

使用すべきではない抗体検査キット

メーカー名	テストキット名	ステータス
Abbexa Ltd	abx294171 - COVID-19 IgG/IgM Rapid Test Kit	Removed - Should Not Be Distributed
Abingdon Health Ltd.	AbC-19™ Rapid Test	Removed - Should Not Be Distributed*
Absology Co., Ltd.	Absoludy COVID-19 IgM/IgG Combo	Removed - Should Not Be Distributed*
Absology Co., Ltd.	Absoludy COVID-19 IgM/IgG RAPID	Removed - Should Not Be Distributed*
Absology Co., Ltd.	INIST COVID-19 IgM/IgG RAPID	Removed - Should Not Be Distributed*
Accel Diagnostics, LLC	Rapid C2T Total Ab (IgG/IgM) Card	Removed - Should Not Be Distributed*
ACCObiotech SDN.BHD	ACCO COVID-19 IgM/IgG TEST	Removed - Should Not Be Distributed
Aegis Sciences Corporation	SARS-CoV-2 Antibody, IgG assay	Removed - Should Not Be Distributed*
AESKU DIAGNOSTICS GmbH & Co. KG	AESKULISA® SARS-CoV-2 NP IgG	Removed - Should Not Be Distributed*
AESKU DIAGNOSTICS GmbH & Co. KG	AESKULISA® SARS-CoV-2 NP IgM	Removed - Should Not Be Distributed*
AESKU DIAGNOSTICS GmbH & Co. KG	AESKULISA® SARS-CoV-2 S1 IgM	Removed - Should Not Be Distributed*
AESKU DIAGNOSTICS GmbH & Co. KG	AESKULISA® SARS-CoV-2 S1 IgG	Removed - Should Not Be Distributed*
Agilent Technologies, Inc	Agilent Dako SARS-CoV-2 IgG ELISA kit	Removed - Should Not Be Distributed*
Akston Biosciences Corporation	AntiCoV-ID IgG ELISA Test	Removed - Should Not Be Distributed
Alfa Scientific Designs, Inc.	Clarity COVID-19 IgG/IgM Antibody Test	Removed - Should Not Be Distributed
Alfa Scientific Designs, Inc.	Instant-view plus COVID-19 IgG/IgM Antibody Test	Removed - Should Not Be Distributed
ALPCO	SARS-CoV-2 IgG Chemiluminescence ELISA	Removed - Should Not Be Distributed*
ALPCO	SARS-CoV-2 IgG ELISA	Removed - Should Not Be Distributed*
ALPCO	SARS-CoV-2 IgM Chemiluminescence ELISA	Removed - Should Not Be Distributed*
ALPCO	SARS-CoV-2 IgM ELISA	Removed - Should Not Be Distributed*
Alpha Pharma Service srl	IRIS SARS-CoV-2 IgG/IgM Rapid Test	Removed - Should Not Be Distributed
AngelWorld Biotech Manufacturing FZ LLC	AngelWorld V2.0 COVID-19 IgG/IgM Antibody Rapid Test	Removed - Should Not Be Distributed
Anhui Deepblue Medical Technology Co., Ltd.	COVID-19 (SARS-CoV-2) IgG/IgM Antibody Test Kit (Colloidal Gold)	Removed - Should Not Be Distributed
Ansh Labs	SARS-CoV2 IgG ELISA (AL-1001)	Removed - Should Not Be Distributed
Antagen Pharmaceuticals, Inc.	COVID-19 IgM/IgG Antibody Test Kit (Colloidal Gold)	Removed - Should Not Be Distributed*
Antibody BioPharm, Inc.	COVID-19 IgM/IgG POCT Kit (Colloidal Gold)	Removed - Should Not Be Distributed*
AnyGo Technology Co., Ltd	COVID-19 Capture ELISA Assay	Removed - Should Not Be Distributed*
Arbor Assays	DetectX SARS-CoV-2 IgG ELISA Kit	Removed - Should Not Be Distributed*
Arbor Vita Corporation	CoVisa IgG Test	Removed - Should Not Be Distributed
Artron BioResearch Inc./ Artron Laboratories Inc.	COVID-19 IgM/IgG Antibody Test	Removed - Should Not Be Distributed*
Asan Pharmaceutical Co., Ltd.	Asan Easy Test COVID-19 IgG/IgM	Removed - Should Not Be Distributed*
Atlas Link (Beijing)Technology Co., Ltd	NovaTest: One Step COVID-19 IgG/IgM rapid test	Removed - Should Not Be Distributed
Audacia Bioscience	CMC-19D SARS-CoV2 (COVID-19) Rapid Antibody Test	Removed - Should Not Be Distributed
Aurora Biomed Inc.	COVID-19 IgG/IgM Rapid Test Cassette (Colloidal Gold)	Removed - Should Not Be Distributed
Autobio Diagnostics Co. Ltd.	Anti-SARS-CoV-2 Rapid Test	Removed - Should Not Be Distributed
Axiom BioResearch, Inc.	AxiomHealth COVID-19 IgG/IgM Antibody Test	Removed - Should Not Be Distributed*
Beacon Analytical Systems, Inc.	SARS-CoV-2 Human IgG Antibody Test 96-Well Microtiter Plate Kit Format	Removed - Should Not Be Distributed*
Beijing Beier Bioengineering Co., Ltd	2019-New Coronavirus IgM/IgG Rapid Test Cassette (WB/S/P)	Removed - Should Not Be Distributed
Beijing Decombio Biotechnology Co., Ltd.	Novel Coronavirus IgM/IgG Combo Rapid Test-Cassette (Serum/Plasma/Whole blood)	Removed - Should Not Be Distributed*
Beijing DiaGreat Biotechnologies Co. Ltd.	2019-nCoV IgM Antibody Determination Kit	Removed - Should Not Be Distributed*
Beijing DiaGreat Biotechnologies Co. Ltd.	2019-nCoV IgG/IgM Antibody Rapid Test Kit	Removed - Should Not Be Distributed*
Beijing DiaGreat Biotechnologies Co. Ltd.	2019-nCoV IgG Antibody Determination Kit	Removed - Should Not Be Distributed*
Beijing Kewei Clinical Diagnostic Reagent Inc.	Genonto RapidTest10 COVID-19 IgG/IgM Antibody Rapid Test Kit	Removed - Should Not Be Distributed
Beijing O&D BIOTECH CO., LTD.	Coronavirus disease (COVID-19) Total Antibody Rapid Test (Colloidal Gold)	Removed - Should Not Be Distributed
Beroni Group	SARS-CoV-2 IgG/IgM Antibody Detection Kit	Removed - Should Not Be Distributed
BestNovo (Jiangsu) Medical Technology Co., Ltd.	BestNovo COVID-19 IgM/IgG Antibody Rapid Test Kit	Removed - Should Not Be Distributed
Bethyl Laboratories, Inc.	Bethyl SARS-CoV-2 IgG IVD ELISA	Removed - Should Not Be Distributed*
Biobase Biodystry (Shandong) Co., Ltd.	SARS-CoV-2 IgM/IgG Antibody Test Kit (Colloidal Gold)	Removed - Should Not Be Distributed
Biocan Diagnostics Inc.	Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test (Strip Format)	Removed - Should Not Be Distributed*
Biolidics Limited	2019-nCoV IgG/IgM Detection Kit (Colloidal Gold)	Removed - Should Not Be Distributed*
BioMedomics, Inc.	COVID-19 IgM-IgG rapid test	Removed - Should Not Be Distributed*
Biomerica, Inc.	COVID-19 IgG/IgM Rapid Test	Removed - Should Not Be Distributed
Bioscience Diagnostic Technology Company Ltd.	Diagnostic Kit for Novel Coronavirus (2019-nCoV) IgG Antibody	Removed - Should Not Be Distributed
Bioscience Diagnostic Technology Company Ltd.	Diagnostic Kit for Novel Coronavirus (2019-nCoV) IgM Antibody	Removed - Should Not Be Distributed
Bioscience(Chongqing) Diagnostic Technology Co., Ltd.	Qualitative Diagnostic Kit for Novel Coronavirus (2019-nCoV) IgM Antibody	Removed - Should Not Be Distributed
Bioscience(Chongqing) Diagnostic Technology Co., Ltd.	Qualitative Diagnostic Kit for Novel Coronavirus (2019-nCoV) IgG Antibody	Removed - Should Not Be Distributed
Bioscience(Tianjin) Diagnostic Technology Co., Ltd.	Qualitative Diagnostic Kit for Novel Coronavirus(2019-nCoV) IgM Antibody	Removed - Should Not Be Distributed
Bioscience(Tianjin) Diagnostic Technology Co., Ltd.	Qualitative Diagnostic Kit for Novel Coronavirus(2019-nCoV) IgG Antibody	Removed - Should Not Be Distributed
Bioscience(Tianjin) Diagnostic Technology Co., Ltd.	Novel Coronavirus (2019-nCoV) Antibody Rapid Test	Removed - Should Not Be Distributed
BioSure (UK) Limited	BioSURE COVID-19 Antibody Rapid Test (REF: 92001COV)	Removed - Should Not Be Distributed*
BioSys Laboratories, Inc.	BioSys Plus COVID-19 IgM/IgG Rapid Test	Removed - Should Not Be Distributed
Bloom Diagnostics AG	Bloom COVID-19 Test	Removed - Should Not Be Distributed*
Boston Bio Lab Inc.	Boston Bio EZ Covid-19	Removed - Should Not Be Distributed*
Boston Biopharma Inc.	BB Rapid-MT	Removed - Should Not Be Distributed*
BreviTest Technologies, LLC	BreviTest SARS-CoV-2 IgG Test	Removed - Should Not Be Distributed*
BTNX, Inc.	Rapid Response™ COVID-19 IgG/IgM Test Cassette	Removed - Should Not Be Distributed*
Calbiotech, Inc.	ErbaLisa® COVID-19 IgG	Removed - Should Not Be Distributed
Camtech Diagnostics Pte Ltd	Camtech Covid-19 IgM/IgG 2C Rapid Test	Removed - Should Not Be Distributed
