Report 2:
Evaluation of 32 rapid tests for detection of IgG 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 32 rapid tests for detection of antibodies against SARS-CoV-2, and specifically their abilities to confirm past COVID-19, where detection of IgG antibodies is considered essential.

Methods

We calculated the sensitivities of the antibody detecting rapid tests using serum samples from 65 recovered RT-PCR-confirmed COVID-19 patients who had not required hospitalization. We calculated specificities of the rapid tests using 197 serum samples collected pre-COVID-19. User-friendliness was evaluated by the biomedical laboratory scientists performing the tests.

Results

31 of 32 tests were lateral flow immunoassays and one test used a novel microfluidic test system. Three tests required an instrument to read the results, while the rest were read visually. Four tests detected "total antibodies", while the rest detected IgM and IgG separately. Both sensitivity and specificity varied considerably. Eleven tests had IgG sensitivity ≥90%, while 14 tests had IgG sensitivity below 85%. Twenty-one rapid tests had IgG specificity of 97% or above, of which six 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 test should detect SARS-CoV-2 IgG antibodies, and the most important consideration should be the test's IgG specificity, which must be very high (≥97%) to minimize false positive results. Also, we recommend using a test with high IgG sensitivity and which is user-friendly in a point-of-care-setting. When evaluating the rapid tests using these criteria, we found that one test had an overall good performance, while nine tests had an acceptable performance.

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 October 30th, there were almost 45 million confirmed cases worldwide and 1.2 million 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 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 and possible immunity, 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 (phase 1), 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, and specifically their ability to confirm past COVID-19. Furthermore, we wanted to evaluate user-friendliness for a point-of-care setting (i.e. primary health care, health center, nursing home, etc.).

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 32 rapid tests chosen for evaluation was a convenience sample, consisting of the tests that could be delivered to Noklus before the set deadlines of May 29th 2020 (phase 2, tests 1-17 (Table 1), analyzed during June 2020) or September 23rd 2020 (phase 3, tests 18-32, analyzed during October 2020). 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. 197 serum samples collected pre-COVID-19, of which 99 were from Vejle Biobank (10) and 98 from Vestre Viken Hospital trust.

Biochemical analyses

All 32 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 tests 8, 31 and 32, an instrument was required to read the result. Tests 1-31 were lateral flow immunoassays, while test 32 used a microfluidic test system.

Statistical analyses

IgM and IgG rapid test results were evaluated separately, except for tests 14, 21, 30 and 32 which detected "total antibodies". Sensitivity was calculated from study arm 1 and defined as the proportion of recovered COVID-19 patients who had detectable antibodies. 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, at Vestre Viken Hospital Trust, 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 99 pre-COVID-19 sera from Vejle Biobank (35 men) had a median age of 59 years (range 26-77) at the time of serum collection. We had no information on donors of the pre-COVID-19 sera from Vestre Viken hospital trust, except it was left-over material after routine microbiology immunological analyses.

Both sensitivity and specificity varied considerably between the tests (Table 2). Five tests had point estimates of sensitivity above 95%, six had IgG sensitivity between 90-95% and another six had between 85-89%. Eight tests had point estimates of IgG sensitivity below 80%. For 21 rapid tests, the point estimate of IgG specificity was 97% or above. For six of these, the lower limit of the 95% confidence interval (CI) was also at 97% or above.

Tests 14, 21, 30 and 32 detected "total antibodies", and IgG sensitivity or specificity could therefore not be calculated (Table 2).

For three rapid tests, more than 10% of test results had to be interpreted by more than two BLS to reach consensus, and for one test, >2% of tests were invalid. The rapid tests were generally considered easy to perform and interpret, but nine tests were judged less user friendly (Table 1).

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, a faulty test, or technical errors when performing the test.

The Norwegian Institute of Public Health (www.fhi.no) has pointed out some areas of possible use of antibody detecting rapid tests, and one is confirmation of past COVID-19 in people who were not tested with PCR. For this purpose, test performance regarding IgG is considered key (4). 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 infection with SARS-CoV-2.

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, to aid users who face a choice between tests, we classified the rapid tests' performance with regard to confirming past COVID-19 in a low prevalence setting 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 ≥97%
    - "acceptable" if the point estimate was ≥97% but the lower limit of the CI was <97%
    - otherwise "not acceptable"
2. IgG sensitivity performance:
    - "good" if the point estimate was ≥90%
    - "acceptable" if the point estimate was 85-89%
    - otherwise "not acceptable"
3. User-friendliness (for health care professionals, not laboratory specialist):
    - "not acceptable" if complicated to perform, or difficult to read result, or >2% of tests invalid
    - otherwise "good"

To get an overall evaluation of "good", all three performance characteristics ha d to be classified as "good". If one was "not acceptable", the overall evaluation was "not acceptable". Otherwise, the evaluation was "acceptable. Using the suggested classification, the performance of test 3 was classified as "good", while tests 2, 4, 5, 7, 12, 15, 16, 24, and 25 were "acceptable". Tests 1, 6, 8-11, 13, 17-20, 22, 23, 26-29, and 31 were considered "not acceptable" for the purpose of detecting past

COVID-19 in a low prevalence setting. 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.

Tests 14, 21, 30, and 32 detected total antibodies and not IgG antibodies specifically. At present, the use of total antibodies detecting tests is not recommended for the purpose of confirming past COVID-19 in a low prevalence setting. However, test 32, using a novel microfluidic test system, demonstrated a very high specificity in combination with a very high sensitivity in our study population. Also, test 31 is intended for use in laboratories of moderate complexity and has for that reason been judged as not acceptable under the user-friendliness criteria designed for laboratories in a primary health care setting. However, that does not imply that this test is not suitable for use in a laboratory facility of moderate complexity.

In our previously published pilot study, 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 be considered a disadvantage that IgM and IgG tests often come in the same test cassette. Since past infection is diagnosed with IgG alone, a positive IgM result may be misinterpreted and cause confusion. This is potentially particularly problematic if the fields marking where to read IgM and IgG results on the test cassette are suboptimally labelled.

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 when the prevalence is low. 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 currently being marketed with very limited manufacturer-independent documentation. Prior to introducing a test, we highly recommend performing an independent evaluation taking into account the population in which the test is intended used.

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 low prevalence setting, it should detect IgG antibodies. Tests 14, 21, 30, and 32 were not considered fit for this purpose because they detected total antibodies, even though test 32 demonstrated a high specificity in combination with a high sensitivity in our population. When the prevalence is low, the most important consideration should be the test's IgG specificity, which must be high (≥ 97%) to minimize false positive results. Also, we recommend using a test with high IgG sensitivity, and which is user-friendly also for non-laboratory specialists in a point-of-care setting. In our study, we found test 3 (Table 1) had an overall good performance, while tests 2, 4, 5, 7, 12, 15, 16, 24, and 25 had an acceptable performance. The rest were not considered 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% 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. 4% 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 % 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% 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% 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% 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% 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. 2% 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% 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). 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% 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% 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). 2% 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% 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. 4% 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). 8% of test results read by more than two BLS.
18	Anti-SARS-CoV-2 Rapid Test	AutoBio Diagnostics	Easy to perform test. Easy to read result but light pink background not optimal for reading weak positive results. 4% of test results read by more than two BLS.
19	Instant-View COVID-19 IgG/IgM Antibody Test	Alfa Scientific Designs, Inc. 13200 Gregg street, Poway CA 92064 USA	Easy to perform test. Easy to read results but not optimal for reading IgM results due to the design of the cassette. 8% of test results read by more than two BLS.
20	2019-nCOV IgG/IgM rapid test (40 tests/kit)	Dynamiker Biotechnology (Tianjin) Co., Ltd., China	Easy to perform test. Easy to read result. 3% of test results read by more than two BLS.
21	INgezim COVID 19 CROM (kassett)	Inmunología y Genética Aplicada, S.A. (INGENASA), Spain	Easy to perform test. Easy to read result. 3% of test results read by more than two BLS.
22	SARS -CoV-2 IgM/IgG Antibody Detection Kit	HONGKONG SENTE INDUSTRIAL 卧JTERNATIONAL TRADE CO., LIMITED, China	Easy to perform test. The cassette was not optimally marked - “T1” and “T2” instead of “IgG” and IgM”, also with white elevations on white background. 3% of test results read by more than two BLS.
23	COVID19 IgG & IgM Test Kit(colloidal gold method)	Zhejiang Anji Saianfu Biotech Co.,Ltd., China	Easy to perform test. Easy to read result, but high proportion of invalid tests (3 %). 10% of test results read by more than two BLS.
24	COVID-19 IgG/IgM Rapid Test	Hangzhou AllTest Biotech Co., Ltd., China	Easy to perform test. Easy to read result. 6% of test results read by more than two BLS.

25	2019-nCovid IgG/IgM Rapid Test Cassette	BioMaxima	Easy to perform test. Easy to read result. 3% of test results read by more than two BLS.
26	Diagnostic Kit for SARS-Cov-2 IgM/IgG Antibody (Collodial Gold)	Shanghai Kehua Biological Engineering Co., Ltd.	Easy to perform test. The cassette was not optimally marked - “T1” and “T2” instead of “IgG” and IgM”. 2% of test results read by more than two BLS.
27	nCOVID-19 IgG & IgM POCT (REF. CVRT2500)	Technogenetics S.r.l, Italy	Easy to perform test. The cassettes were not optimally marked - “T1” and “T2” instead of “IgG” and IgM”. 3% of test results read by more than two BLS.
28	*StrongStep®* COVID-19 IgG/IgM Combo Test	NanJing Liming Bio-products Co. Ltd.	Easy to perform test. Easy to read result but light pink background not optimal for reading weak positive results, especially in the IgM area. 3% of test results read by more than two BLS.
29	COVID-19 IgG/IgM RAPID TEST	ASSUT EUROPE SPA	Easy to perform test. Easy to read result. 5% of test results read by more than two BLS.
30	EBS Alert SARS-CoV-2 ANTIBODY RAPID TEST	Excelsior Bio-System Incorporation	Easy to perform test, but hard to avoid air bubbles in buffer vial. The cassette was not optimally marked with white elevations on white background. The positive line often incomplete. 4% of test results read by more than two BLS.
31	Chembio DPP COVID-19 IgM/IgG System 2,0	Chembio Diag. Systems Inc	Requires pre analytical mixing of blood and buffer, a pipette for analyses, and an instrument for reading of result. Numerous procedure steps.
32	LumiraDx SARS-CoV-2 Ab Test	LumiraDx AB, Västra Vägen 5A, 16961 Solna, Sweden	Easy to perform, requires instrument for reading.

Table 2. Results and classification of performance[1]

Rapid test	IgM		IgG		User-friendliness	Overall evaluation
	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)		
1	72.3 (60.4-81.8)	89.3 (84.2-93.0)	84.6 (73.7-91.6)	90.9 (85.9-94.2)	Good	Not acceptable
2	67.7 (55.6-77.8)	99.0 (96.1-99.96)	98.5 (91.0-100)	99.0 (96.1-99.96)	Good	Acceptable
3	70.7 (58.7-80.5)	98.0 (94.7-99.4)	90.8 (81.0-96.0)	99.5 (96.9-100)	Good	Good
4	15.4 (8.4-26.3)	96.4 (92.7-98.4)	92.3 (82.8-97.1)	99.0 (96.1-99.96)	Good	Acceptable
5	73.8 (62.0-83.1)	95.9 (91.9-98.0)	84.6 (73.7-91.6)	100 (97.7-100)	Good	Acceptable
6[2]	9.2 (4.0-19.0)	98.0 (92.5-99.9)	78.5 (66.9-86.8)	100 (95.5-100)	Good	Not acceptable
7	15.4 (8.4-26.3)	95.4 (91.4-97.7)	87.7 (77.3-93.9)	99.0 (96.1-99.96)	Good	Acceptable
8	4.6 (1.1-13.2)	99.5 (96.9-100)	92.3 (82.8-97.1)	95.9 (92.1-98.1)	Not acceptable	Not acceptable
9	20.0 (11.9-31.4)	97.0 (93.4-98.7)	81.5 (70.3-89.3)	98.5 (95.4-99.7)	Good	Not acceptable
10	55.4 (43.3-66.8)	99.5 (96.9-100)	60.0 (47.8-71.0)	100 (97.7-100)	Good	Not acceptable
11[2]	46.2 (34.6-58.1)	95.9 (89.6-98.7)	58.5 (46.3-69.6)	95.9 (89.6-98.7)	Not acceptable	Not acceptable
12	63.1 (50.9-73.8)	96.4 (92.7-98.4)	98.5 (91.0-100)	98.5 (95.4-99.7)	Good	Acceptable
13	67.7 (55.6-77.8)	95.4 (91.4-97.7)	75.4 (63.6-84.3)	99.5 (96.9-100)	Not acceptable	Not acceptable
15	81.5 (70.3-89.3)	94.9 (90.8-97.3)	87.7 (77.3-93.9)	98.5 (95.4-99.7)	Good	Acceptable
16	69.2 (57.2-79.2)	98.0 (94.7-99.4)	92.3 (82.8-97.1)	98.0 (94.7-99.4)	Good	Acceptable
17[2]	78.5 (66.9-86.8)	80.8 (71.9-87.4)	96.9 (88.8-99.8)	91.9 (84.6-96.1)	Good	Not acceptable
18	16.9 (9.5-28.0)	99.5 (96.9-100)	90.8 (81.0-96.0)	92.9 (88.3-95.8)	Good	Not acceptable
19	96.9 (88.8-99.8)	82.1 (76.0-86.8)	78.5 (66.9-86.8)	99.5 (96.9-100)	Good	Not acceptable
20	76.9 (65.5-85.6)	92.8 (88.2–95.7)	66.2 (54.0-76.5)	99.0 (96.1-99.96)	Good	Not acceptable
22	60.0 (47.8-71.0)	97.9 (94.6-99.4)	53.8 (41.9-65.4)	98.0 (94.7-99.4)	Not acceptable	Not acceptable
23	47.6 (35.8-59.7)	95.2 (91.0-97.6)	92.1 (82.3-96.9)	95.2 (91.0-97.6)	Not acceptable	Not acceptable

24	55.4 (43.3-66.8)	96.4 (92.6-98.4)	96.9 (88.8-99.8)	96.9 (93.2-98.7)	Good	Acceptable
25	20.0 (11.9-31.4)	96.9 (93.3-98.7)	84.6 (73.7-91.6)	98.5 (95.4-99.7)	Good	Acceptable
26	24.6 (15.7-36.4)	98.5 (95.4-99.7)	78.5 (66.9-86.8)	98.5 (95.4-99.7)	Not acceptable	Not acceptable
27	27.7 (18.2-39.6)	98.5 (95.4-99.7)	86.2 (77.5-92.8)	97.0 (93.4-98.7)	Not acceptable	Not acceptable
28	75.4 (63.6-84.3)	96.9 (93.3-98.7)	67.7 (55.6-77.8)	99.5 (96.9-100)	Good	Not acceptable
29	73.8 (62.0-83.1)	94.3 (90.0-96.9)	83.1 (72.0-90.5)	98.5 (95.3-99.7)	Good	Not acceptable
31	56.9 (44.8-68.2)	98.9 (96.0-99.96)	95.4 (86.8-98.9)	98.9 (96.0-99.96)	Not acceptable	Not acceptable
			Total antibodies, lateral flow assays		**User-friendliness**	
14			83.1 (72.0-90.5)	98.0 (94.7-99.4)	Good	
21			80.0 (68.6-88.1)	99.5 (96.9-100)	Good	
30			64.6 (52.4-75.2)	91.7 (86.9-94.9)	Not acceptable	
			Total antibodies , microfluidic system		**User-friendliness**	
32			100 (93.3-100)	99.5 (96.8-100)	Good	

[1]Green – good, yellow - acceptable, red – not acceptable

[2]Spesificites calculated only from 99 serum samples from Vejle biobank