National Collaborating Centre for Methods and Tools

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Rapid Review: What serological tests are available, and what are their sensitivities and specificities?

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Executive Summary

Background

Early in the COVID-19 pandemic, diagnostic testing was only available to symptomatic individuals who met specific testing criteria. Many individuals with mild or no symptoms may not have been tested, so the extent of the spread of the virus that causes COVID-19 is not known.

Serological tests, also known as antibody tests, can detect the presence of antibodies for previous infections and may be able to inform how widespread transmission of the virus that causes COVID-19 is. Most tests are designed to detect antibodies called immunoglobin M (IgM), a marker of active infection, or immunoglobulin G (IgG), a marker of late-stage active infection or previous infection (**Figure 1**).

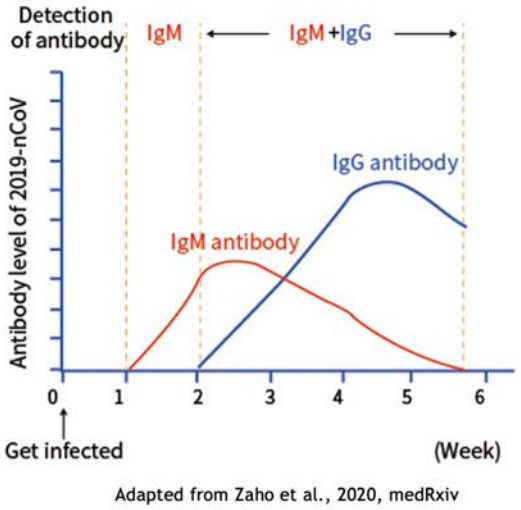

Figure 1: Immunoglobulin levels during COVID-19 infection (www.augurix.com)

The main challenges with serological tests are sensitivity, or the degree to which the test is able to detect the presence of antibodies to the virus that causes COVID-19, and specificity, or the degree to which the test detects ONLY the antibodies for virus that causes COVID-19, and not antibodies to other viruses or coronaviruses.

This rapid review was produced to support public health decision makers' response to the coronavirus disease (COVID-19) pandemic. This review seeks to identify, appraise, and summarize emerging research evidence to support evidence-informed decision making.

This rapid review is based on the most recent research evidence available at the time of release. This version includes evidence available up to May 29, 2020.

In this rapid review, we provide the most recent evidence to answer the question: **What serological tests are available, and what are their sensitivities and specificities?**

Key Points

- There are many serological tests available from many different manufacturers for the detection of antibodies to the virus that causes COVID-19.
- Overall, the sensitivity of these tests is highly variable, with a wide range of estimates from as low as 18.4% to as high at 100.0%. Results were inconsistent; quality of evidence was low-moderate.
- The reported specificity of tests is higher, ranging from 84.3% to 100.0%. Results were consistent; quality of evidence was low-moderate.

Overview of Evidence and Knowledge Gaps

- There are many studies evaluating a number of different serological tests for antibodies to the virus that causes COVID-19. Methodological quality of these studies varies from low to moderate. Very few tests have been evaluated in more than one study.
- There are a number of different serological test types, including chemiluminescent immunoassays (CLIA), enzyme-linked immunosorbent assays (ELISA), lateral flow immunochromatographic assays (LFIA) and colloidal gold immunochromatography (GICA). The main differentiator for these tests in terms of clinical application, is whether the tests must be conducted in a laboratory setting or if they can be conducted rapidly at the point of patient care.
- To date, RT-PCR for viral RNA has been considered the “gold standard” for the diagnosis of COVID-19 and has been used as the reference test for all studies included in this rapid evidence service. RT-PCR tests have been shown to have sensitivity limitations in detecting the virus that causes COVID-19, which makes it challenging to establish the sensitivity of serological tests.
- The timing of serological testing may have contributed to study heterogeneity, as IgM antibodies are produced earlier in the immune response and IgG antibodies are produced later in the immune response. Combining test results may help determine the clinical stage of infection (**Figure 2**).
- Although several syntheses are available, there is a large amount of overlap of single studies within the reviews. While a total of 73 studies are included across three syntheses, there were only 48 unique studies. This may inflate the impact of some studies on the overall findings of this evidence service.
- An update on a high-quality rapid review of evidence for COVID-19 diagnostic and serological tests is currently underway by the European Network for Health Technology Assessment. It will include evidence up to May 22, 2020 and is expected on June 18, 2020.

Test results			Clinical Significance
RT-qPCR	IgM	IgG	
+	–	–	Patient may be in the window period of infection.
+	+	–	Patient may be in the early stage of infection.
+	+	+	Patients is in the active phase of infection.
+	–	+	Patient may be in the late or recurrent stage of infection.
–	+	–	Patient may be in the early stage of infection. RT-qPCR result may be false-negative.
–	–	+	Patient may have had a past infection, and has recovered.
–	+	+	Patient may be in the recovery stage of an infection, or the RT-qPCR result may be false-negative.

Figure 2: Interpreting COVID-19 test results (www.diazyme.com/covid-19-antibody-tests)

Methods

Research Question

What serological tests are available, and what are their sensitivities and specificities?

Search

On May 25 and 26, 2020, the following databases were searched for evidence regarding the sensitivity and specificity of serological tests for COVID-19. The search was limited to evidence released after May 4, 2020, to build on evidence included in the most recent synthesis (Jarrom, 2020).

- Pubmed's curated COVID-19 literature hub: LitCovid
- Trip Medical Database
- World Health Organization's Global literature on coronavirus disease
- Joanna Briggs Institute COVID-19 Special Collection
- COVID-19 Evidence Alerts from McMaster PLUS™
- Public Health +
- COVID-19 Living Overview of the Evidence (L·OVE)
- Cochrane Rapid Reviews Question Bank
- Prospero Registry of Systematic Reviews
- NCCMT COVID-19 Rapid Evidence Reviews
- MedRxviv preprint server for health sciences

A copy of the search strategy is available on request.

Study Selection Criteria

The search first included recent, high-quality syntheses. If no syntheses were found, single studies were included. English-language, peer-reviewed sources and sources published ahead-of-print before peer review were included. Grey literature was excluded.

Single studies were included if they met the following criteria: available in English, evaluated tests in COVID-19 cases confirmed by RT-PCR rather than presumed based on symptoms or imaging tests, and evaluated test(s) available commercially.

Data on study design, samples, tests and outcomes were extracted when reported.

Data Extraction and Synthesis

Data on study design, setting, location, population characteristics, interventions or exposure and outcomes were extracted when reported. We synthesized the results narratively due to the variation in methodology and outcomes for the included studies.

We evaluated the quality of included evidence using critical appraisal tools as indicated by the study design below. Quality assessment was completed by one reviewer and verified by a second reviewer. Conflicts were resolved through discussion.

Study Design	Critical Appraisal Tool
Synthesis	Health Evidence™ Quality Appraisal Tool
Diagnostic	QUADAS-2 for Primary Diagnostic Accuracy Studies

Completed quality assessments for each included study are available on request.

Findings

Quality of Evidence

This document includes three completed and five in-progress syntheses and 14 single studies, for a total of 22 publications included in this evidence review. The quality of the evidence included in this review is as follows:

		Total	Quality of Evidence
Syntheses	Completed Reviews	3	2 Low 1 High
	In Progress Reviews	5	-
Single Studies	Completed	14	2 Low 10 Moderate 2 High

Warning

Given the need to make emerging COVID-19 evidence quickly available, many emerging studies have not been peer reviewed. As such, we advise caution when using and interpreting the evidence included in this rapid review. We have provided a summary of the quality of the evidence as low, moderate or high to support the process of decision making. Where possible, make decisions using the highest quality evidence available.

Table 1: Syntheses

Reference	Date Released	Description of included studies	Summary of Findings	Quality Rating: Synthesis	Quality Rating: Included Studies
Riccò, M., Ferraro, P., Gualerzi, G., Ranzieri, S., Henry, B. M., Said, Y. B., Pyatigorskaya, N. V., Nevolina, E., Wu, J., Bragazzi, N. L., & Signorelli, C. (2020). Point-of-Care Diagnostic Tests for Detecting SARS-CoV-2 Antibodies: A Systematic Review and Meta-Analysis of Real-World Data. *Journal of Clinical Medicine*, *9*(5), 1515	May 18, 2020 (Search to Apr 17, 2020)	Ten studies evaluating point-of-care LFIA serological tests for antibodies for the virus causing COVID-19, including: • 8 preprints (non-peer reviewed studies) • 2 peer reviewed studies Across the studies, point-of-care tests from 9 different manufacturers were evaluated. Test results from 2252 samples were meta-analyzed.	Meta-analysis resulted in a pooled sensitivity of 64.8% (95% CI 54.5–74.0), and specificity of 98.0% (95% CI 95.8–99.0). Heterogeneity was high, as studies tested patients at varying time points in disease progression and disease severity of patients was also variable. Sample sizes were small. The low pooled sensitivity reveals the limitations in detection of antibodies for the virus that causes COVID-19.	Low	Not reported
Jarrom, D., Elston, L., Washington, J., Cann, K., Prettyjohns, M., Groves, P., McAllister, S., & Myles, S. (2020, May 14). *The clinical effectiveness of tests to detect the presence of SARS-CoV-2 virus, and antibodies to SARS-CoV-2, to inform COVID-19 diagnosis.* Health Technology Wales.	May 14, 2020 (Search to May 4, 2020)	Twenty-five studies evaluating laboratory or point-of-case serological tests for antibodies for the virus causing COVID-19, including: • 9 preprints (non-peer reviewed studies) • 14 peer reviewed studies • 2 Chinese-language studies for which data was extracted from the abstract Across studies, tests from 21 different manufacturers were evaluated. Data were not meta-analyzed.	Included studies reported sensitivity of tests ranging from 18.4% to 96.1%. Two studies reported sensitivity <50%. The study reporting sensitivity of 18.4% tested patients at their initial presentation to the emergency room, which may be too early in the disease progression to detect antibodies. For the study reporting sensitivity of 36.4%, it is unclear how many days post-onset of symptoms patients were tested. Specificity of tests ranged from 88.9% to 100%. Authors note that there remain key limitations in the evidence for serological tests for antibodies to the virus that causes COVID-19 and do not provide recommendations for implementing large-scale testing of populations.	High	Unclear or high risk of bias
Kontou, P. I., Braliou, G. G., Dimou, N. L., Nikolopoulos, G., & Bagos, P. G. (2020). Antibody Tests in Detecting SARS-CoV-2 Infection: A Meta-Analysis. *Preprint*.	Apr 25, 2020 (Search to Apr 17, 2020)	Thirty-eight studies evaluating laboratory or point-of-case serological tests for antibodies for the virus causing COVID-19, including:	Meta-analysis of 14 studies of ELISA tests found a pooled sensitivity of 93.5% (95%CI 90.0–97.1). Specificities ranged from 96.1% to 99.5%.	Low	Not reported

		• 22 preprints (non-peer reviewed studies) • 16 peer reviewed studies Across the studies, tests from 25 different manufacturers were evaluated. Test results from 7848 samples were meta-analyzed by test type.	Meta-analysis of 13 studies of CLIA tests found a pooled sensitivity of 90.7% (95%CI 75.3–100.0). Specificities ranged from 97.1% to 98.4%. Meta-analysis of 13 studies of LFIA tests found a pooled sensitivity of 80.0% (95%CI 66.3–93.5). Specificities ranged from 91.4% to 99.4%. Three studies of FIA tests found sensitivity ranging from 78.6% to 89.0%. The sample was too small to meta-analyze. Specificities were consistent at 85.0%. Authors conclude that ELISA tests were more sensitive than other test types, but that more research is needed before implementing testing on a large scale.		

Abbreviations:

CLIA Chemiluminescent immunoassay
ELISA Enzyme-linked immunosorbent assay
LFIA Lateral flow immunochromatographic assay
FIA Flow immunochromatographic assay

Table 2: In Progress Syntheses

Title	Anticipated Release Date	Description of document
Zou, Y., Chen, Q., He, S., Zao, L., & Ye, H. Diagnostic value of nucleic acid detection and serological test for SARS-CoV-2: a systematic review and meta-analysis. PROSPERO 2020 CRD42020176777	Jun 30, 2020	The review seeks to meta-analyze data on serological testing in combination with nucleic acid detection of the virus that causes COVID-19 to inform infection control measures.
European Network for Health Technology Assessment. (2020). The role of antibody tests for novel coronavirus SARS-CoV-2 in the management of the current pandemic	Jun 18, 2020	This review will update the available review by Jarrom et al (2020). It will address questions on the use of antibody tests for screening, surveillance and diagnosis of COVID-19.
Li, F.Z., Zhang, Z.L., Li, D.T., & Hour, Y.L. A meta-analysis of diagnostic efficacy of SARS-CoV-2 IgG/IgM antibody test for Covid-19. PROSPERO 2020 CRD42020184771	Jun 7, 2020	This review will meta-analyze data on the sensitivity and specificity of serological tests for antibodies to the virus that causes COVID-19.
Vengasai, A., Midzi, H., Kasambala, M., Mduluza-Jokonya, T.,Naicker, T., Mutapi, F., Mduluza, T. A systematic review on the diagnostic accuracy of serological tests for COVID-19. PROSPERO 2020 CRD42020179112	May 30, 2020	This review will summarize evidence on serological tests for antibodies to the virus that causes COVID-19 and investigate sources of heterogeneity.
Zhong, S. & Ao, X. The diagnostic value of the SARS-CoV-2 IgM/IgG antibody test in COVID-19: a systematic review and meta-analysis. PROSPERO 2020 CRD42020176998	Apr 30, 2020	This review will meta-analyze evidence whether serological tests for antibodies to the virus that causes COVID-19 can complement nucleic acid testing. [*Anticipated release date has passed but no completed review found*]

Table 3: Serology Tests

Summary of study characteristics and quality ratings is presented after this table.