Camtech Diagnostics Pte Ltd	Camtech Covid-19 IgM/IgG 1C Rapid Test	Removed - Should Not Be Distributed
Cell ID Pte Ltd	Smart COVID-19 IgM/IgG Rapid Diagnostic Test (RDT)	Removed - Should Not Be Distributed*
Changchun Wancheng Bio-Electron Co., Ltd.	COVID-19 IgG/IgM ANTIBODY RAPID TEST KIT (Colloidal gold immunochromatography)	Removed - Should Not Be Distributed
Chembio Diagnostic Systems, Inc.	DPP COVID-19 IgM/IgG System	Removed - Should Not Be Distributed
Chemtron Biotech, Inc.	Chemtrue®Rapid COVID-19 IgM/IgG Antibody Test	Removed - Should Not Be Distributed
ClearSign Diagnostics Co	Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test	Removed - Should Not Be Distributed
ClearSign Diagnostics Co., LLC	ClearSign Diagnostics SARS-CoV-2 Antibody (IgM and IgG) Test	Removed - Should Not Be Distributed
Core Technology Co., Ltd.	RapidTest COVID-19 IgM/IgG Ab Test	Removed - Should Not Be Distributed
CoreMedica Laboratories, Inc.	Capillary Blood Collection Kit & Laboratory Analysis for SARS-CoV-2 ELISA IgG and IgM	Removed - Should Not Be Distributed
CTK Biotech, Inc.	OnSite® COVID-19 IgG/IgM Rapid Test	Removed - Should Not Be Distributed
Diabetomics, Inc	CovAbScreen™ SARS-CoV-2 Ab Test	Removed - Should Not Be Distributed*
DIALAB(ZJG) Biotech Co., Ltd.	SARS-CoV-2 IgG/IgM Antibody Test (Fluorescence Immunoassay)	Removed - Should Not Be Distributed*
Diazyme Laboratories, Inc.	Diazyme SARS-CoV-2 Antibody Rapid Test	Removed - Should Not Be Distributed*
Discount Diagnostics	Global WholeHealth Partners RDT IgG/IgM Antibody test	Removed - Should Not Be Distributed
DLS Research & Ventures	SCOV Immune Response Test	Removed - Should Not Be Distributed
DLS Research & Ventures	Screen For Coronaviruses (SCOV) Immune Response Test	Removed - Should Not Be Distributed
DLS Research & Ventures	Screen For Coronaviruses (SCOV) Test	Removed - Should Not Be Distributed
DNALink, Inc.	AccuFind COVID19 IgG	Removed - Should Not Be Distributed*
DxGen Corp.	Epithod616 COVID-19 IgG Test Kit	Removed - Should Not Be Distributed*
DxGen Corp.	EDGC RapidCheck COVID-19 IgG Test Kit	Removed - Should Not Be Distributed*
Dynamiker Biotechnology (Tianjin) Co., Ltd.	RapidCOV™ 2019-nCoV IgG/IgM Rapid Test	Removed - Should Not Be Distributed
EACHY Biopharmaceuticals Co., Ltd.	AccuRapid™ SARS-CoV-2 IgM/IgG Test Kit (Fluorescence Lateral Flow Immunoassay)	Removed - Should Not Be Distributed
EACHY Biopharmaceuticals Co., Ltd.	AccuRapid™ SARS-CoV-2 IgM/IgG Test Kit (Lateral Flow Immunoassay)	Removed - Should Not Be Distributed
EACHY Biopharmaceuticals Co., Ltd.	SmartScreen COVID-19 IgM/IgG Test Kit	Removed - Should Not Be Distributed

Edinburgh Genetics Limited	ActivXpress+ COVID-19 IgG/IgM Immunoassay Complete Testing Kit	Removed - Should Not Be Distributed*
EpiGentek	SeroFlash SARS-CoV-2 IgM/IgG Antibody Detection Kit	Removed - Should Not Be Distributed*
Epitope Diagnostics, Inc.	EDI COVID-19 Nucleocapsid IgG Quantitative ELISA Kit	Removed - Should Not Be Distributed
Epitope Diagnostics, Inc.	KT-1033 EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit	Removed - Should Not Be Distributed*
Epitope Diagnostics, Inc.	KT-1032 EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit	Removed - Should Not Be Distributed*
ET Healthcare Inc.	Pylon COVID-19 IgM/IgG Assay	Removed - Should Not Be Distributed*
EUROIMMUN AG	Anti-SARS-CoV-2 ELISA (IgA)	Removed - Should Not Be Distributed*
Fosun Pharma USA Inc.	Fosun COVID-19 IgG/IgM Rapid Antibody Detection Kit	Removed - Should Not Be Distributed*
Genabio LLC	SARS-CoV-2 IgM/IgG (GICA) Test	Removed - Should Not Be Distributed
GenBody Inc.	GenBody COVID-19 IgM/IgG	Removed - Should Not Be Distributed
