

SARS-CoV-2 Lower Respiratory Testing

This document provides information on available tests that accept lower respiratory tract specimens authorized by the Food and Drug Administration (FDA). A full list of all emergency use authorized (EUA) in vitro diagnostic tests for SARS-CoV-2 can be found on the [FDA website](#), as well as [analytical data on their comparative performance](#).

Laboratories using these assays are not required to agree to take all specimen types authorized, and in addition some labs can individually validate additional specimen types for assays other than those listed. If none of the labs that you currently work with are able or willing to process lower respiratory samples, you can find [additional CLIA-certified laboratories on the CDC website](#). You can search for additional labs able to perform high-complexity testing under “advanced search”, by selecting “accreditation”, “compliance”, and “registration” under certificate type. Additional search parameters are available as well, such as laboratory type and state. In addition, the New York State Department of Health (NYSDOH) provides a [weekly list of laboratories](#) with excess capacity for diagnostic SARS-CoV-2 testing.

Below is information on commercially available and laboratory developed tests and the lower respiratory tests that are currently authorized as of March 2, 2021. This information is subject to change over time as assays are added, removed, or amended. The [FDA webpage for In Vitro Diagnostics EUAs](#) will have the most current and complete information. Commercially available tests are able to be procured by and distributed to many different laboratories. Laboratory developed tests are designed, manufactured, and used only within that single laboratory.¹

Table 1: Commercially available molecular diagnostic tests for lower respiratory tract specimens, sorted by date of initial authorization*

Test	Sponsor	Emergency Use Authorized (EUA) lower respiratory tract specimens	Testing Platform
CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	Centers for Disease Control and Prevention (CDC)	Lower respiratory (any)	7500 Fast Dx
New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel	Wadsworth Center, New York State Department of Health (NYSDOH)	Sputum	7500 Fast Dx
TaqPath COVID-19 Combo Kit	Thermo Fisher Scientific Inc.	Bronchoalveolar lavage (BAL)	7500 Fast Dx, QuantStudio 7 Flex, QuantStudio 5
Panther Fusion SARS-CoV-2 Assay	Hologic, Inc	Lower respiratory (BAL)	Panther System

¹ <https://www.fda.gov/medical-devices/vitro-diagnostics/laboratory-developed-tests>

Quest SARS-CoV-2 rRT-PCR	Quest Diagnostics Infectious Disease, Inc.	Lower respiratory (any)	7500 or 7500 Fast run in standard mode
Simplexa COVID-19 Direct	DiaSorin Molecular LLC	BAL	Liaison MDX
Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	Primerdesign Ltd.	BAL	7500, CFX Connect, Lightcycler 480 II
Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2	BGI Genomics Co, Ltd	BAL	7500
Logix Smart Coronavirus Disease 2019 (COVID-19) Kit	Co-Diagnostics, Inc.	Lower respiratory (any)	CoDx Box
ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit	ScienCell Research Laboratories	BAL	LightCycler 96
Viracor SARS-CoV-2 assay	Viracor Eurofins Clinical Diagnostics	BAL	7500
QuantiVirus SARS-CoV-2 Test Kit	DiaCarta, Inc.	Sputum	QuantStudio 5, 7500 Fast Dx, CFX 384, LightCycler 480 II
SARS-CoV-2 RT-PCR Assay	Stanford Health Care Clinical Virology Laboratory	BAL	Rotor-Gene Q
Fosun COVID-19 RT-PCR Detection Kit	Fosun Pharma USA, Inc.	Lower respiratory (any)	7500
GeneFinder COVID-19 Plus RealAmp Kit	OSANG Healthcare	BAL	7500, 7500 Fast, CFX-96
PhoenixDx 2019-CoV	Trax Management Services Inc.	BAL	CFX-96, Rotor-Gene Q, 7500 Fast Dx
Allplex 2019-nCoV Assay	Seegene, Inc.	BAL, sputum	CFX-96, CFX-96 Touch, 7500, 7500 Fast Dx
Standard M nCoV Real-Time Detection Kit	SD Biosensor, Inc.	Sputum	LightCycler 480, CFX-96 Dx, 7500
FTD SARS-CoV-2	Fast Track Diagnostics Luxemborg (Siemens Healthineers)	BAL	7500
OPTI SARS-CoV-2 RT PCR Test	OPTI Medical Systems, Inc.	Lower respiratory (any)	7500 Fast, QuantStudio 5, Mx3005P, Mic qPCR, LightCycler 480

Sherlock CRISPR SARS-CoV-2	Sherlock BioSciences, Inc.	BAL	Any standard microplate reader
Quick SARS-CoV-2 rRT-PCR Kit	Zymo Research Corporation	Lower respiratory (any)	CFX-96 Touch
Alinity m SARS-CoV-2 assay	Abbott Molecular, Inc.	BAL	Alinity m System
Neoplex COVID-19 Detection Kit	GeneMatic, Inc.	Lower respiratory (any)	7500 Fast Dx
Fulgent COVID-19 by RT-PCR Test	Fulgent Therapeutics, Inc.	Lower respiratory (any)	QuantStudio 6, QuantStudio 7
Color SARS CoV-2 RT-LAMP Diagnostic Assay	Color Genomics, Inc.	BAL	PE Chemagic 360
AQ-TOP COVID-19 Rapid Detection Kit	Seasun Biomaterials, Inc.	Lower respiratory (any)	CFX-96, 7500
BioCore 2019-nCoV Real Time PCR Kit	Biocore Co., LTD.	Lower respiratory (any)	CFX-96, 7500, SLAN-96P
DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	SolGent Co., LTD.	BAL	7500, 7500 Fast, CFX-96
Express Gene 2019-nCoV RT-PCR Diagnostic Panel	Express Gene LLC., DPA: Express Gene Molecular Diagnostic	BAL	QuantStudio 12 Flex
Hymon SARS-CoV-2 Test Kit	DbA SpectronRx	BAL	7500
Gravity Diagnostics COVID-19 Assay	Gravity Diagnostics, LLC	BAL	QuantStudio 7 Flex, QuantStudio 12 Flex
Phosphorus COVID-19 RT-qPCR Test	Phosphorus Diagnostics LLC	BAL	CFX-384 Touch
EUROReal Time SARS-CoV-2	Euroimmun US Inc.	BAL	7500 Fast, LightCycler 480 II, CFX-96 Touch
Illumina COVIDSeq Test	Illumina, Inc.	BAL	NovaSeq6000, NextSeq500, NextSeq550, NextSeq500Dx
BioCode SARS-CoV-2 Assay	Applied BioCode, Inc.	BAL	BioCode MDx-3000
COVID-19 Coronavirus Real Time PCR Kit	Jiangsu Biopertectus Technologies Co., Ltd.	BAL	7500, QuantStudio 5, LightCycler 480
TRUPCR SARS-CoV-2 Kit	3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.	BAL	QuantStudio 3, QIAGEN Rotor-Gene Q, 5Plex HRM

DSL COVID-19 Assay	Diagnostic Solutions Laboratory LLC	BAL	QuantStudio 5
Acupath COVID-19 Real-Time (RT-PCR) Assay	Acupath Laboratories Inc.	BAL	QuantStudio 12 Flex
LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel	LifeHope Labs	BAL	QuantStudio 5
COVID-19 RT-PCR Peptide Nucleic Acid (PNA) Kit	TNS Co., Ltd (Bio TNS)	BAL	CFX-96, 7500, 7500 Fast
Psoma COVID-19 RT Test	Psomagen, Inc.	BAL	LightCycler 480
Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay	Centers for Disease Control and Prevention (CDC)	Lower respiratory (any)	7500 Fast Dx
Laboratorio Clinico Toledo SARS-CoV-2 Assay	Laboratorio Clinico Toledo	BAL	MP96, LightCycler 480
CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard	BAL	ViiA7, QuantStudio 7 Flex
BMC-CReM COVID-19 Test	Boston Medical Center	BAL	Mastercycler Nexus X2 (RT step), QuantStudio 6 Flex
PhoenixDx SARS-CoV-2 Multiplex	Trax Management Services	BAL	CFX-96, QuantStudio (1,3,5,7), Rotor-Gene Q, 7500 Fast Dx, DTPPrime5, Jena qTower
Boston Heart COVID-19 RT-PCR Test	Boston Heart Diagnostics	BAL	QuantStudio 12k Flex
QuantiVirus SARS-CoV-2 Multiplex Test Kit	DiaCarta, Inc.	Sputum	QuantStudio 5, 7500 Fast Dx, CFX 384
SNL-NM 2019 nCoV Real-Time RT-PCR Diagnostic Assay	Sandia National Laboratories	BAL	7500, QuantStudio 5, CFX Connect, CFX 96
SARS-CoV-2 Test Kit (Real-time PCR)	Xiamen Zeesan Biotech Co., Ltd.	BAL	QuantStudio 3
Cleveland Clinic SARS-CoV-2 Assay	Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine	BAL, tracheal aspirate, sputum	LightCycler 480, cobas z 480

Ethos Laboratories SARS-CoV-2 MALDI-TOF Assay	Ethos Laboratories	BAL	Veriti 96 Fast, MassARRAY (MALDI-TOF)
Wren Laboratories COVID-19 PCR Test	Wren Laboratories LLC	BAL	QuantStudio 7 Flex
GWU SARS-CoV-2 RT-PCR Test	George Washington University Public Health Laboratory	BAL	LightCycler 480
Solaris Multiplex SARS-CoV-2 Assay	Solaris Diagnostics	BAL	QuantStudio 5
LumiraDx SARS-CoV-2 RNA STAR	LumiraDx UK Ltd.	BAL	LightCycler 480 II, 7500 Fast Dx, QuantStudio 5, Aligent Aria Mx, Stratagene Mx3005P
Texas Department of State Health Services (DSHS) SARS-CoV-2 Assay	Texas Department of State Health Services, Laboratory Services Section	BAL	7500 Fast Dx
T2SARS-CoV-2 Panel	T2 Biosystems, Inc.	BAL	T2Dx
KimForest SARS-CoV-2 Detection Kit	KimForest Enterprise Co., Ltd.	BAL	StepOne, StepOnePlus
Clear Dx SARS-CoV-2 Test	Clear Labs, Inc.	BAL	Clear DX system with Venus version 4 software
SARS-CoV-2 MassArray Test	National Jewish Health	BAL	Veriti 96 Thermal Cycler and MassARRAY system with SpectroACQUIRE software v4.3.145 and v5.0 and TyperAnalyzer software v4.1.83 and v5.0.1
Aeon Global Health SARS-CoV-2 Assay	Aeon Global Health	BAL	QuantStudio 12k Flex
UMass Molecular Virology Laboratory 2019-nCoV rRT-PCR Dx Panel	UMass Memorial Medical Center	BAL	QiaCube QIAGEN, KingFisher Flex, CFX 96
AQ-TOP COVID-19 Rapid Detection Kit PLUS	Seasun Biomaterials, Inc.	BAL	CFX 96, 7500
MassARRAY SARS-CoV-2 Panel	Agena Bioscience, Inc.	BAL	MassARRAY System

Ezplex SARS-CoV-2 G Kit	SML Genetree Co., Ltd.	Sputum	CFX 96, 7500
BD MAX COVID-19 ASSAY (Authorized by HHS/OASH)	Hospital of the University of Pennsylvania	Tracheal aspirate	BD MAX
Procelix SARS-CoV-2 Assay	Grifols Diagnostic Solutions, Inc.	BAL	Panther System

*Test information current as of 03/02/2021

Table 2: Laboratory developed molecular diagnostic tests for lower respiratory tract specimens, sorted by date of initial authorization*

Test	Sponsor	Emergency Use Authorized (EUA) lower respiratory tract specimens
Aspirus SARS-CoV-2 rRT-PCR Assay	Aspirus Reference Laboratory	Bronchoalveolar lavage (BAL)
Avera Institute for Human Genetics SARS-CoV-2 Assay	Avera Institute for Human Genetics	BAL
Biollections Worldwide SARS-CoV-2 Assay	Biollections Worldwide	BAL
CirrusDx SARS-CoV-2 Assay	CirrusDx Laboratories	BAL
COVID-19 Key	Southwest Regional PCR Laboratory LLC. Dba MicroGen Dx	Sputum
CSI SARS-CoV-2 RT PCR Test	CSI Laboratories	BAL
NEcov19 RT-PCR Assay	Nebraska Medicine Clinical Laboratory	BAL
SARS-CoV-2 Assay	AIT Laboratories	Lower respiratory (any)
SARS-CoV-2 Assay	Diagnostic Molecular Laboratory Northwestern Medicine	BAL
SARS-CoV-2 Assay	Nationwide Children's Hospital	Lower respiratory (any)
SARS-CoV-2 Molecular Detection Assay	Mayo Clinic Laboratories, Rochester, MN	Lower respiratory (any)
SARS-CoV-2 PCR Test	Diatherix Eurofins Laboratory	Bronchial aspirates, sputum
SARS-CoV-2 RT-PCR Assay	Massachusetts General Hospital	BAL
SARS-CoV-2 RT-PCR Test	Infectious Disease Diagnostics Laboratory- Children's Hospital of Philadelphia	Tracheal aspirate, BAL
SARS-CoV-2 Test	Biocerna	BAL
UNC Health SARS-CoV-2 real-time RT-PCR test	University of North Carolina Medical Center	BAL/bronchial washings, tracheal aspirate
Warrior Diagnostics SARS-CoV-2 Assay	Warrior Diagnostics	BAL

*Test information current as of 03/02/2021