Test Type	Manufacturer	Setting	Health Canada status as of May 28 2020	Sensitivity (%)			Specificity (%)			Reference [Quality Rating]
				IgM	IgG	IgM/IgG	IgM	IgG	IgM/IgG	
CLIA	Diazyme	Laboratory	No application	89.5	94.7	100.0	99.6	99.1	98.7	Suhandynata et al. (2020) [Low]
CLIA	Shenzhen YHLO Biotech	Laboratory	No application	48.1	88.9	NR	100.0	90.9	NR	Jin et al. (2020) [Moderate]
CMIA	Abbott Laboratories	Laboratory	Authorized May 14, 2020	NR	100.0	NR	NR	100.0	NR	Bryan et al. (2020) [Moderate]
				NR	93.8	NR	NR	99.4	NR	Tang et al. (2020) [Moderate]
CMIA	Xiamen InnoDx Biotech Co	Laboratory	No application	86.3	NR	NR	99.3	NR	NR	Bin et al. (2020) [Low]
ELISA	Beijing Wantai Biological Pharmacy Enterprise	Laboratory	No application	82.7	64.7	NR	98.6	NR	NR	Zhao et al. (2020) [Moderate]
				92.5	88.8	NR	100.0	100.0	NR	Bin et al. (2020) [Low]
ELISA	Epitope Diagnostics	Laboratory	Awaiting response from manufacturer	81.8	90.9	81.8	NR	NR	89.8	Whitman et al. (2020) [Moderate]
ELISA	Euroimmun	Laboratory	Under review	NR	NR	NR	NR	92.3	NR	Jääskeläinen et al. (2020) [Moderate]
				NR	85.4	NR	NR	94.8	NR	Tang et al. (2020) [Moderate]
ELISA	Livzon Inc	Laboratory	No application	77.3	83.3	NR	100.0	95.0	NR	Xiang et al. (2020) [Low]
GICA	Shanghai Outdo Biotech Co. Ltd	Point of care	No application	NR	NR	71.1	NR	NR	96.2	Shen et al. (2020) [High]
LFIA	Autobio	Point of care	No application	100.0	100.0	NR	97.4	97.4	NR	Demey et al. (2020) [Moderate]
LFIA	Beijing Diagreat Biotechnologies Co	Point of care	No application	NR	NR	82.6	NR	NR	92.9	Spicuzza et al. (2020) [Moderate]
LFIA	Beijing Wantai Biological Pharmacy Enterprise Co	Point of care	No application	88.8	86.3	NR	98.1	99.5	NR	Bin et al. (2020) [Low]
LFIA	Biolidics	Point of care	No application	100.0	100.0	NR	100.0	100.0	NR	Demey et al. (2020) [Moderate]
LFIA	Biomedomics	Point of care	No application	81.8	81.8	81.8	87.9	96.3	86.9	Whitman et al. (2020) [Moderate]
LFIA	Bioperfectus	Point of care	No application	100.0	90.0	100.0	97.1	98.1	95.2	Whitman et al. (2020) [Moderate]
LFIA	Biotime	Point of care	No application	100.0	100.0	NR	100.0	100.0	NR	Demey et al. (2020) [Moderate]

LFIA	DecomBio	Point of care	No application	90.9	90.9	90.9	90.7	91.6	89.7	Whitman et al. (2020) [Moderate]
LFIA	DeepBlue	Point of care	No application	90.9	81.8	90.9	84.3	99.1	84.3	Whitman et al. (2020) [Moderate]
LFIA	Innovita	Point of care	No application	16.7	66.7	83.3	96.3	100.0	96.3	Whitman et al. (2020) [Moderate]
LFIA	ISIA Biotechnology	Point of care	No application	100.0	100.0	NR	100.0	100.0	NR	Demey et al. (2020) [Moderate]
LFIA	Jiangsu Medomics	Point of care	No application	NR	NR	88.7	NR	NR	90.6	Li et al. (2020) [Moderate]
LFIA	Premier Biotech	Point of care	No application	90.9	81.8	90.9	98.1	99.1	97.2	Whitman et al. (2020) [Moderate]
LFIA	Sure Bio-Tech	Point of care	No application	72.7	90.9	90.9	100.0	100.0	100.0	Whitman et al. (2020) [Moderate]
LFIA	UCP Biosciences	Point of care	No application	90.9	81.8	90.9	98.1	98.1	98.1	Whitman et al. (2020) [Moderate]
LFIA	VivaChek	Point of care	No application	63.3	NR	18.4	NR	NR	92.0	Cassaniti et al. (2020) [High]
				90.0	90.0	90.0	94.9	96.0	94.9	Whitman et al. (2020) [Moderate]
LFIA	WondFo	Point of care	Under review	NR	NR	81.8	97.2	90.7	99.1	Whitman et al. (2020) [Moderate]

-Note: All values have been rounded to one decimal place.
-For longitudinal studies, values on day 15 post symptom onset reported, as seroconversion has typically occurred at this point.
-Information regarding Health Canada applications for diagnostic devices for use against coronavirus was retrieved from https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html on May 26, 2020
-Abbreviations:

CLIA Chemiluminescent immunoassay
CMIA Chemiluminescent microparticle immunoassay
ELISA Enzyme-linked immunosorbent assay
GICA Colloidal gold immunochromatography
LFIA Lateral flow immunochromatographic assay
NR Not Reported

Table 4: Single Studies

Reference	Date Released	Test Type(s)	Manufacturer(s)	No. of samples	Quality Rating:
Lou, B., Li, T., Zheng, S., Su, Y., Li, Z., Wei, L, Yu, F., Ge, S., Zou, Q., Yuan, Q., Lin, S., Hong, C, Yao, X., Zhang, X., Wu, D., Zhou, G., Hour, W., Li, T., Zhang, Y, Zhang, S…Yu, C. (2020). Serology characteristics of SARS-CoV-2 infection since exposure and post symptom onset. *European Respiratory Journal.* Epub ahead of print.	May 19, 2020	CMIA	Xiamen InnoDx Biotech Co	80 confirmed cases 300 unconfirmed controls	Low
		ELISA	Beijing Wantai Biological Pharmacy Enterprise Co		
		LFIA	Beijing Wantai Biological Pharmacy Enterprise Co		
Suhandynata, R. T., Hoffman, M. A., Kelner, M. J., McLawhon, R. W., Reed, S. L., & Fitzgerald, R. L. (2020). Longitudinal Monitoring of SARS-CoV-2 IgM and IgG Seropositivity to Detect COVID-19. *The Journal of Applied Laboratory Medicine*. Epub ahead of print.	May 19, 2020	CLIA	Diazyme	54 confirmed cases 78 unconfirmed controls	Low
Whitman, J.D., Hiatt, J., Mowery, C.T., Shy, B.R., Yu, R., Yamamoto, T.N., Rathore, U., Goldgof, G.M., Whitty, C., Woo, J.M., Gallman, A.E., Miller, T.E., Levine, A.G., Nguyen, D.N., Bapat, S.P., Balcerek, J., Bylsma, S., Lyons, A.M., Li, S., Wong, A.W., Gillis-Buck, E.M… Marson, A. (2020). Test performance evaluation of SARS-CoV-2 serological assays. *Preprint*.	May 17, 2020	ELISA	Epitope Diagnostics	79 confirmed cases 108 negative controls	Moderate
		LFIA	Biomedomics		
		LFIA	Bioperfectus		
		LFIA	DecomBio		
		LFIA	DeepBlue		
		LFIA	Innovita		
		LFIA	Premier Biotech		
		LFIA	Sure Bio-Tech		
		LFIA	UCP Biosciences		
		LFIA	VivaChek		
		LFIA	WondFo		
Tang, M.S., Hock, K.G., Hayes, J.E., Gronowski, A.M., Anderson, N.W., & Farnsworth, C.W. (2020). Clinical Performance of Two SARS-CoV-2 Serologic Assays. *Clinical Chemistry.* Epub ahead of print.	May 12, 2020	CMIA	Abbott Laboratories	48 confirmed cases 153 negative controls	Moderate
		ELISA	Euroimmun		
Bryan, A., Pepper, G., Wener, M. H., Fink, S. L., Morishima, C., Chaudhary, A., Jerome, K. R., Mathias, P. C., & Greninger, A. L. (2020). Performance Characteristics of the Abbott Architect SARS-CoV-2 IgG Assay and	May 7, 2020	CMIA	Abbott Laboratories	125 confirmed cases 1020 negative controls	Moderate

Seroprevalence in Boise, Idaho. *Journal of Clinical Microbiology.* Epub ahead of print.					
Demey, B., Daher, N., François, C., Lanoix, J.-P., Duverlie, G., Castelain, S., & Brochot, E. (2020). Dynamic profile for the detection of anti-SARS-CoV-2 antibodies using four immunochromatographic assays. *The Journal of Infection*. Epub ahead of print.	May 7, 2020	LFIA	Autobio; Biolidics; Biotime; ISIA Biotechnology	22 confirmed cases	Moderate
Jääskeläinen, A. J., Kekäläinen, E., Kallio-Kokko, H., Mannonen, L., Kortela, E., Vapalahti, O., Kurkela, S., & Lappalainen, M. (2020). Evaluation of commercial and automated SARS-CoV-2 IgG and IgA ELISAs using coronavirus disease (COVID-19) patient samples. *Eurosurveillance*, *25*(18).	May 7, 2020	ELISA	Euroimmun	40 confirmed cases 37 negative controls	Moderate
Spicuzza, L., Montineri, A., Manuele, R., Crimi, C., Pistorio, M. P., Campisi, R., Vancheri, C., & Crimi, N. (2020). Reliability and usefulness of a rapid IgM-IgG antibody test for the diagnosis of SARS-CoV-2 infection: a preliminary report. *Journal of Infection.* Epub ahead of print.	Apr 23, 2020	LFIA	Beijing Diagreat Biotechnologies Co	23 confirmed cases 7 negative controls	Moderate
Xiang, F., Wang, X., He, X., Peng, Z., Yang, B., Zhang, J., Zhou, Q., Ye, H., Ma, Y., Li, H., Wei, X., Cai, P., & Ma, W.-L. (2020). Antibody Detection and Dynamic Characteristics in Patients with COVID19. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America.* Epub ahead of print.	Apr 19, 2020	ELISA	Livzon Inc	85 confirmed cases 60 unconfirmed controls	Low
Shen, B., Zheng, Y., Zhang, X., Zhang, W., Wang, D., Jin, J… Gao, H. (2020). Clinical evaluation of a rapid colloidal gold immunochromatography assay for SARS-Cov-2 IgM/IgG. *American Journal of Translational Research*, *12*(4), 1348–1354.	Apr 15, 2020	GICA	Shanghai Outdo Biotech Co. Ltd	97 confirmed cases 53 negative controls	High
Jin, Y., Wang, M., Zuo, Z., Fan, C., Ye, F., Cai, Z., Wang, Y., Cui, H., Pan, K., & Xu, A. (2020). Diagnostic value and dynamic variance of serum antibody in coronavirus disease 2019. *International Journal of Infectious Diseases. 94*: 49-52	Apr 3, 2020	CLIA	Shenzhen YHLO Biotech Co	43 confirmed cases 33 negative controls	Moderate

Cassaniti, I., Novazzi, F., Giardina, F., Salinaro, F., Sachs, M., Perlini, S., Bruno, R., Mojoli, F., & Baldanti, F. (2020). Performance of VivaDiag COVID-19 IgM/IgG Rapid Test is inadequate for diagnosis of COVID-19 in acute patients referring to emergency room department. *Journal of Medical Virology.* Epub ahead of print.	Mar 30, 2020	LFIA	VivaChek	30 confirmed cases 30 negative controls	High
Zhao, J., Yuan, Q., Wang, H., Liu, W., Liao, X., Su, Y… Zhang, Z. (2020). Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. *Clinical Infectious Diseases.* Epub ahead of print.	Mar 28, 2020	ELISA	Beijing Wantai Biological Pharmacy Enterprise	173 confirmed cases 213 negative controls	Moderate
Li, Z., Yi, Y., Luo, X., Xiong, N., Liu, Y., Li, S… Ye, F (2020). Development and clinical application of a rapid IgM-IgG combined antibody test for SARS-CoV-2 infection diagnosis. *Journal of Medical Virology.* Epub ahead of print.	Feb 27, 2020	LFIA	Jiangsu Medomics	397 confirmed cases 128 negative controls	Moderate

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Li, Z., Yi, Y., Luo, X., Xiong, N., Liu, Y., Li, S… Ye, F (2020). Development and clinical application of a rapid IgM-IgG combined antibody test for SARS-CoV-2 infection diagnosis. *Journal of Medical Virology.* Epub ahead of print.

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