

Report 2: Evaluation of 17 rapid tests for detection of antibodies against SARS-CoV-2

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1 Summary

Background

SARS-CoV-2, the virus causing COVID-19, has emerged to cause a human pandemic. Detection of SARS-CoV-2 in respiratory samples by using PCR is the standard laboratory diagnostic tool. Immunological tests detecting antibodies (immunoglobulins type M (IgM) and/or IgG or total antibodies) against SARS-CoV-2 have also become available, including many rapid tests (point-of-care tests). In most cases, the rapid tests come with limited documentation and without independent evaluation.

Objective

Our aim was to evaluate the diagnostic accuracy of 17 rapid tests for detection of antibodies against SARS-CoV-2, and specifically their abilities to confirm past COVID-19.

Methods

We calculated the sensitivities of the antibody detecting rapid tests using serum samples from 65 recovered PCR-confirmed COVID-19 patients who had not required hospitalization. We calculated specificities of the rapid tests using 100 serum samples collected pre-COVID-19. User-friendliness was evaluated by the biomedical laboratory scientists performing the tests.

Results

Both sensitivity and specificity varied considerably between the tests. Seven tests had IgG sensitivity $\geq 90\%$, while five tests had IgG sensitivity below 85%. Twelve rapid tests had IgG specificity of 97% or above. Among the tests with very high IgG specificity, three tests also had IgG sensitivity above 90%. With some exceptions, the rapid tests were judged easy to perform and interpret.

Conclusions and recommendations

When a rapid test is used to confirm past COVID-19 in a population where the prevalence is low, the most important consideration should be the test's IgG specificity, which must be very high ($\geq 97\%$) to minimize false positive results. Also, we recommend using a test with high IgG sensitivity and which is user-friendly. When evaluating the rapid tests using these criteria, we found tests 2, 3 and 16 (Table 1) had an overall good performance, while tests 4, 5, 7, 12, and 15 had an acceptable performance. Tests 1, 6, 8, 9, 10, 11, 13, 14, and 17 were considered not acceptable for the purpose of confirming past COVID-19 in a low prevalence setting.

2 Background

In December 2019, Wuhan city in Hubei Province, China, became the center of an outbreak of a severe pneumonia, later identified as caused by a novel coronavirus SARS-CoV-2 (1). The clinical presentation of COVID-19 varies from asymptomatic disease, via mild upper respiratory infection to severe pneumonia with respiratory failure and death. By June 28th, there were 9.8 million confirmed cases worldwide and 496 000 reported deaths (2).

Laboratory methods for diagnosing COVID-19

Current COVID-19 is diagnosed by detection of SARS-CoV-2 RNA by PCR in a sample collected with a swab from the upper airways. PCR is performed at medical microbiology laboratories, requiring advanced analytical instruments and trained personnel.

Detecting humoral immune response to the virus is a different analytical approach. Several enzyme immune assays (EIA-methods) detecting antibodies against SARS-CoV-2, have recently become available at medical laboratories. At the same time, a substantial number of point-of-care rapid test kits are being marketed. These rapid tests are for professional use, they make use of capillary or venous whole blood, plasma, or serum, and they are designed to qualitatively detect antibodies against SARS-CoV-2. The results are read after 10-15 minutes. To determine a rapid test's ability to detect past infection, its performance with regard to immunoglobulin type G (IgG) antibodies has been emphasized (3, 4).

Even though most of the rapid tests are CE/IVD approved, they generally come with very limited documentation on test performance, and with a few exceptions without any manufacturer independent evaluation (5-9). In our pilot evaluation of eleven rapid tests, we found that the tests' sensitivities varied with the population they were used in (8).

3 Objectives

Our main objective was to evaluate the diagnostic accuracy of a selection of rapid test for COVID-19 entering the Norwegian market, and specifically their ability to confirm past COVID-19. Furthermore, we wanted to evaluate their user-friendliness.

4 Methods

The evaluation was organized as a collaboration between the Kristiansand Municipality, Norway, Vestre Viken Hospital Trust, Norway, Lillebælt Hospital, Denmark, and the Norwegian Organization for Quality Improvement of Laboratory Examinations (Noklus). Sørlandet hospital in Kristiansand, Norway, also contributed.

Study design

The 17 rapid tests chosen for evaluation was a convenience sample, consisting of the tests that could be delivered to Noklus before the set deadline of May 29th, 2020 (Table 1). Suppliers provided their tests free of charge to Noklus and did not pay for the evaluation. In sending the tests, they consented to having the results published.

We evaluated the performance of the rapid tests in two study arms:

1. 65 serum samples from recovered PCR-confirmed COVID-19 patients who had not required hospitalization.
2. 100 serum samples from Vejle Biobank collected pre-COVID-19 (10).

Biochemical analyses

All 17 rapid tests were performed in accordance with manufactures' instructions under optimal and standardized conditions by experienced biomedical laboratory scientists (BLS). The results were read independently by two BLS, and in cases with discrepancy, a third BLS had the final word. For test number 8, an instrument was required to read the result.

Statistical analyses

IgM and IgG rapid test results were evaluated separately, except for test 14, which detected "total antibodies". Sensitivity of the rapid tests was calculated from study arm 1 and defined as the proportion of recovered COVID-19 patients who had detectable IgM or IgG antibodies on the rapid tests. Specificity was calculated from study arm 2 (pre-COVID-19 sera) and defined as the proportion of SARS-CoV-2 antibody negative samples. We computed 95% confidence intervals (CI) for the sensitivities and specificities using the adjusted Wald method (11).

We also report user-friendliness reported by the BLSs performing the tests.

Ethical considerations

The project was considered a method evaluation study and therefore exempt from ethical board approval in Norway. Recovered COVID-19 patients gave written informed consent to participate. In Denmark, use of restmaterial as separated plasma/serum from anonymous healthy persons for technical quality control is not restricted. The project was approved by the Data protection officers in Kristiansand Municipality and at Noklus.

5 Results

The 65 recovered COVID-19 outpatients, of whom 38 were men, had a median age of 53 years (range 15-75). At the time of serum collection, the median number of days since onset of symptoms was 67 (range 37-89 days). The donors of the 100 pre-COVID-19 sera (35 men) had a median age of 59 years (range 26-77) at the time of serum collection.

Both sensitivity and specificity varied considerably between the tests (Table 2). Three tests had point estimates of IgG sensitivity above 95%, four had sensitivity of 90-95% and another four had IgG sensitivity of 85-89%. Five tests had IgG sensitivity below 85%. Twelve rapid tests had IgG specificity of 97% or above. Test 14 detected "total antibodies", and IgG sensitivity or specificity could therefore not be calculated.

For two rapid tests, more than 10% of test results had to be interpreted by more than two BLS to reach consensus. The tests were generally considered easy to perform and interpret, but tests 8, 11, and 13 were judged less user friendly.

6 Discussion

If a participant with PCR-confirmed COVID-19 has no detectable antibodies against SARS-CoV-2, there are several possible explanations. First, the stage of the infection could have been too early for antibodies to be formed. This was not the case in our population, as median seroconversion time has been reported at around 13-14 days after onset of symptoms (12, 13). Second, the participant could have produced no antibodies, or not enough antibodies to be detected. This is possible, since not all COVID-19 patients seem to form (detectable) antibodies (12, 14). Finally, if the antibodies produced are not long-lasting, patients with high antibody levels during the acute infection could be tested negative at a later stage. Thus, the sensitivity of the rapid test may depend on the time from acute infection to testing, and we cannot expect any antibody detecting test to have 100% sensitivity. Also, a false negative rapid test result, or a false positive PCR result, are possible explanations if a PCR-confirmed COVID-19 participant has no detectable antibodies. On the other hand, if there are detectable antibodies giving a positive result for SARS-CoV-2 in sera collected before the virus was in circulation, there is only one possible explanation: a false positive test result. This could be due to cross-reactivity with other antibodies or technical errors when performing the test.

As of June 2020, the Norwegian Institute of Public Health (www.fhi.no) has pointed out two areas of possible use of antibody detecting rapid tests: 1) confirmation of past infection in people who were not tested with PCR, and 2) as a supplement to PCR at hospitalization for lower respiratory infections. We were only able to evaluate the first area of use, where test performance regarding IgG is what matters. An isolated positive IgM test result may be repeated after two weeks if less than six weeks has passed since onset of symptoms. If there is still no IgG detectable, the positive IgM result could very well be due to unspecific cross-reactivity and should not be confused with evidence of past COVID-19.

For any test, there is usually a trade-off between sensitivity and specificity. To minimize the risk of a false positive test result when the prevalence of previous COVID-19 is low, a rapid test must have a very high IgG specificity, ideally 97% or more (4). In addition, a high IgG sensitivity is important (3, 4). We did not *a priori* decide performance specifications for the rapid tests to fulfill, mostly because we were unsure about the current “state of the art” and of their intended use. Nevertheless, we classified the rapid tests’ performance with regard to confirming past COVID-19 in three overall categories (“good”, “acceptable” and “not acceptable”) using the following criteria:

1. IgG specificity performance:
 - “good” if the lower limit of the CI was ≥ 0.97
 - “acceptable” if the point estimate was ≥ 0.97 and the lower limit of the CI was < 0.97
 - otherwise “not acceptable”
2. IgG sensitivity performance:
 - “good” if the point estimate was ≥ 0.90
 - “acceptable” if the point estimate was 0.85-0.89
 - Otherwise “not acceptable”
3. User-friendliness:
 - “not acceptable” if complicated to perform or difficult to read result
 - otherwise “good”

To get an overall evaluation of “good”, all three performance characteristics had to be classified as “good”. If one was “not acceptable”, the overall evaluation was “not acceptable”. Otherwise, the evaluation was “acceptable”. Since test 14 detected total antibodies and not IgG specifically, its performance was considered not acceptable for confirmation of past COVID-19. Using this classification, the performances of tests 2, 3, and 16 were classified as “good”, while tests 4, 5, 7, 12, and 15 were “acceptable”. Tests 1, 6, 8, 9, 10, 11, 13, 14, and 17 were considered “not acceptable”

for the purpose of detecting past COVID-19. Under different clinical circumstance, e.g. with a higher prevalence of people with past COVID-19, the evaluation may be different. If left to choose between acceptable tests in the current situation, we recommend prioritizing a very high IgG specificity above other performance specifications, because a false positive test may give the wrongful impression that the patient has some protection against future infection with SARS-CoV-2, which may lead to increased risk of infection and spread of the virus.

In our previously published pilot, evaluating eleven rapid tests, we showed that most tests had higher IgG sensitivity (positivity rate) in hospitalized COVID-19 patients than in recovered, community treated participants (8). More severe infection has been associated with higher levels of antibodies (12, 13), and asymptomatic infection with lower levels than symptomatic (15). In this report, we have evaluated the tests in a population that was not hospitalized, but with varying degrees of symptoms. We were not able to evaluate the tests' performances in a population that was not tested with PCR and went through a COVID-19 with very little or no symptoms. We therefore do not know if the rapid tests can be used to establish regional or national seroprevalence, or to determine more accurately the number of previously infected individuals in a population. However, some of the rapid tests are probably useful to establish whether an individual who was symptomatic, but not tested with PCR, most likely had COVID-19 or not. In this setting, it may actually be considered a disadvantage that IgM and IgG tests often come in the same test cassette; past infection is diagnosed with IgG alone, and the IgM result may be misinterpreted and cause confusion.

Strengths and limitations

Strengths of our evaluation include the large number of samples from recovered COVID-19 outpatients, who should all have had enough time to develop IgG antibodies against SARS-CoV-2. Also, the fact that they had not required hospitalization allowed us to evaluate the rapid tests' performances in a population where the tests could potentially be useful. Furthermore, having access to a substantial number of pre-COVID-19 sera allowed us to evaluate specificities of the tests, which is of particular importance in the current stage of the pandemic (June 2020). Another strength is the large number of rapid tests evaluated simultaneously, allowing comparison of several tests under identical conditions.

One weakness is that we did not have access to sera with known antibodies to further challenge the tests for cross-reactivity. Also, since all manufacturers stated that serum, plasma or whole blood could be used for their tests, we have evaluated them using only serum. This may not, however, be the most commonly used material in for instance general practice, and we do not know if the rapid tests' performance is comparable when using other test materials. Finally, since testing was performed under optimal conditions and not by intended users, both pre-analytical and analytical errors were minimized, and performance may be poorer in real life.

