

Removal Lists of Tests That Should No Longer Be Used and/or Distributed for COVID-19: FAQs on Testing for SARS-CoV-2

This page provides answers to frequently asked questions related to tests that should no longer be used and/or distributed for COVID-19.

This section includes questions and answers regarding the policies outlined in the *Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff: Policy for Coronavirus Disease-2019 Tests during the Public Health Emergency (Revised)* (</regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>). In this section, this guidance is referred to as the Policy for Coronavirus Disease-2019 Tests.

For a directory of FAQs related to SARS-CoV-2 testing, see [FAQs on Testing for SARS-CoV-2](/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) (</medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2>).

Q: What laboratories that had previously provided notification to the FDA that they had developed and validated a diagnostic SARS-CoV-2 test under the policy outlined in Section IV.A of the Policy for Coronavirus Disease-2019 Tests have now been removed from that notification list because the FDA has determined the test should no longer be used? (Updated 7/15/21)

Q: What commercial manufacturers of diagnostic tests that had previously provided notification to the FDA under the policy outlined in Section IV.C of the Policy for Coronavirus Disease-2019 Tests have now been removed from that notification list and should no longer be offering that test? (Updated 7/6/21)

Although the FDA had previously included them on the website notification list of the commercial manufacturers in the list below provided notification to the FDA that they developed and validated a diagnostic SARS-CoV-2 test as set forth in Section IV.A of the *Policy for Coronavirus Disease-2019 Tests* (</regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>). Although the FDA had previously included them on the website notification list of the commercial manufacturers in the list below provided notification to the FDA that they developed and validated a diagnostic SARS-CoV-2 test as set forth in Section IV.C of the *Policy for Coronavirus Disease-2019 Tests* (</regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>). The FDA has determined that there are significant problems with the tests commercial manufacturers distributing diagnostic test kits under that policy, but they have now been removed from that notification list and placed on the list below. As noted in the guidance, among other things, if significant problems are identified with such a test that cannot be or have not been addressed in a timely manner, the FDA intends to remove the laboratory from the notification list. The FDA has determined that there are significant problems with the tests commercial manufacturers distributing diagnostic test kits under that policy, but they have now been removed from that notification list and placed on the list below. As noted in the guidance, if an EUA request is not submitted by a commercial manufacturer of a diagnostic test within a reasonable period of time, or if significant problems are identified with such a test that cannot be or have not been addressed in a timely manner, the FDA intends to

The FDA expects that laboratories from this list will continue to use their in-house diagnostic SARS-CoV-2 laboratory developed tests that test specifically on the notification list. Other tests that are FDA authorized may be available for use by these laboratories, in accordance with those EUAs.

The FDA expects that the tests on this list will not be distributed unless and until an EUA is issued for the test, and the FDA may take additional actions as appropriate.

Search:

Search:

Laboratory

Status

Manufacturer	Test	Status
Advanced Biological Laboratories (ABL) S.A.	UltraGene Combo2Screen SARS-CoV-2 Assay	Removed - Should Not Be Distributed*
Beckman Coulter	Access SARS-CoV-2 Antigen	Removed - Should Not Be Distributed*
CardiAI Inc.	CoviLamp™ Fluorometric Test Kit	Removed - Should Not Be Distributed*
Caspr Biotech Corporation	Direct Caspr Lyo-CRISPR SARS-CoV-2	Removed - Should Not Be Distributed*
Caspr Biotech Corporation	Caspr Lyo-CRISPR SARS-CoV-2	Removed - Should Not Be Distributed*
Ender Diagnostics AG	Ender MASS COVID-19 isothermal PCR detection kit	Removed - Should Not Be Distributed
Healgen	Aegle Rapid COVID-19 Antigen Test	Removed - Should Not Be Distributed
Healgen	Biosynex Rapid COVID-19 Antigen Test	Removed - Should Not Be Distributed
Healgen	CLINITEST Rapid COVID-19 Antigen Test	Removed - Should Not Be Distributed
Healgen	Healgen Rapid COVID-19 Antigen Test	Removed - Should Not Be Distributed
Healgen	Verasure Rapid COVID-19 Antigen Test	Removed - Should Not Be Distributed
Melbourne Biotech	MB QRT-PCR TEST SARS-COV2(COVID-19)	Removed - Should Not Be Distributed
Meridian Bioscience Inc.	Revogene® SARS-CoV-2 assay	Removed - Should Not Be Distributed*

Manufacturer	Test	Status
Nanjing Norman Biological Technology Co., Ltd	Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)	Removed - Should Not Be Distributed
QIAGEN QIAreach™	SARS-CoV-2 Antigen Test	Removed - Should Not Be Distributed*
Sanwa BioTech Limited	ALiA SARS-CoV-2 Antigen FIA Test	Removed - Should Not Be Distributed*
Spring Healthcare Services	AG SARS COV-2 Antigen Rapid Test Kit	Removed - Should Not Be Distributed
SUREDX	V-CHEK Coronavirus (SARS-CoV-2) Antigen Detection Kit	Removed - Should Not Be Distributed
Thermo Fisher Scientific Inc. (Life Technologies)	TaqPath™ COVID-19 Fast PCR Combo Kit 2.0	Removed - Should Not Be Distributed*