Genelogic Research Limited	Genelogic COVID-19 IgM/IgG Antibody Rapid Test	Removed - Should Not Be Distributed
General Biologicals Corporation	GB SARS-CoV-2 Ab ELISA, Cat. No. 4ECO001	Removed - Should Not Be Distributed*
GeneScan Diagnostics, LLC	AmeriDx® SARS-CoV-2 IgG/IgM Rapid Test Kit	Removed - Should Not Be Distributed
GeneScan Diagnostics, LLC	AmeriDx® SARS-CoV-2 IgG/IgM-T Antibody Rapid Test Kit	Removed - Should Not Be Distributed
Genesprint Group, Ltd.	Genesprint Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 test	Removed - Should Not Be Distributed*
Genlantis Diagnostics, Inc.	CovidQuik Coronavirus (COVID-19) IgM/IgG Antibody Test	Removed - Should Not Be Distributed*
Genobio Pharmaceutical Co., Ltd.	COVID-19 IgM/IgG Lateral Flow Assay	Removed - Should Not Be Distributed*
Genrui Biotech Inc.	Novel Coronavirus (2019-nCoV) IgG/IgM Test Kit (Colloidal Gold)	Removed - Should Not Be Distributed
Getein Biotech Inc.	One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold)	Removed - Should Not Be Distributed
Global Go (Distributed Core Technology Co., Ltd.)	RapidTest COVID-19 IgM/IgG Ab Test	Removed - Should Not Be Distributed
Gold Standard Diagnostics	SARS-CoV-2 IgM ELISA Test Kit	Removed - Should Not Be Distributed
Gold Standard Diagnostics	INgezim® COVID 19 CROM Rapid Test Kit	Removed - Should Not Be Distributed*
Gold Standard Diagnostics	INgezim® COVID 19 DR ELISA Test Kit	Removed - Should Not Be Distributed*
Goldsite Diagnostics Inc	SARS-CoV-2 IgG/IgM kit	Removed - Should Not Be Distributed*
GREEN ENERGY TECHNOLOGY SOLUTIONS, LLC	AMP Rapid Test SARS-CoV-2 IgG/IgM	Removed - Should Not Be Distributed*
Guangdong Hecin Scientific, Inc.	SARS-CoV-2 IgM Antibody Rapid Test Kit	Removed - Should Not Be Distributed*
Guangzhou Decheng biotechnology	DOCHEK™ SARS-CoV-2 Antibody Rapid Test Kit	Removed - Should Not Be Distributed*
Guangzhou Fenghua Bioengineering Co., Ltd.	SARS-CoV-2 IgG/IgM Rapid Test	Removed - Should Not Be Distributed
H&Z Life Science Co. Ltd.	Anti-COVID-19 Virus IgM/IgG Test Kit (lateral flow assay)	Removed - Should Not Be Distributed
H-Guard (China) Co., Ltd.	Novel Coronavirus COVID-19 IgM/IgG Test Kit (colloidal gold)	Removed - Should Not Be Distributed*
Hangzhou AllTest Biotech Co., Ltd.	AllTest 2019-nCoV IgG/IgM Rapid Test Cassette	Removed - Should Not Be Distributed
Hangzhou AllTest Biotech Co., Ltd.	AllTest COVID-19 IgG/IgM Rapid Test Strip	Removed - Should Not Be Distributed
Hangzhou Clongene Biotech Co., Ltd.	COMBRA COVID-19 IgM/IgG Rapid Test Cassette	Removed - Should Not Be Distributed
Hangzhou Realy Tech Co Ltd.	2019-nCoV IgG/IgM Rapid Test	Removed - Should Not Be Distributed
Hangzhou Sejoy Electronics & Instrument Co., Ltd.	COVID-19 IgG/IgM Rapid Test Cassette	Removed - Should Not Be Distributed*
Hangzhou Testsea Biotechnology Co., Ltd.	One Step SARS-CoV-2(COVID-19) IgG/IgM Test	Removed - Should Not Be Distributed*
Horizon Pharmaceuticals, Inc.	Horizon RDT SARS CoV-2 IgM/IgG Antibody Test	Removed - Should Not Be Distributed
Hunan RunKun Pharmaceutical Co., Ltd.	SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)	Removed - Should Not Be Distributed*
ICT international	2019-nCoV IgG/IgM Rapid Test Cassette	Removed - Should Not Be Distributed*
IMMY, Inc.	clarus SARS-CoV-2 Total Antibody EIA	Removed - Should Not Be Distributed*
Innovation Biotech (Beijing) Co., Ltd.	SARS-COV-2 IgM/IgG Antibody Rapid Test (Immunochromatographic Method)	Removed - Should Not Be Distributed
Invenio Medical	COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)	Removed - Should Not Be Distributed
Invenio Medical	COVID-19 IgG/IgM Ab Rapid Test	Removed - Should Not Be Distributed
