Summary of the Evaluation of 32 rapid tests for detection of IgG antibodies against SARS-CoV-2 From the Norwegian Organization for Quality Improvement of Laboratory Examinations (NOKLUS)

Full Report here: https://www.noklus.no/media/t42oxn4z/report_2_v4_covid19_ab_rapidtests_noklus_2021.pdf
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Aim

The 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. Furthermore, the user friendliness of the tests in point-of-care settings (i.e. primary health care, health centre, nursing home, etc.) was evaluated.

Materials and methods

The evaluation was designed with 2 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.

IgM and IgG rapid test results were evaluated separately, except for 4 tests 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. 95% confidence intervals (CI) for the sensitivities and specificities were calculated using the adjusted Wald method*.

User-friendliness was evaluated by the Biomedical Laboratory Scientists (BLS) performing the tests and was deemed to be "not acceptable" if the test was complicated to perform, or difficult to read result, or >2% of tests invalid. 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.

Results

31 of 32 tests in this evaluation were lateral flow immunoassays and one test (The LumiraDx SARS-CoV-2 Ab Test) is a novel microfluidic test system. Three tests required an instrument to read the results (1 of which is the LumiraDx Test), 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 another 14 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.

Both sensitivity and specificity varied considerably between the tests (Table 1). There were 4 tests† which detected "total antibodies" which meant that IgG sensitivity or specificity could therefore not be calculated (Table 1).

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.

The findings from the NOKLUS evaluation of the LumiraDx SARS-CoV-2 Ab Test demonstrated sensitivity of 100% (93.3-100) and specificity of 99.5% (96.8-100) and the User-friendliness rating was "Good".

Table 1: Results and Classification of Performance

Rapid test	IgM		IgG		User-friendliness	Overall evaluation
	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)		
iCare Covid-19 Rapid Test (Covid-19 IgG/IgM Rapid test Kit)	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
Healgen COVID-19 IgG/IgM Rapid Test Cassette	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
NADAL COVID-19 IgG/IgM Test	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
BIOZEK Medical COVID-19 IgG/IgM Rapid Test Cassette	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
BIOSYNEX COVID -19 BSS	73.8 (62.0-83.1)	95.9 (91.9-98.0)	84.6 (73.7-91.6)	100 (97.7-100)	Good	Acceptable
Panbio COVID-19 IgG/IgM Rapid Test Device[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
Acro 2019-nCoV IgG/IgM Rapid Teset	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
ichroma COVID-19 Ab + ichroma II instrument	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
COVID-19 IgG-IgM Rapid test	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
Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)	55.4 (43.3-66.8)	99.5 (96.9-100)	60.0 (47.8-71.0)	100 (97.7-100)	Good	Not acceptable
COVISURE™ COVID-19 IgG-IgM Rapid Test[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
STANDARD Q COVID-19 IgM/IgG Combo Test	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
Novel Coronavirus (2019-nCoV) IgG/IgM Test Kit (Colloidal gold)	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
Leccurate SARS-CoV-2 Antibody Test Kit	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
OnSite Covid-19 IgG/IgM	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
COVID-19 IgG/IgM Rapid Test Kit[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
Anti-SARS-CoV-2 Rapid Test	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
Instant-View COVID-19 IgG/IgM Antibody Test	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
2019-nCOV IgG/IgM rapid test (40 tests/kit)	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
SARS -CoV-2 IgM/IgG Antibody Detection Kit	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
COVID19 IgG & IgM Test Kit (colloidal gold method)	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
COVID-19 IgG/IgM Rapid Test	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
2019-nCovid IgG/IgM Rapid Test Cassette	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
Diagnostic Kit for SARS-Cov-2 IgM/IgG Antibody (Collodial Gold)	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
nCOVID-19 IgG & IgM POCT (REF. CVRT2500)	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
StrongStep® COVID-19 IgG/IgM Combo Test	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
COVID-19 IgG/IgM RAPID TEST	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
Chembio DPP COVID-19 IgM/IgG System 2,0	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

Table 1: Results and Classification of Performance – continued

Rapid test		Total antibodies, lateral flow assays		User-friendliness	
		Sensitivity (95% CI)	Specificity (95% CI)		
† WANTAI SARS-CoV-2 Ab Rapid Test		83.1 (72.0-90.5)	98.0 (94.7-99.4)	Good	
† INgezim COVID 19 CROM (kassett)		80.0 (68.6-88.1)	99.5 (96.9-100)	Good	
† EBS Alert SARS-CoV-2 ANTIBODY RAPID TEST		64.6 (52.4-75.2)	91.7 (86.9-94.9)	Not acceptable	

		Total antibodies, microfluidic system		User-friendliness	
† LumiraDx SARS-CoV-2 Ab Test		100 (93.3-100)	99.5 (96.8-100)	Good	

1. Green – Good; Yellow – Acceptable; Red – Not acceptable

2. Specificities calculated only from 99 serum samples from Vejle biobank.

Conclusion

The LumiraDx SARS-CoV-2 Ab Test, using a novel microfluidic test system, demonstrated a very high specificity in combination with a very high sensitivity in the NOKLUS study population.

* MeasuringU. Confidence Interval Calculator for a Completion Rate (cited 2020). Available from: https://measuringu.com/wald/.