

# Diagnostic Tests for SARS-Cov-2 for Travel to French Polynesia

## Approved Tests

### 1. List of FDA (USA): Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 (FDA)

Date EUA Issued	Manufacturer	Name of the test	Technology
05/01/2020	BioFire Diagnostics, LLC	<a href="#">BioFire Respiratory Panel 2.1 (RP2.1)</a>	Molecular, Multi-analyte
05/11/2020	1drop Inc.	<a href="#">1copy COVID-19 qPCR Multi Kit</a>	Molecular
03/18/2020	Abbott Molecular	<a href="#">Abbott RealTime SARS-CoV-2 assay</a>	Molecular
06/29/2020	Acupath Laboratories, Inc.	<a href="#">Acupath COVID-19 Real-Time (RT-PCR) Assay</a>	Molecular
05/11/2020	Abbott Molecular Inc.	<a href="#">Alinity m SARS-CoV-2 assay</a>	Molecular
04/21/2020	Seegene, Inc.	<a href="#">Allplex 2019-nCoV Assay</a>	Molecular
07/07/2020	Enzo Life Sciences, Inc.	<a href="#">AMPIPROBE SARS-CoV-2 Test System</a>	Molecular
05/14/2020	Hologic, Inc.	<a href="#">Aptima SARS-CoV-2 assay</a>	Molecular
04/03/2020	Luminex Corporation	<a href="#">ARIES SARS-CoV-2 Assay</a>	Molecular
03/25/2020	Avellino Lab USA, Inc.	<a href="#">AvellinoCoV2 test</a>	Molecular
04/08/2020	Becton, Dickinson & Company	<a href="#">BD SARS-CoV-2 Reagents for BD MAX System</a>	Molecular
06/15/2020	Applied BioCode, Inc.	<a href="#">BioCode SARS-CoV-2 Assay</a>	Molecular
05/21/2020	BioCore Co., Ltd.	<a href="#">BioCore 2019-nCoV Real Time PCR Kit</a>	Molecular
03/23/2020	BioFire Defense, LLC	<a href="#">BioFire COVID-19 Test</a>	Molecular
04/02/2020	Becton, Dickinson & