
36	42	M	Negative	Negative	Capable	Capable	Capable
37	26	M	Negative	Negative	Capable	Capable	Capable
38	49	M	Negative	Negative	Capable	Capable	Capable
39	35	F	Negative	Negative	Capable	Capable	Capable
40	56	M	Negative	Negative	Capable	Capable	Capable

41	25	M	Negative	Negative	Capable	Capable	Capable
42	20	M	Negative	Negative	Capable	Capable	Capable
43	35	F	Negative	Negative	Capable	Capable	Capable
44	42	F	Negative	Negative	Capable	Capable	Capable
45	16	F	Negative	Negative	Capable	Capable	Capable
46	27	M	Negative	Negative	Capable	Capable	Capable
47	17	F	Negative	Negative	Capable	Capable	Capable
48	30	M	Negative	Negative	Capable	Capable	Capable
49	49	F	Negative	Negative	Capable	Capable	Capable
50	45	M	Negative	Negative	Capable	Capable	Capable
51	53	M	Negative	Negative	Capable	Capable	Capable
52	58	M	Negative	Negative	Capable	Capable	Capable
53	40	M	Negative	Negative	Capable	Capable	Capable
54	37	M	Negative	Negative	Capable	Capable	Capable
55	62	M	Negative	Negative	Capable	Capable	Capable
56	47	M	Negative	Negative	Capable	Capable	Capable
57	40	M	Negative	Negative	Capable	Capable	Capable
58	44	M	Negative	Negative	Capable	Capable	Capable
59	23	F	Negative*	Negative	Capable	Capable	Capable
60	60	F	Negative	Negative	Capable	Capable	Capable
61	29	M	Negative	Negative	Capable	Capable	Capable
62	42	M	Negative	Negative	Capable	Capable	Capable
63	28	M	Negative	Negative	Capable	Capable	Capable
64	37	M	Negative	Negative	Capable	Capable	Capable
65	19	M	Negative	Negative	Capable	Capable	Capable
66	34	M	Negative	Negative	Capable	Capable	Capable
67	43	M	Negative	Negative	Capable	Capable	Capable
68	44	F	Negative	Negative	Capable	Capable	Capable
69	21	M	Negative	Negative	Capable	Capable	Capable
70	19	F	Negative	Negative	Capable	Capable	Capable
71	24	M	Negative	Negative	Capable	Capable	Capable
72	25	F	Negative	Negative	Capable	Capable	Capable
73	36	F	Negative	Negative	Capable	Capable	Capable
74	33	M	Negative	Negative	Capable	Capable	Capable
75	40	F	Negative	Negative	Capable	Capable	Capable
76	45	M	Negative	Negative	Capable	Capable	Capable
77	41	M	Negative	Negative	Capable	Capable	Capable
78	31	M	Negative	Negative	Capable	Capable	Capable
79	46	M	Negative	Negative	Capable	Capable	Capable
80	35	M	Negative	Negative	Capable	Capable	Capable
81	27	M	Negative	Negative	Capable	Capable	Capable
82	34	M	Negative	Negative	Capable	Capable	Capable
83	27	F	Negative	Negative	Capable	Capable	Capable
84	25	M	Negative	Negative	Capable	Capable	Capable
85	31	M	Negative	Negative	Capable	Capable	Capable
86	32	F	Negative	Negative	Capable	Capable	Capable

87	59	M	Negative	Negative	Capable	Capable	Capable
88	30	F	Negative	Negative	Capable	Capable	Capable
89	65	F	Negative	Negative	Capable	Capable	Capable
90	52	F	Negative	Negative	Capable	Capable	Capable
91	52	F	Negative	Negative	Capable	Capable	Capable
92	50	M	Negative	Negative	Capable	Capable	Capable
93	51	M	Negative	Negative	Capable	Capable	Capable
94	44	M	Negative	Negative	Capable	Capable	Capable
95	47	M	Negative	Negative	Capable	Capable	Capable
96	73	M	Negative	Negative	Capable	Capable	Capable
97	30	M	Negative	Negative	Capable	Capable	Capable
98	64	F	Negative	Negative	Capable	Capable	Capable
99	46	F	Negative	Negative	Capable	Capable	Capable
100	65	M	Negative	Negative	Capable	Capable	Capable

*Participant's first attempt was invalid. Upon second attempt test result was negative.