Showing 1 to 19 of 19 entries

Q: What commercial manufacturers of serological tests that had previously provided notification to the FDA under the policy outlined in Section IV.D of the Policy for Coronavirus Disease-2019 Tests have now been removed from that notification list and should no longer be offering that test? (Updated 7/2/21)

The commercial manufacturers in the list below provided notification to the FDA that they validated and intended to distribute a serology test as set forth in Section IV.D of the [Policy for Coronavirus Disease-2019 Tests \(/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised\)](#). The FDA had previously included them on the website notification list of commercial manufacturers distributing serology test kits under that policy, but they have now been removed from that notification list and placed on the list below. As noted in the guidance, if an EUA request is not submitted by a commercial manufacturer of a serology test within a reasonable period of time, or if significant problems are identified with such a test that cannot be or have not been addressed in a timely manner, the FDA intends to remove the manufacturer and test from the notification list. Commercial manufacturers may also voluntarily withdraw their test notification, and such tests are noted with an asterisk.

The FDA expects that the tests on this list will not be distributed unless and until an EUA is issued for the test, and the FDA may take additional actions as appropriate.

Recommendations for clinical laboratories and health care providers regarding these tests may be found in the FDA's June 19, 2020, [Letter to Clinical Laboratory Staff and Health Care Providers \(/medical-devices/letters-health-care-providers/certain-covid-19-serologyantibody-tests-should-not-be-used-letter-clinical-laboratory-staff-and\)](/medical-devices/letters-health-care-providers/certain-covid-19-serologyantibody-tests-should-not-be-used-letter-clinical-laboratory-staff-and).

Search:

Manufacturer	Test	Status
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*

Manufacturer	Test	Status
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

Manufacturer	Test	Status
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

Manufacturer	Test	Status
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

Manufacturer	Test	Status
Bethyl Laboratories, Inc.	Bethyl SARS-CoV-2 IgG IVD ELISA	Removed - Should Not Be Distributed*
Biobase Bioindustry (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

Manufacturer	Test	Status
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*

Manufacturer	Test	Status
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

Manufacturer	Test	Status
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*

Manufacturer	Test	Status
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

Manufacturer	Test	Status
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*

Manufacturer	Test	Status
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-CoV2(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*

Manufacturer	Test	Status
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*

Manufacturer	Test	Status
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*

Manufacturer	Test	Status
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 Weiyun 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

Manufacturer	Test	Status
Nantong Egens Biotechnology Co., Ltd	EGENS COVID-19 IgG/IgM Rapid Test Kit	Removed - Should Not Be Distributed
Naturitious LLC	Viralert COVID-19 IgG/IgM ANTIBODY RAPID TEST KIT	Removed - Should Not Be Distributed*
Newscen Bio-Pharmaceutical Co., Ltd.	COVID-19 Microfluidic IgG/IgM Test	Removed - Should Not Be Distributed
Newscen Coast Bio-Pharmaceutical Co., Ltd.	COVID-19 Microfluidic Combo Test	Removed - Should Not Be Distributed
Newscen Coast Bio-Pharmaceutical Co., Ltd.	COVID-19 IgG/IgM Rapid Test	Removed - Should Not Be Distributed
Oncosem Onkolojik 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 Milo, 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

Manufacturer	Test	Status
PerGrande BioTech Development Co., Ltd.	SARS-CoV-2 Antibody Detection Kit (Colloidal Gold Immunochromatographic assay)	Removed - Should Not Be Distributed*
Phamatech	COVID19 IgG / IgM Rapid Test	Removed - Should Not Be Distributed*
Pharmact GmbH	BeI TEST 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 Boson Biotech Ltd. Co)	Rapid 2019-nCoV IgG/IgM Combo Test Card	Removed - Should Not Be Distributed

Manufacturer	Test	Status
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

Manufacturer	Test	Status
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*
Shenzen 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
Singuway 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

Manufacturer	Test	Status
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.	SGTi-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
SUREDIX	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

Manufacturer	Test	Status
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*

Manufacturer	Test	Status
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	E diagnosis COVID-19 (SARS-CoV-2) IgM/IgG Antibody Test	Removed - Should Not Be Distributed

Manufacturer	Test	Status
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

Manufacturer	Test	Status
Zhongshan Bio-Tech Co Ltd.	SARS-CoV-2 IgM/IgG (GICA)	Removed - Should Not Be Distributed*
Zhuhai Encode Medical Engineering Co., Ltd	Novel Coronavirus (COVID-19) IgG/IgM Rapid Test Device	Removed - Should Not Be Distributed*
Zhuhai Keyu Biological Engineering Co., Ltd.	SARS-CoV-2 IgG/IgM Rapid Test Kit	Removed - Should Not Be Distributed
Zhuhai 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

Showing 1 to 267 of 267 entries