



Antibody Tests for COVID-19 (issued 5/7/20, updated 6/11/20) Issued by the USET Tribal Epidemiology Center

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 Rapid Test	Lat Flow	S, P	IgM, IgG	Spike	Sensitivity - Combined Specificity - Combined PPV NPV	88.1% (357/405) 99% (309/312) 82.9% 99.4%	84.6 - 90.9% 97.2 - 99.7% 61.4 - 94.1% 99.2 - 99.5%	Tested for HCoV - Negative for CR
Cellex qSARS-CoV-2 IgG/IgM Rapid Test	Lat Flow	S,P, WB	IgM, IgG	Not reported	Sensitivity - Combined Specificity - Combined PPV NPV	93.8% (120/128) 96% (240/250) 55.2% 99.7%	88.2 - 96.8% 92.8 - 97.8% 39.2 - 69.8% 99.3 - 99.8%	Tested, but number not specified
Chembio Diagnostic DPP Covid-19 IgM/IgG	Lat Flow	S, P, WB, FS	IgM, IgG	NucCap	Sensitivity - Combined Specificity - Combined PPV NPV	93.5% (29/31) 94.4% (118/125) 46.8% 99.6%	79.3 - 98.2% 88.9 - 97.3% 27.3 - 65.7% 98.8 - 99.9%	Tested - CR with some HCoV (2/9)
Hangzhou Biotest RightSign COVID-19 IgG/IgM Rapid Test	Lat Flow	S, P, WB	IgM, IgG	S1	Sensitivity - Combined Specificity - Combined PPV NPV	100% (30/30) 100% (80/80) 100% 100%	88.7 - 100% 95.4 - 100% 50.5 - 100% 99.4 - 100%	Tested for HCoV - Negative for CR (0/7)
Healgen COVID-19 IgM-IgG Rapid Test Cassette	Lat Flow	S, P, WB	IgM, IgG	S1	Sensitivity - Combined Specificity - Combined PPV NPV	100% (30/30) 97.5% (78/80) 67.8% 100.0%	88.7 - 100% 97.50% 35.0 - 88.4% 99.4 - 100%	Not tested against HCoV
Abbott Alinity i SARS-CoV-2 IgG	CLMIA	S, P	IgG	NucCap	Sensitivity - Combined Specificity - Combined PPV NPV	100% (34/34) 99% (99/100) 84.0% 100%	89.9 - 100% 94.6 - 99.8% 46.7 - 96.3% 99.4 - 100%	Not tested against HCoV
Abbott Architect SARS-CoV-2 IgG	CLMIA	S, P	IgG	NucCap	Sensitivity - Combined Specificity - Combined PPV NPV	100% (88/88) 99.6% (1066/1070) 92.9% 100%	95.8 - 100% 99.0 - 99.9% 83.4 - 98.1% 99.8 - 100%	Not tested against HCoV

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BioRad Platelia SARS-CoV-2 Total Antibody	ELISA	S, P	Total Ab	NucCap	Sensitivity - Combined Specificity - Combined PPV NPV	92.2% (47/51) 99.6% (684/687) 91.7% 99.6%	81.5 - 96.9% 98.7 - 99.9% 76.7 - 98.1% 99.0 - 99.8%	Tested for HCoV - Negative for CR
DiaSorin LIAISON SARS-CoV-2 S1/S2 IgG	CLIA	S, P	IgG	S1 & S2	Sensitivity - Combined Specificity - Combined PPV NPV	97.6% (40/41) 99.3% (1082/1090) 88.0% 99.9%	87.4 - 99.6% 98.6 - 99.6% 76.7 - 92.9% 99.3 - 100%	Tested for HCoV - Negative for CR
EUROIMMUN	ELISA	S, P	IgG	S1	Sensitivity - Combined Specificity - Combined PPV NPV	90% (27/30) 100% (80/80) 100% 99.5%	74.4 - 96.5% 95.4 - 100% 46 - 100% 98.6 - 99.8%	Tested for HCoV - Negative for CR
Mt Sinai Lab	ELISA	S, P	IgG	Spike	Sensitivity - Combined Specificity - Combined PPV NPV	92.5% (37/40) 100% (74/74) 100% 99.6%	80.1 - 97.4% 95.1 - 100% 46.2 - 100% 98.9 - 99.9%	Not tested against HCoV
Ortho Diagnostics VITROS Anti-SARS-CoV-2 IgG	CLIA	S, P	IgG	Spike	Sensitivity - Combined Specificity - Combined PPV NPV	87.5% (42/48) 100% (407/407) 100% 99.3%	75.3 - 94.1% 99.1 - 100% 81.5 - 100% 98.7 - 99.7%	Not tested against HCoV
Ortho Diagnostics VITROS Anti-SARS-CoV2 Total	CLIA	S, P	Total Ab	Spike	Sensitivity - Combined Specificity - Combined PPV NPV	83.3% (30/36) 100% (400/400) 100% 99.1%	68.1 - 92.1% 99.0 - 100% 78.2 - 100% 98.3 - 99.6%	Not tested against HCoV
Roche Elecys Anti-SARS-CoV-2	CLIA	S, P	Total Ab	NucCap	Sensitivity - Combined Specificity - Combined PPV NPV	100% (29/29) 99.8% (5262/5272) 96.5% 100%	88.3 - 100% 99.7 - 99.9% 93.9 - 98.1% 99.4 - 100%	Tested for HCoV - Negative for CR
Siemens Healthcare ADVIA Centaur SARS-CoV-2 Total	CLMIA	S, P	Total Ab	Spike	Sensitivity - Combined Specificity - Combined PPV NPV	100% (47/47) 99.8% (1586/1589) 96.50% 100%	92.4 - 100% 99.4 - 99.9% 89.8 - 98.8% 99.6 - 100%	Not tested against HCoV

Company - Test	Type of Test	Sample	Antibody	Antigen	Performance Measure	Estimated Performance	95% Confidence Interval	Cross Reactivity
Siemens Healthcare Attelica IM SARS-CoV-2 Total	CLMIA	S, P	Total Ab	Spike	Sensitivity - Combined Specificity - Combined PPV NPV	100% (42/42) 99.8% (1089/1091) 97% 100%	91.6 - 100% 99.3 - 99.9% 87.9 - 99.1% 99.6 - 100%	Not tested against HCoV
Vibrant Labs COVID-19 Ab Assay	CLSIA	S, FS	IgM, IgG	Spike + NucCap	Sensitivity - Combined Specificity - Combined PPV NPV	98.1% (52/53) 98.6% (494/501) 78.7% 99.9%	90.1 - 99.7% 97.1 - 99.3% 62.1 - 88.1% 99.5 - 100%	Tested for HCoV - Negative for CR (0/22)
Wadsworth NYS Lab SARS-CoV Microsphere IA	MSIA	S, P	Total Ab	NucCap	Sensitivity - Combined Specificity - Combined PPV NPV	88% (95/108) 98.8% (428/433) 79.4% 99.4%	80.5 - 92.8% 97.3 - 99.5% 61.1 - 90.7% 99.0 - 99.6%	Not tested against HCoV

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: Fingertick 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%.