Iontox	COVID-19 (SARS-CoV-2) IgG antibody test kit	Removed - Should Not Be Distributed*
Jiangsu Dablood Pharmaceutical Co. Ltd.	AssuranceAB™ COVID-19 IgM/IgG Rapid Antibody Test	Removed - Should Not Be Distributed*
Jiangsu Dablood Pharmaceutical Co. Ltd.	COVID-19 IgM/IgG Rapid Test	Removed - Should Not Be Distributed
Jiangsu Eubo Biotechnology Co., Ltd.	EUBO COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)	Removed - Should Not Be Distributed
Jiangsu Macro & Micro-Test Med-Tech Co., Ltd.	SARS-CoV-2 IgM/IgG Rapid Assay Kit (Colloidal Gold)	Removed - Should Not Be Distributed*
Jiangsu Superbio Biomedical (Nanjing) Co., Ltd.	SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)	Removed - Should Not Be Distributed*
Jiangsu Superbio Biomedical (Nanjing) Co., Ltd.	ThermoGenesis SARS-CoV-2(COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)	Removed - Should Not Be Distributed*
JOYSBIO (Tianjin) Biotechnology Co., Ltd.	COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)	Removed - Should Not Be Distributed
Leinco Technologies, Inc.	COVID-19 ImmunoRank Neutralization MICRO-ELISA	Removed - Should Not Be Distributed
Lepu Medical Technology (Beijing) Co., Ltd.	Lepu SARS-CoV-2 Antibody Rapid Test	Removed - Should Not Be Distributed
Leritas LLC	DualTec SARS-CoV-2 Test Kit	Removed - Should Not Be Distributed*
Lifeassay Diagnostics (Pty) Ltd	Test-it COVID-19 IgM/IgG Lateral Flow Assay	Removed - Should Not Be Distributed
LumiQuick Diagnostics, Inc.	QuickProfile™ 2019-nCoV IgG/IgM Antibody Test	Removed - Should Not Be Distributed
Maccura Biotechnology Co., Ltd.	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) IgM/IgG Antibody Assay Kit by Colloidal Gold Method	Removed - Should Not Be Distributed*
MedicalSystem Biotechnology Co., Ltd.	Coronavirus Disease 2019 Antibody (IgM/IgG) Combined Test Kit	Removed - Should Not Be Distributed*
Medicon Company Limited	Trueline COVID-19 IgG/IgM Rapid Test	Removed - Should Not Be Distributed
MedMira Inc.	REVEALCOVID-19™ Total Antibody Test	Removed - Should Not Be Distributed*
Melbourne Biotech	MB COVID-19 Antibody Detection Kit	Removed - Should Not Be Distributed
Mokobio Biotechnology R&D Center	SARS-CoV-2 IgM & IgG Quantum Dot Immunoassay	Removed - Should Not Be Distributed*
Mokobio Biotechnology R&D Center Inc	COVID-19 IgM & IgG Rapid Test (Colloidal Gold Assay)	Removed - Should Not Be Distributed*
Molecular Innovations	SARS-CoV-2 IgG Seroconversion ELISA Kit	Removed - Should Not Be Distributed*
Multi-G bvba	COVID-19 IgG/IgM Rapid Test Cassette	Removed - Should Not Be Distributed*
Nanjing Norman Biological Technology Co., Ltd	Novel Coronavirus (2019-nCoV) IgG/IgM Antibody Testing Kit (Colloidal Gold)	Removed - Should Not Be Distributed*
Nanjing SYNTHGENE Medical Technology Co., Ltd.	SYNTHGENE COVID-19 IgM/IgG Rapid Detection Kit (Colloidal Gold Method)	Removed - Should Not Be Distributed
Nanjing Vazyme Medical Technology Co., LTD.	2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)	Removed - Should Not Be Distributed*
Nanjing Weiyn Biotechnology Co., Ltd.	SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)	Removed - Should Not Be Distributed
Nano-Ditech Corporation	Nano-Check COVID-19 IgG/IgM Antibody Test	Removed - Should Not Be Distributed*
NanoEntek, Inc.	FREND COVID-19 IgG/IgM Duo	Removed - Should Not Be Distributed*
Nanomix, Inc.	Nanomix eLab® COVID-19 Rapid IgG/IgM Panel	Removed - Should Not Be Distributed*
NanoResearch, Inc.	NanoMedicina™ SARS-COV-2 IgM/IgG Antibody Rapid Test	Removed - Should Not Be Distributed
Nantong Diagnos Biotechnology Co., Ltd.	(2019-nCoV) New coronavirus Antibody Test (Colloidal Gold)	Removed - Should Not Be Distributed
