

Table 3. Serological detection of SARS-CoV-2 with FDA emergency use authorization (EUA)

Manufacturer	Diagnostic Test	Technology	Antibody(s)	Manufacturer Estimated Testing Time	Sample Types	No. Samples / Test Run	Instrument(s) / System(s)	SARS-CoV-2 Antigen Target(s)	Internal Control (IC) Gene Target(s)	EUA Issue Date
EUROIMMUN US, Inc.	Anti-SARS-CoV-2 ELISA (IgG)	ELISA	IgG	Not specified	Plasma, serum	93	Microplate reader	S1	N/A	05/04/2020
Roche Diagnostics	Elecsys Anti-SARS-CoV-2	ECLIA	Total antibody	18 min	Plasma, serum	18	cobas e immunoassay analyzer	N	N/A	05/02/2020
Wadsworth Center, New York State Department of Health	New York SARS-CoV Microsphere Immunoassay for Antibody Detection*	MIA	IgG, IgA, IgM	Not specified	Serum	94	Luminex FlexMap dual laser cytometer	N	N/A	04/30/2020
Bio-Rad Laboratories	Platelia SARS-CoV-2 Total Ab assay	ELISA	Total antibody	Not specified	Plasma, serum	91	Microplate reader	N	N/A	04/29/2020
Abbott Laboratories, Inc.	SARS-CoV-2 IgG assay	CMIA	IgG	1 hr	Plasma, serum	200	ARCHITECHT i2000SR/i1000SR Instrument	N	N/A	04/26/2020
DiaSorin Inc.	LIAISON SARS-CoV-2 S1/S2 IgG	ELISA	IgG	17 min	Serum	120	LIAISON XL Analyzer	S1, S2	N/A	04/24/2020
Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack	ELISA	IgG	48 min	Plasma, serum	50	VITROS ECi/ECiQ, 3600, 5600, XT 7600	S	N/A	04/24/2020
Autobio Diagnostics Co. Ltd.	Anti-SARS-CoV-2 Rapid Test*	LFIA	IgG, IgM	15-20 min	Plasma, serum	1	N/A	S	Mouse anti-human IgG/IgM	04/24/2020
Mount Sinai Laboratory	COVID-19 ELISA IgG Antibody Test**	ELISA	IgG	Not specified	Serum, plasma	46	Microplate reader	RBD, S	N/A	04/15/2020
Chembio Diagnostic System, Inc	DPP COVID-19 IgM/IgG System*	LFIA	IgG, IgM	15-20 min	Serum, plasma, whole blood	1	DPP Micro Reader II	S	Protein A	04/14/2020

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Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack	ELISA	Total antibody	48 min	Plasma, serum	50	VITROS ECi/ ECiQ, 3600, 5600, XT 7600	N	N/A	4/14/2020
Cellex Inc.	qSARS-CoV-2 IgG/IgM Rapid Test*	LFIA	IgG, IgM	15-20 min	Serum, plasma, whole blood	1	N/A	Not specified	Goat anti-rabbit IgG/IgM	04/01/2020

Adapted from FDA Website: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>

*Rapid Point-of-Care (POC) diagnostics; ** Restricted use to specific CLIA laboratories

LFIA, lateral flow immunoassay; ELISA, enzyme-linked immunosorbent assay; CMIA, chemiluminescent microparticle immunoassay; MIA, microsphere immunoassay; ECLIA, electrochemiluminescence immunoassay; RBD, receptor binding domain of spike protein; S, spike; N, nucleocapsid; N/A, Not applicable.

Online version accessible at: <https://tmclinicalab.jabsom.hawaii.edu/lab-services/fda-emergency-use-authorizations-euas-for-covid-19-diagnostics/>