7 Conclusions and recommendations

Many rapid tests are now marketed with very limited documentation. Prior to introducing a test, we highly recommend performing an independent evaluation taking into account the population in which the test is intended for use.

As a negative antibody test performed during the early phase of infection cannot rule out COVID-19, we recommend not using a rapid test until at least two weeks after onset of symptoms. A negative test may be repeated, but not all COVID-19 patients develop antibodies, and not all antibodies are necessarily detected by the rapid test. Thus, a negative rapid test does not rule out current nor past COVID-19.

Similarly, an isolated positive IgM result should not be misinterpreted as evidence of past infection but may be followed by a second sample if the suspected COVID-19 happened less than six weeks previously. If there is no IgG-seroconversion, an unspecific IgM result is a likely interpretation.

When a rapid test is used to confirm past COVID-19 in a population where the prevalence is low, the most important consideration should be the test's IgG specificity, which must be very high ($\geq 97\%$) to minimize false positive results. Also, we recommend using a test with high IgG sensitivity, and which is user-friendly. In our study, we found tests 2, 3 and 16 (Table 1) had an overall good performance, while tests 4, 5, 7, 12, and 15 had an acceptable performance. Tests 1, 6, 8, 9, 10, 11, 13, 14, and 17 were considered not acceptable for the purpose of detecting past COVID-19 in a low prevalence setting.

8 Acknowledgements

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10 Tables

Table 1. Rapid tests included and user-friendliness.

Test number	Test name	Manufacturer	User-friendliness
1	iCare Covid-19 Rapid Test (Covid-19 IgG/IgM Rapid test Kit)	Nantong Egens Biotechnology Co., Ltd, China	Easy to perform test. Easy to read result. The fields on the test cassette were suboptimally marked for one lot (white elevations on white background). 14.5% of test results read by more than two BLS.
2	Healgen COVID-19 IgG/IgM Rapid Test Cassette	Healgen Scientific Limited Liability Company, USA	Easy to perform test. Easy to read result. The fields on the test cassette were suboptimally marked (white elevations on white background). Did not correspond with picture on kit. 3.6% of test results read by more than two BLS.
3	NADAL COVID-19 IgG/IgM Test	nal von minden GmbH, Germany	Easy to perform test. Easy to read result. The fields on the test cassette were suboptimally marked (white elevations on white background). 3.0 % of test results read by more than two BLS.
4	BIOZEK Medical COVID-19 IgG/IgM Rapid Test Cassette	Inzec International Trading, The Netherlands	Easy to perform test. Weak color on control and test lines. 3.0% of test results read by more than two BLS.
5	BIOSYNEX COVID -19 BSS	BIOSYNEX SWISS SA, Switzerland	Easy to perform test. Weak color on control and test lines. 10.3% of test results read by more than two BLS.
6	Panbio COVID-19 IgG/IgM Rapid Test Device	Abbott Rapid Diagnostics Jena GmbH, Germany	Easy to perform test. Easy to read result. The fields on the test cassette were suboptimally marked (white elevations on white background). 3.0% of test results read by more than two BLS.
7	Acro 2019-nCoV IgG/IgM Rapid Teset	Acro Biotech Inc, USA	Easy to perform test. Easy to read result. 3.0% of test results read by more than two BLS.
8	ichroma COVID-19 Ab + ichroma II instrument	Boditech Med Incorporated, Republic of Korea	Requires pre analytical mixing of blood and buffer, a pipette for analyses, and an instrument for reading of result.
9	COVID-19 IgG-IgM Rapid test	DIASource ImmunoAssays S.A., Belgium	Easy to perform test. Easy to read result. 1.8% of test results read by more than two BLS.
10	Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)	Zhuhai Livzon Diagnostics Inc., China	Two test cassettes (one for IgM and one for IgG). Difficult to open buffer vial without spilling contents. Easy to read result.5.5% of test results read by more than two BLS.

11	COVISURE™ COVID-19 IgG-IgM Rapid Test	W.H.P.M. Biosearch & Technology Co.,Ltd., China	Easy to perform test. Difficult to read result due to pink background. The fields on the test cassette were suboptimally marked (white elevations on white background). 6.7% of test results read by more than two BLS.
12	STANDARD Q COVID-19 IgM/IgG Combo Test	SD Biosensor, Republic of Korea	Easy to perform test. Easy to read result. 6.1% of test results read by more than two BLS.
13	Novel Coronavirus (2019-nCoV) IgG/IgM Test Kit (Colloidal gold)	Genrui Biotech Inc., China	Difficult to apply serum into the sample well. The test cassette did not correspond with picture on kit. Easy to read result. 3.0% of test results read by more than two BLS.
14	WANTAI SARS-CoV-2 Ab Rapid Test	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China	Easy to perform test. Difficult to read result due to pink background. The fields on the test cassette were suboptimally marked for one lot (white indentations on white background). 1.8% of test results read by more than two BLS.
15	Leccurate SARS-CoV-2 Antibody Test Kit	Beijing Lepu Medical Technology Co., Ltd., China	Easy to perform test. Particularly easy to read result due larger test cassette. 4.2% of test results read by more than two BLS.
16	OnSite Covid-19 IgG/IgM	CTK Biotech, USA	Easy to perform test. Easy to read result. 3.6% of test results read by more than two BLS.
17	COVID-19 IgG/IgM Rapid Test Kit	Abbexa Ltd, UK	Easy to perform test. Usually easy to read result, but occasionally white lines would appear in IgG test field (read as negative). 7.9% of test results read by more than two BLS.

Table 2. Test results and classification of performance*

	IgM		IgG		User-friendliness	Overall evaluation
	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)		
1	0.72 (0.60-0.82)	0.79 (0.70-0.86)	0.85 (0.74-0.92)	0.93 (0.86-0.97)	Good	Not acceptable
2	0.68 (0.56-0.78)	1.00 (0.97-1.00)	0.98 (0.91-1.00)	1.00 (0.97-1.00)	Good	Good
3	0.71 (0.59-0.80)	0.99 (0.94-1.00)	0.91 (0.81-0.96)	1.00 (0.97-1.00)	Good	Good
4	0.15 (0.08-0.26)	0.98 (0.93-1.00)	0.92 (0.83-0.97)	0.98 (0.93-1.00)	Good	Acceptable
5	0.74 (0.62-0.83)	0.94 (0.87-0.97)	0.85 (0.74-0.92)	0.98 (0.93-1.00)	Good	Acceptable
6	0.09 (0.04-0.19)	0.98 (0.93-1.00)	0.78 (0.67-0.87)	1.00 (0.97-1.00)	Good	Not acceptable
7	0.15 (0.08-0.26)	0.96 (0.90-0.99)	0.88 (0.77-0.94)	0.99 (0.94-1.00)	Good	Acceptable
8	0.05 (0.01-0.13)	1.00 (0.97-1.00)	0.92 (0.83-0.97)	0.93 (0.86-0.97)	Not acceptable	Not acceptable
9	0.20 (0.12-0.31)	0.98 (0.93-1.00)	0.82 (0.70-0.89)	0.99 (0.94-1.00)	Good	Not acceptable
10	0.55 (0.43-0.67)	1.00 (0.97-1.00)	0.60 (0.48-0.71)	1.00 (0.97-1.00)	Good	Not acceptable
11	0.46 (0.35-0.58)	0.95 (0.89-0.98)	0.58 (0.46-0.70)	0.95 (0.89-0.98)	Not acceptable	Not acceptable
12	0.63 (0.51-0.74)	1.00 (0.97-1.00)	0.98 (0.91-1.00)	0.97 (0.91-0.99)	Good	Acceptable
13	0.68 (0.56-0.78)	0.98 (0.93-1.00)	0.75 (0.64-0.84)	1.00 (0.97-1.00)	Not acceptable	Not acceptable
14**			0.83 (0.72-0.90)	0.99 (0.94-1.00)	Good	Not acceptable
15	0.82 (0.70-0.89)	0.99 (0.94-1.00)	0.88 (0.77-0.94)	0.99 (0.94-1.00)	Good	Acceptable
16	0.69 (0.57-0.79)	0.99 (0.94-1.00)	0.92 (0.83-0.97)	1.00 (0.97-1.00)	Good	Good
17	0.78 (0.67-0.87)	0.80 (0.71-0.87)	0.97 (0.89-1.00)	0.92 (0.85-0.96)	Good	Not acceptable

*Green – good, yellow - acceptable, red – not acceptable

**Total antibodies