Nantong Egens Biotechnology Co., Ltd	EGENS COVID-19 IgG/IgM Rapid Test Kit	Removed - Should Not Be Distributed
Naturintus LLC	Viralert COVID-19 IgG/IgM ANTIBODY RAPID TEST KIT	Removed - Should Not Be Distributed*
Newscon Bio-Pharmaceutical Co., Ltd.	COVID-19 Microfluidic IgG/IgM Test	Removed - Should Not Be Distributed
Newscon Coast Bio-Pharmaceutical Co., Ltd.	COVID-19 Microfluidic Combo Test	Removed - Should Not Be Distributed
Newscon Coast Bio-Pharmaceutical Co., Ltd.	COVID-19 IgG/IgM Rapid Test	Removed - Should Not Be Distributed
Oncosem Onkologjik Sistemler San.ve Tic. A.S	CRT (COVID-19 Rapid Test)	Removed - Should Not Be Distributed*
One Lambda, Inc.	LABScreen™ COVID Plus	Removed - Should Not Be Distributed*
One Mito, Inc.	InstantRapid® SARS CoV-2 IgG IgM Test	Removed - Should Not Be Distributed
Otogenetics	OTO-Artron COVID-19 IgM/IgG Antibody Rapid Detection test	Removed - Should Not Be Distributed*
Pacific Connect Group LLC (US)	SARS-CoV-2 IgG/IgM Rapid Test Kit	Removed - Should Not Be Distributed
PCL Inc.	COVID19 IgG/IgM Rapid Gold	Removed - Should Not Be Distributed
Pellecome LLC (Distributed Core Technology Co., Ltd.)	CoreTest COVID-19 IgM/IgG Ab Test	Removed - Should Not Be Distributed
PerGrande BioTech Development Co., Ltd.	SARS-CoV-2 Antibody Detection Kit (Colloidal Gold Immunochromatographic assay)	Removed - Should Not Be Distributed*
Phamatch	COVID19 IgG / IgM Rapid Test	Removed - Should Not Be Distributed*
Pharmact GmbH	BeiTEST It SARS CoV-2 IgM/IgG Rapid Test (Pharmact CoV-2 Rapid Test)	Removed - Should Not Be Distributed*
Pinnacle Biolabs	SARS-CoV-2 IgG/IgM Rapid Test	Removed - Should Not Be Distributed
Plexense, Inc.	ACCEL ELISA COVID-19	Removed - Should Not Be Distributed*
Profarma, UAB	ProRapid Coronavirus Disease (SARS-CoV-2) IgG/IgM Rapid Test Cassette Single Use Kit	Removed - Should Not Be Distributed
ProGnosis Biotech SA	Bio-Shield 2019-nCoV Total Ig ELISA	Removed - Should Not Be Distributed*
Promedical	COVID-19 Rapid Test	Removed - Should Not Be Distributed*

Promedical Equipment Pty Ltd	Promedical IgM/IgG Rapid Detection Kit	Removed - Should Not Be Distributed
Prometheus Bio Inc.	2019-nCoV IgG/IgM Test (Whole blood/Serum/Plasma) Colloidal Gold	Removed - Should Not Be Distributed*
ProteomeTech Inc.	KOVIcheck COVID-19 IgG/IgM	Removed - Should Not Be Distributed*
Pure Genetic Medical Ltd. (Distributed Bosen Biotech Ltd. Co)	Rapid 2019-nCoV IgG/IgM Combo Test Card	Removed - Should Not Be Distributed
Qualigen, Inc.	FastPack® SARS-CoV-2 IgG Immunoassay	Removed - Should Not Be Distributed*
RayBiotech Life, Inc.	Novel Coronavirus (SARS-CoV-2) IgM and IgG Antibody Detection Kits for Serum	Removed - Should Not Be Distributed
RayBiotech Life, Inc.	Novel Coronavirus (SARS-CoV-2) IgM and IgG Dual Combined Antibody Detection Kit for Serum	Removed - Should Not Be Distributed
Reszon Diagnostics International Sdn. Bhd.	RESZON (COVID-19) (Sars-Cov-2) IgG/IgM Antibody Test	Removed - Should Not Be Distributed*
Reszon Diagnostics International Sdn. Bhd.	Reszon COVID-19 Rapid IgG/IgM Test	Removed - Should Not Be Distributed*
Ring Biotechnology Co Ltd	COVID-19 IgM/IgG Rapid Test Kit	Removed - Should Not Be Distributed*
SA Scientific	SAS™ COVID-19 Antibody Detection test	Removed - Should Not Be Distributed*
Safecare Biotech (Hagzhou) Co., Ltd.	SAFECARE COVID-19 IgG/IgM Rapid Test Device	Removed - Should Not Be Distributed
Saladax Biomedical	COVID-19 IgG/IgM Rapid Antibody Test	Removed - Should Not Be Distributed*
ScheBo® • Biotech AG ScheBo®	SARS-CoV-2 Quick	Removed - Should Not Be Distributed*
Sciteck Diagnostics	COVID19 Automated Antibody Assay	Removed - Should Not Be Distributed
SD Biosensor	STANDARD Q COVID-19 IgM/IgG Duo	Removed - Should Not Be Distributed
Sensing Self Pte. Ltd.	COVID-19 Rapid IgM/IgG Combined Antibody Assay Pre-Screening Kit	Removed - Should Not Be Distributed
Shandong ThinkLab Biotechnology Co., Ltd.	2019-nCoV IgM/IgG antibody Test Kit (Colloidal-gold Assay)	Removed - Should Not Be Distributed
Shanghai Eugene Biotech Co., Ltd.	SARS-CoV2 (COVID-19) IgG/IgM Rapid Test	Removed - Should Not Be Distributed
Shanghai Fosun Long March Medical Science Co., Ltd.	Fosun COVID-19 IgG/IgM Rapid Antibody Detection Kit	Removed - Should Not Be Distributed*
Shanghai Liangrun Biomedicine Technology Co., Ltd.	Liangrun COVID-19 IgM/IgG Antibody Test	Removed - Should Not Be Distributed
Shanghai Outdo Biotech Co., Ltd.	Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test	Removed - Should Not Be Distributed*
Shenzhen Landwind Medical Co., Ltd.	COVID-19 IgG/IgM Rapid Test	Removed - Should Not Be Distributed*
Shenzhen Kingfocus Biomedical Engineering Co., Ltd.	True-Dot™ Novel Coronavirus (2019-nCoV) IgM/IgG Rapid Antibody Detection Kit (Quantum Dot Immunochromatography)	Removed - Should Not Be Distributed*
Shenzhen Lvshiyuan Biotechnology Co., Ltd	COVID-19 (2019-nCoV) Coronavirus IgG/IgM Rapid Test Kit	Removed - Should Not Be Distributed
Shijiazhuang Hipro Biotechnology Co., Ltd.	COVID-19 IgM/IgG Antibody Test Kit (Colloidal Gold)	Removed - Should Not Be Distributed
Singway Biotech Inc.	COVID-19 IgG/IgM Detection Kit (Colloidal Gold)	Removed - Should Not Be Distributed
Sinocare, Inc.	SARS-CoV-2 Antibody Test Kit (Colloidal Gold Method)	Removed - Should Not Be Distributed
Sober Holdings, LLC	ProMed Rapid Testing - COVID-19 IgG/IgM Test Kit	Removed - Should Not Be Distributed
Sober Holdings, LLC	ProMed Rapid Test	Removed - Should Not Be Distributed
South Jersey Diagnostics, LLC	COVID-19-CHECK-1	Removed - Should Not Be Distributed*
Spartacus-Biomed	LFA COVID-19 IgG & IgM Rapid Test Device	Removed - Should Not Be Distributed
Spring Health Care AG	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	Removed - Should Not Be Distributed
Sugentech, Inc.	SGT-flex COVID-19 IgM/IgG	Removed - Should Not Be Distributed*
Sunbeam Laboratories, LLC.	Sunbeam Laboratories Covid-19 Rapid Test Kit	Removed - Should Not Be Distributed*
Sure Bio-tech	API Covid-Rapid IgM/IgG Antibody Test Kit	Removed - Should Not Be Distributed
Sure Bio-Tech	API Pharma Covid-Rapid IgM/IgG Antibody Test	Removed - Should Not Be Distributed
SUREDX	V-CHEK™ SARS-CoV-2 Antibody Rapid Test Kit	Removed - Should Not Be Distributed
Suzhou Kangheshun Medical Technology Co., Ltd	SARS-CoV-2 IgG/IgM Rapid Test Cassette	Removed - Should Not Be Distributed
Telepoint Medical Services	SARS-CoV-2 IgG/IgM Rapid Qualitative Test	Removed - Should Not Be Distributed
Tetracore Inc.	Tetracore FlexImmArray SARS-CoV-2 Human IgG Test	Removed - Should Not Be Distributed
TheraTest Laboratories, Inc.	EL-Anti-SARS-CoV-2 IgG	Removed - Should Not Be Distributed*
Tianjin Beroni Biotechnology Co. Ltd	SARS-CoV-2 IgG/IgM Antibody Detection Kit	Removed - Should Not Be Distributed
Tianjin New Bay Bioresearch Co., Ltd.	Quikpac II COVID-19 IgG/IgM	Removed - Should Not Be Distributed*
TM Testing, Inc.	TM Test Kits, CoVID-19 Rapid Antibody Serology Test	Removed - Should Not Be Distributed
Top Biotech Sdn. Bhd	TOP RAPID COVID-19 Rapid Antibody IgG/IgM Test Kit	Removed - Should Not Be Distributed
Truvian Sciences Inc.	Easy Check COVID-19 IgM/IgG™ POC Antibody Test	Removed - Should Not Be Distributed*
Universal Meditech Inc.	DiagnosUS® SARS-CoV-2 Antibody (IgG/IgM) Test	Removed - Should Not Be Distributed
Velox Biosystems	COVID-19 Microarray IgG Immunoassay	Removed - Should Not Be Distributed*
VicTorch Meditek Inc.	COVID-19 Serology IgM ELISA	Removed - Should Not Be Distributed*
VicTorch Meditek Inc.	COVID-19 Serology IgG ELISA	Removed - Should Not Be Distributed*
VicTorch Meditek Inc.	COVID-19 IgG/IgM Rapid test Cassette	Removed - Should Not Be Distributed*
Victory Square Health Canada, Inc.	Safetest-COVID19 IgG / IgM - Elisa Kit	Removed - Should Not Be Distributed*
Victory Square Health, Inc.	Safetest Covid-19 IgG/IgM Rapid Test	Removed - Should Not Be Distributed*
Virintel, LLC	Virintel COVID-19 Antibody Test	Removed - Should Not Be Distributed
Virotech Diagnostics GmbH	Gold Standard Diagnostics SARS-CoV-2 IgA ELISA Test Kit	Removed - Should Not Be Distributed*
VITA Testing	COVID-19 IgM/IgG Antibody Rapid Test Kit	Removed - Should Not Be Distributed
Vitro Diagnostics	Vitro Diagnostics COVID 19 IgG/IgM Rapid Test Cassette Serology Device	Removed - Should Not Be Distributed
VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiag COVID-19 IgM/IgG Rapid Test	Removed - Should Not Be Distributed
Vivera Pharmaceuticals, Inc.	Vivera Pharma COVID-19 Rapid Test	Removed - Should Not Be Distributed*
Vivera Pharmaceuticals, Inc.	COVx-RT	Removed - Should Not Be Distributed
W.H.P.M., Inc.	COVID-19 IgM/IgG Rapid Test	Removed - Should Not Be Distributed
W.H.P.M., Inc.	COVISURE™ COVID-19 IgM/IgG Rapid Test	Removed - Should Not Be Distributed
Wuhan EasyDiagnosis	Ediagnosis COVID-19 (SARS-CoV-2) IgM/IgG Antibody Test	Removed - Should Not Be Distributed
Wuhan UNscience Biotechnology Co., Ltd.	Coronavirus-19 (COVID-19) Antibody (IgM/IgG) Rapid Test Kit (Colloidal gold immunochromatography)	Removed - Should Not Be Distributed*
Wuhu 3H Biotechnology Co. Ltd.	COVID-19 IgG/IgM Test Kit (Colloidal Gold Method)	Removed - Should Not Be Distributed
Xiamen AmonMed Biotechnology Co., Ltd.	Helix-19 COVID-19 IgM/IgG Test Kit (Colloidal Gold)	Removed - Should Not Be Distributed
Xiamen AmonMed Biotechnology Co., Ltd.	COVID-19 IgM/IgG test kit (Colloidal Gold)	Removed - Should Not Be Distributed*
Xiamen Wiz Biotech Co., Ltd.	Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2	Removed - Should Not Be Distributed
Zalgen Labs, LLC.	ReSARS CoV-2 (N) IgG ELISA	Removed - Should Not Be Distributed*
Zepto Life Technology	ZepMIA20 SARS-CoV-2 IgG assay	Removed - Should Not Be Distributed*
ZEUS Scientific, Inc.	ZEUS Rapid SARS-CoV-2 IgM/IgG Test System	Removed - Should Not Be Distributed*
Zhejiang Orient Gene Biotech, Co., Ltd.	COVID-19 IgG/IgM Rapid Test Cassette	Removed - Should Not Be Distributed
Zhengzhou Fortune Bioscience Co., Ltd.	COVID-19 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography Method)	Removed - Should Not Be Distributed
Zhengzhou Fortune Bioscience Co., Ltd.	COVID-19 IgM Antibody Rapid Test Kit	Removed - Should Not Be Distributed
Zhengzhou Fortune Bioscience Co., Ltd.	COVID-19 IgG Antibody Rapid Test Kit	Removed - Should Not Be Distributed
Zhongshan Bio-Tech Co Ltd.	SARS-CoV-2 IgM/IgG (GICA)	Removed - Should Not Be Distributed*
Zuhai Encode Medical Engineering Co., Ltd	Novel Coronavirus (COVID-19) IgG/IgM Rapid Test Device	Removed - Should Not Be Distributed*
Zuhai Keyu Biological Engineering Co., Ltd.	SARS-CoV-2 IgG/IgM Rapid Test Kit	Removed - Should Not Be Distributed
Zuhai Livzon Diagnostics, Inc.	Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Colloidal Gold)	Removed - Should Not Be Distributed*
Zybio Inc.	SARS-CoV-2 IgM/IgG Antibody Assay Kit (Colloidal Gold Method)	Removed - Should Not Be Distributed

參照URL : <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/removal-lists-tests-should-no-longer-be-used-and-or-distributed-covid-19-faqs-testing-sars-cov-2>