



COVID-19 Diagnostic Technologies

FDA EUA-Approved Diagnostic Product Pairings

FDA Recommended Specimen Collection Materials

FDA EUA-Approved Diagnostic Product Procurement Information

FDA EUA-Approved Diagnostic Product Pairings

Diagnostic Platform	Diagnostic Test	Extraction Method
Cepheid GeneXpert® Systems	Cepheid Xpert Xpress SARS-CoV-2 test	Not needed (Point of Care test)
DiaSorin Liaison MDX instrument	DiaSorin Molecular LLC Simplexa COVID-19 Direct	Not needed (direct input of collection specimen into diagnostic test)
GenMark ePlex Sample-to-Answer System	GenMark Diagnostics, Inc - ePlex SARS-CoV-2 Test	Proprietary GenMark Kit
Abbott m2000 RealtimeSystem	Abbott Molecular - Abbott Real Time SARS-CoV-2 assay	Proprietary Abbott m2000sp compliant extraction process
Hologic Panther Fusion System	Hologic, Inc - Panther Fusion SARS-CoV-2	Proprietary Panther Fusion Extraction Reagents-S
Roche cobas 6800/8800 Systems	Roche Molecular Systems, Inc - cobas SARS-CoV-2	Proprietary Roche Kit
Bio-Rad CFX Connection Real-Time PCR Detection System	Primerdesign Ltd - COVID-19 genesig Real-Time PCR assay	GXT DNA/RNA Extraction Kit (GenoXtract®, Bruker-HAIN, Lifescience GmbH)
Roche LightCycler 480 II	Primerdesign Ltd - COVID-19 genesig Real-Time PCR assay	GXT DNA/RNA Extraction Kit (GenoXtract®, Bruker-HAIN, Lifescience GmbH)
Roche LightCycler 480	Quidel Corp-Lyra SARS-CoV-2 Assay	bioMérieux NucliSENS easyMAG
Roche LightCycler 480	Quidel Corp-Lyra SARS-CoV-2 Assay	Roche MagNA Pure
Applied Biosystems QuantStudio7 Flex	Laboratory Corporation of America - COVID-19 RT-PCR Test	Roche MagNA Pure 96 Kit
Applied Biosystems 7500	Primerdesign Ltd - COVID-19 genesig Real-Time PCR assay	GXT DNA/RNA Extraction Kit (GenoXtract®, Bruker-HAIN, Lifescience GmbH)
Applied Biosystems 7500	Thermo Fisher Scientific - TaqPath COVID-19 Combo Kit	Thermo Fisher MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit
Applied Biosystems 7500	Quest Diagnostics Infectious Disease, Inc.- Quest SARS-CoV-2 rRT-PCR	Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit
Applied Biosystems 7500	Quidel Corp- Lyra SARS-CoV-2 Assay	bioMérieux NucliSENS easyMAG



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For more information, visit [the FDA website](https://www.fda.gov)

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Diagnostic Platform	Diagnostic Test	Extraction Method
Applied Biosystems 7500	Quidel Corp- Lyra SARS-CoV-2 Assay	Roche MagNA Pure
Applied Biosystems 7500	Wadsworth Center, NYSDOH - SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel	bioMérieux NucliSENS easyMAG
Applied Biosystems 7500	Wadsworth Center, NYSDOH - SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel	QIAGEN EZ1 Advanced XL Kit
Applied Biosystems 7500	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	bioMérieux NucliSENS easyMAG
Applied Biosystems 7500	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	QIAamp DSP Viral RNA Mini Kit
Applied Biosystems 7500	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	QIAamp Viral RNA Mini Kit
Applied Biosystems 7500	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	QIAGEN EZ1 DSP Virus Kit
Applied Biosystems 7500	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	QIAGEN EZ1 Virus Mini Kit 2.0
Applied Biosystems 7500	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	Roche MagNA Pure Total Nucleic Acid Kit
Applied Biosystems 7500	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	Roche MagNA Pure Nucleic Acid Isolation Kit
Applied Biosystems 7500	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit
Applied Biosystems 7500	PerkinElmer® New Coronavirus Nucleic Acid Detection Kit	The PerkinElmer® Nucleic Acid Extraction Kits
Qiagen Rotator-Gene Q	Quidel Corp- Lyra SARS-CoV-2 Assay	bioMérieux NucliSENS easyMAG
Qiagen Rotator-Gene Q	Quidel Corp- Lyra SARS-CoV-2 Assay	Roche MagNA Pure
BioFire® FilmArray Systems	BioFire® Covid-19 Test	Not needed (Point of care test)
Accula® System	Accula® SARS-CoV-2 test	Not needed (Point of care test)



FDA Recommended Specimen Collection Materials

Cat #	Vendor	Name	Type	Platform
305C	Copan	NP swab - UTM/MTM	Swab Kit	N/A
307C	Copan	NP swab - UTM/MTM	Swab Kit	N/A
360C	Copan	NP swab - UTM/MTM	Swab Kit	N/A
519CS01 (flocked OP swab)	Copan	NP swab - UTM/MTM	Swab Kit	N/A
UT-367	Puritan	NP swab - UTM/MTM	Swab Kit	N/A
UT-317	Puritan	NP swab - UTM/MTM	Swab Kit	N/A
UT-302 (flocked OP swab)	Puritan	NP swab - UTM/MTM	Swab Kit	N/A
UT-366 (polyester swab)	Puritan	NP swab - UTM/MTM	Swab Kit	N/A
330CHL	Hardy/Healthlink	NP swab - UTM/MTM	Swab Kit	N/A
220526	BD	NP swab - UTM/MTM	Swab Kit	N/A
220258 (flocked OP swab)	BD	NP swab - UTM/MTM	Swab Kit	N/A
220529	BD	NP swab - UTM/MTM	Swab Kit	N/A
220531	BD	NP swab - UTM/MTM	Swab Kit	N/A
330C.DHI	DHI/Quidel	NP swab - UTM/MTM	Swab Kit	N/A
503CS01.DHI	DHI/Quidel	NP swab - UTM/MTM	Swab Kit	N/A



FDA Recommended Specimen Collection Materials

Cat #	Vendor	Name	Type	Platform
23001718	Fisher Healthcare	NP swab - UTM/MTM	Swab Kit	N/A
23600952	Fisher Healthcare	NP swab - UTM/MTM	Swab Kit	N/A
23600956	Fisher Healthcare	NP swab - UTM/MTM	Swab Kit	N/A
23600950	Fisher Healthcare	NP swab - UTM/MTM	Swab Kit	N/A
23600957 (flocked OP swab)	Fisher Healthcare	NP swab - UTM/MTM	Swab Kit	N/A
LH-1-02	PrimeStore MTM	NP swab - UTM/MTM	Swab Kit	N/A
481C	Copan	NP swab - Liquid Amies Media	Swab Kit	N/A
482C	Copan	NP swab - Liquid Amies Media	Swab Kit	N/A
480C (flocked OP swab)	Copan	NP swab - Liquid Amies Media	Swab Kit	N/A
480CFA (flocked OP swab)	Copan	NP swab - Liquid Amies Media	Swab Kit	N/A
LA-117	Puritan	NP swab - Liquid Amies Media	Swab Kit	N/A
LA-116-H	Puritan	NP swab - Liquid Amies Media	Swab Kit	N/A
220246	BD	NP swab - Liquid Amies Media	Swab Kit	N/A
220532	BD	NP swab - Liquid Amies Media	Swab Kit	N/A
220245 (flocked OP swab)	BD	NP swab - Liquid Amies Media	Swab Kit	N/A



FDA Recommended Specimen Collection Materials

Cat #	Vendor	Name	Type	Platform
R723481	ThermoFisher	NP swab - Liquid Amies Media	Swab Kit	N/A
R723482	ThermoFisher	NP swab - Liquid Amies Media	Swab Kit	N/A
R723480 (flocked OP swab)	ThermoFisher	NP swab - Liquid Amies Media	Swab Kit	N/A
481C	Hardy/Healthlink	NP swab - Liquid Amies Media	Swab Kit	N/A
482C	Hardy/Healthlink	NP swab - Liquid Amies Media	Swab Kit	N/A
480C (flocked OP swab)	Hardy/Healthlink	NP swab - Liquid Amies Media	Swab Kit	N/A
480CFA (flocked OP swab)	Hardy/Healthlink	NP swab - Liquid Amies Media	Swab Kit	N/A
89136-656	VWR	NP swab - Liquid Amies Media	Swab Kit	N/A
89136-658	VWR	NP swab - Liquid Amies Media	Swab Kit	N/A
89136-654 (flocked OP swab)	VWR	NP swab - Liquid Amies Media	Swab Kit	N/A
76181-494 (flocked OP swab)	VWR	NP swab - Liquid Amies Media	Swab Kit	N/A
23600901	Fisher Healthcare	NP swab - Liquid Amies Media	Swab Kit	N/A
23600902	Fisher Healthcare	NP swab - Liquid Amies Media	Swab Kit	N/A
23600900 (flocked OP swab)	Fisher Healthcare	NP swab - Liquid Amies Media	Swab Kit	N/A
23600905 (flocked OP swab)	Fisher Healthcare	NP swab - Liquid Amies Media	Swab Kit	N/A



FDA Recommended Specimen Collection Materials

Cat #	Vendor	Name	Type	Platform
25-3316-H	Puritan	Nasopharyngeal (NP), Hydra Flocked	Swab	N/A
25-3316-U	Puritan	Nasopharyngeal (NP), Ultra Flocked	Swab	N/A
25-3317-H	Puritan	Nasopharyngeal (NP), Hydra Flocked	Swab	N/A
25-3317-U	Puritan	Nasopharyngeal (NP), Ultra Flocked	Swab	N/A
25-3318-H	Puritan	Nasopharyngeal (NP), Hydra Flocked	Swab	N/A
25-3318-U	Puritan	Nasopharyngeal (NP), Ultra Flocked	Swab	N/A
25-3319-H	Puritan	Nasopharyngeal (NP), Hydra Flocked	Swab	N/A
25-3319-U	Puritan	Nasopharyngeal (NP), Ultra Flocked	Swab	N/A
25-3320-H	Puritan	Nasopharyngeal (NP), Hydra Flocked	Swab	N/A
25-3320-U	Puritan	Nasopharyngeal (NP), Ultra Flocked	Swab	N/A
25-3320-H EMB 80	Puritan	Nasopharyngeal (NP), Hydra Flocked	Swab	N/A
25-3320-U EMB 80	Puritan	Nasopharyngeal (NP), Ultra Flocked	Swab	N/A
25-3320-H EMB 100	Puritan	Nasopharyngeal (NP), Hydra Flocked	Swab	N/A
25-3320-U EMB 100	Puritan	Nasopharyngeal (NP), Ultra Flocked	Swab	N/A
25-1406 1PF 50f	Puritan	Nasopharyngeal (NP), Foam	Swab	N/A



FDA Recommended Specimen Collection Materials

Cat #	Vendor	Name	Type	Platform
25-800 1PD 50	Puritan	Nasopharyngeal (NP), Polyester	Swab	N/A
25-800 1PD ALUM 50	Puritan	Nasopharyngeal (NP), Polyester	Swab	N/A
503CS01	Copan	Nasopharyngeal (NP), Flocked	Swab	N/A
518CS01	Copan	Nasopharyngeal (NP), Flocked	Swab	N/A
501CS01	Copan	Nasopharyngeal (NP), Flocked	Swab	N/A
502CS01	Copan	Nasopharyngeal (NP), Flocked	Swab	N/A
220252	BD	Nasopharyngeal (NP), Flocked	Swab	N/A
220251	BD	Nasopharyngeal (NP), Flocked	Swab	N/A
23600952	DHI/Quidel	Nasopharyngeal (NP), Flocked	Swab	N/A
23600956	DHI/Quidel	Nasopharyngeal (NP), Flocked	Swab	N/A
23600950	DHI/Quidel	Nasopharyngeal (NP), Flocked	Swab	N/A
25-1506 1PF SOLID	Puritan	Oropharyngeal (OP), Foam	Swab	N/A
25-1506 1PF 100	Puritan	Oropharyngeal (OP), Foam	Swab	N/A
25-3206-H	Puritan	Oropharyngeal (OP), Hydra Flocked	Swab	N/A
25-3206-U	Puritan	Oropharyngeal (OP), Ultra Flocked	Swab	N/A



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Cat #	Vendor	Name	Type	Platform
25-3706-H	Puritan	Oropharyngeal (OP), Hydra Flocked	Swab	N/A
25-806 1PD	Puritan	Oropharyngeal (OP), Polyester	Swab	N/A
25-806 1PD BT	Puritan	Oropharyngeal (OP), Polyester	Swab	N/A
502CS01	Copan	Oropharyngeal (OP), Flocked	Swab	N/A
519CS01	Copan	Oropharyngeal (OP), Flocked	Swab	N/A
164KS01	Copan	Oropharyngeal (OP), Polyester	Swab	N/A
175KS01	Copan	Oropharyngeal (OP), Polyester	Swab	N/A
220250	BD	Oropharyngeal (OP), Flocked	Swab	N/A
23600950	Fisher Healthcare	Oropharyngeal (OP), Flocked	Swab	N/A
23600957	Fisher Healthcare	Oropharyngeal (OP), Flocked	Swab	N/A
1490650	Fisher Healthcare	Oropharyngeal (OP), Polyester	Swab	N/A
25-1506 1PF SOLID	Puritan	Mid-Turbinate (MT), Foam	Swab	N/A
25-1506 1PF 100	Puritan	Mid-Turbinate (MT), Foam	Swab	N/A
25-3206-H	Puritan	Mid-Turbinate (MT), Hydra Flocked	Swab	N/A
25-3206-H	Puritan	Anterior Nares, Hydra Flocked	Swab	N/A



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Cat #	Vendor	Name	Type	Platform
25-3206-U	Puritan	Anterior Nares, Ultra Flocked	Swab	N/A
25-3706-H	Puritan	Anterior Nares, Hydra Flocked	Swab	N/A
25-1506 1PF 100	Puritan	Anterior Nares, Foam	Swab	N/A
25-1506 1PF solid	Puritan	Anterior Nares, Foam	Swab	N/A
25-1506 1PF BT	Puritan	Anterior Nares, Foam	Swab	N/A
25-1506 1PF TT MC	Puritan	Anterior Nares, Foam	Swab	N/A
25-1506 2PF BT	Puritan	Anterior Nares, Foam	Swab	N/A
25-1406 1PF BT*	Puritan	Anterior Nares, Foam	Swab	N/A
25-1406 1PF 50*	Puritan	Anterior Nares, Foam	Swab	N/A
20103	Quidel	Anterior Nares, Foam	Swab	N/A
502CS01	Copan	Anterior Nares, Flocked	Swab	N/A
519CS01	Copan	Anterior Nares, Flocked	Swab	N/A
23600950	Fisher Healthcare	Anterior Nares, Flocked	Swab	N/A
23600957	Fisher Healthcare	Anterior Nares, Flocked	Swab	N/A
220144	BD	Anterior Nares, Foam	Swab	N/A
220145	BD	Anterior Nares, Foam	Swab	N/A
220250	BD	Anterior Nares, Flocked	Swab	N/A



FDA Recommended Specimen Collection Materials

Cat #	Vendor	Name	Type	Platform
UT-300	Puritan	UTM/MTM (no swab)	Media and Vials	N/A
LA-100	Puritan	Liquid Amies Media (no swab)	Media and Vials	N/A
LH-1-03	PrimeStore MTM	UTM/MTM (no swab)	Media and Vials	N/A
R064430	ThermoFisher	Scientific Saline Collection Tubes (no swab)	Collection Tubes	N/A
R064432	ThermoFisher	Scientific Saline Collection Tubes (no swab)	Collection Tubes	N/A
R064434	ThermoFisher	Scientific Saline Collection Tubes (no swab)	Collection Tubes	N/A
R064436	ThermoFisher	Scientific Saline Collection Tubes (no swab)	Collection Tubes	N/A
R064438	ThermoFisher	Scientific Saline Collection Tubes (no swab)	Collection Tubes	N/A
D185	Hardy/Healthlink	Scientific Saline Collection Tubes (no swab)	Collection Tubes	N/A
K248	Hardy/Healthlink	Scientific Saline Collection Tubes (no swab)	Collection Tubes	N/A
R45	Hardy/Healthlink	Scientific Saline Collection Tubes (no swab)	Collection Tubes	N/A
R55	Hardy/Healthlink	Scientific Saline Collection Tubes (no swab)	Collection Tubes	N/A
T-0625	Edge Biologicals	Scientific Saline Collection Tubes (no swab)	Collection Tubes	N/A
T-0110f	Edge Biologicals	Scientific Saline Collection Tubes (no swab)	Collection Tubes	N/A



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Cat #	Vendor	Name	Type	Platform
09N77-095; 09N77-085; 09N77-010	Abbott Molecular	Abbott Real Time SARS-CoV-2 assay	Test	Abbott m2000 System
423745 (6 pack tests). 423744 (30pack test). 423748 (6pack (+) control)	BioFire	BioFire® Covid-19 Test	Test	BioFire ® FilmArray 2.0
2019-nCoV-EUA-01	CDC	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	Test	Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument
EXPRSARS-COV-2-10	Cepheid	Xpert ® Express SARS-CoV-2 Test	Test	GeneXpert DX or GeneXpert Infinity Systems
MOL4151	DiaSorin Molecular LLC	Simplexa COVID-19 Direct	Test	Liaison MDX instrument
EA008212	GenMark Diagnostics, Inc	ePlex SARS-CoV-2 Test	Test	ePlex Sample-to-Answer System
PRD-04303; PRD-04332; PRD-06404; PRD-04331; PRD-04334; PRD-06391; PRD-04335; PRD-04304	Hologic, Inc	Panther Fusion SARS-CoV-2	Test	Panther Fusion System
139900	Laboratory Corporation of America	COVID-19 RT-PCR Test	Test	Applied Biosystems QuantStudio7 Flex
COV4100	Mesa BioTech	Accula® SARS-CoV-2 test	Test	Accula® System
TBD	PerkinElmer	PerkinElmer® New Coronavirus Nucleic Acid Detection Kit	Test	Applied Biosystems 7500 Real Time PCR System
Z-Parth-COVID-19-CE	Primerdesign Ltd	COVID-19 genesig Real-Time PCR assay	Test	Applied Biosystems 7500 Real-Time PCR System; Bio-Rad CFX Connection Real-Time PCR Detection System; Roche LightCycler 480 II
61904	Qiagen	QIAGEN QIAamp® DSP Viral RNA Mini Kit	Extraction Kit	QIAGEN QIAcube
1020953	Qiagen	QIAamp® Viral RNA Mini Kit	Extraction Kit	QIAGEN QIAcube



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Cat #	Vendor	Name	Type	Platform
62724; Supplied Separately: Buffer AVL Cat# 19073; EZ1 Advanced XL DSP Virus Card Cat# 9018703	Qiagen	QIAGEN EZ1 DSP Virus Kit	Extraction Kit	QIAGEN EZ1 Advanced XL
955134; Supplied Separately: Buffer AVL Cat# 19073; EZ1 Advanced XL Virus Card v2.0 Cat#9018708	Qiagen	QIAGEN EZ1 Virus Mini Kit v2.0	Extraction Kit	QIAGEN EZ1 Advanced XL
39433	Quest Diagnostics Infectious Disease, Inc.	Quest SARS-CoV-2 rRT-PCR	Test	Applied Biosystems 7500 Real Time PCR System
M120	Quidel Corp	Lyra SARS-CoV-2 Assay	Test	Applied Biosystems 7500 Fast DX instruments
5323738001	Roche	Roche MagNA Pure Total Nucleic Acid Kit	Extraction Kit	Roche MagNA Pure LC
3730964001	Roche	Roche MagNA Pure Nucleic Acid Isolation Kit I	Extraction Kit	Roche MagNA Pure Compact
6543588001	Roche	Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit	Extraction Kit	Roche MagNA Pure 96
09175431190; 09175440190; 07002238190	Roche Molecular Systems, Inc	cobas SARS-CoV-2	Test	cobas 6800/8800 Systems
A47813; A47814	Thermo Fisher Scientific	TaqPath COVID-19 Combo Kit	Test	Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument
LVD SOF-151.1	Wadsworth Center, NYSDOH	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel	Test	Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument

