Antibody Tests for Covid-19 with FDA Emergency Use Authorization (as of 6 May 2020)

Company - Test	Type of Test	Sample	Antibody	Antigen	Performance Measure	Estimated Performance	95% Confidence Interval	Cross Reactivity
Autobio Diagnostics Anti-SARS-CoV-2 Rapid Test	Lat Flow	S, P	IgM, IgG	Spike	Sensitivity - Combined	88.1% (357/405)	84.6 - 90.9%	Tested for HCoV - Negative for CR
					Specificity - Combined	99% (309/312)	97.2 - 99.7%	
					PPV	82.9%	61.4 - 94.1%	
					NPV	99.4%	99.2 - 99.5%	
Cellex qSARS-CoV-2 IgG/IgM Rapid Test	Lat Flow	S,P, WB	IgM, IgG	Not reported	Sensitivity - Combined	93.8% (120/128)	88.2 - 96.8%	Tested, but number not specified
					Specificity - Combined	96% (240/250)	92.8 - 97.8%	
					PPV	55.2%	39.2 - 69.8%	
					NPV	99.7%	99.3 - 99.8%	
Chembio Diagnostic DPP Covid-19 IgM/IgG	Lat Flow	S, P, WB, FS	IgM, IgG	NucCap	Sensitivity - Combined	93.5% (29/31)	79.3 - 98.2%	Tested - CR with some HCoV (2/9)
					Specificity - Combined	94.4% (118/125)	88.9 - 97.3%	
					PPV	46.8%	27.3 - 65.7%	
					NPV	99.6%	98.8 - 99.9%	
Abbott Architect SARS-CoV-2 IgG	CLMIA	S, P	IgG	NucCap	Sensitivity	100% (88/88)	95.8 - 100%	Not tested against HCoV
					Specificity	99.6% (1066/1070)	99.0 - 99.9%	
					PPV	92.9%	83.4 - 98.1%	
					NPV	100%	99.8 - 100%	
BioRad Platelia SARS-CoV-2 Total Antibody	ELISA	S, P	Total Ab	NucCap	Sensitivity	92.2% (47/51)	81.5 - 96.9%	Tested for HCoV - Negative for CR
					Specificity	99.6% (684/687)	98.7 -99.9%	
					PPV	91.7%	76.7 - 98.1%	
					NPV	99.6%	99.0 - 99.8%	

Company - Test	Type of Test	Sample	Antibody	Antigen	Performance Measure	Estimated Performance	95% Confidence Interval	Cross Reactivity
DiaSorin LIAISON SARS-CoV-2 S1/S2 IgG	CLSIA	S, P	IgG	S1 & S2	Sensitivity	97.6% (40/41)	87.4 - 99.6%	Tested for HCoV - Negative for CR
					Specificity	99.3% (1082/1090)	98.6 - 99.6%	
					PPV	88.0%	76.7 - 92.9%	
					NPV	99.9%	99.3 - 100%	
EUROIMMUN	ELISA	S, P	IgG	S1	Sensitivity	90% (27/30)	74.4 - 96.5%	Tested for HCoV - Negative for CR
					Specificity	100% (80/80)	95.4 - 100%	
					PPV	100%	46 - 100%	
					NPV	99.5%	98.6 - 99.8%	
Mt Sinai Lab	ELISA	S, P	IgG	Spike	Sensitivity	92.5% (37/40)	80.1 - 97.4%	Not tested against HCoV
					Specificity	100% (74/74)	95.1 - 100%	
					PPV	100%	46.2 - 100%	
					NPV	99.6%	98.9 - 99.9%	
Ortho Diagnostics VITROS Anti-SARS-CoV-2 IgG	CLSIA	S, P	IgG	Spike	Sensitivity	87.5% (42/48)	75.3 - 94.1%	Not tested against HCoV
					Specificity	100% (407/407)	99.1 - 100%	
					PPV	100%	81.5 - 100%	
					NPV	99.3%	98.7 - 99.7%	
Ortho Diagnostics VITROS Anti-SARS-CoV2 Total	CLSIA	S, P	Total Ab	Spike	Sensitivity	83.3% (30/36)	68.1 - 92.1%	Not tested against HCoV
					Specificity	100% (400/400)	99.0 - 100%	
					PPV	100%	78.2 - 100%	
					NPV	99.1%	98.3 - 99.6%	
Roche Elecsys Anti-SARS-CoV-2	CLSIA	S, P	Total Ab	NucCap	Sensitivity	100% (29/29)	88.3 - 100%	Tested for HCoV - Negative for CR
					Specificity	99.8% (5262/5272)	99.7 - 99.9%	
					PPV	96.5%	93.9 - 98.1%	
					NPV	100%	99.4 - 100%	

Company - Test	Type of Test	Sample	Antibody	Antigen	Performance Measure	Estimated Performance	95% Confidence Interval	Cross Reactivity
Wadsworth NYS Lab	MSIA	S, P	Total Ab	NucCap	Sensitivity	88% (95/108)	80.5 - 92.8%	Not tested
SARS-CoV					Specificity	98.8% (428/433)	97.3 - 99.5%	against
Microsphere IA					PPV	79.4%	61.1 - 90.7%	HCoV
					NPV	99.4%	99.0 - 99.6%	

NOTES (All information taken from FDA website and product package inserts - none of the tests are "CLIA-Waived")

Type of Test:
Lat Flow: Lateral Flow Chromatographic Immunoassay
ELISA: Enzyme-Linked Immunosorbant Assay
High Throughput ELISA Tests:
CLSIA: Chemiluminescent Immunoassay
CLMIA: Chemiluminescent Microparticle Immunoassay
MSIA: Microsphere Immunoassay

Sample: S: Serum P: Plasma WB: Venipuncture Whole Blood FS: Fingerstick Whole Blood

Antigen:
Spike: viral spike glycoprotein
S1: spike S1 subunit (host cell receptor binding region)
S2: spike S2 subunit (cellular membrane fusion region)
NucCap: viral nucleocapsid

Sensitivity and specificity data given for tests that are for more than one antibody are for combined results (i.e., either IgG or IgM were positive). All sensitivity and specificity data is for best results obtained; most antibody tests give highest positive results when performed 2 to 3 weeks after onset of symptoms or positive molecular test results.
CR (Cross Reactivity): HCoV are other human coronaviruses (NL63, 229E, OC43, HKU1). Most products not extensively tested for HCoV.
Performance Measures: The Positive Predictive Values (PPV) and Negative Predictive Values (NPV) are all calculated for a prevalence rate of 5%.

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance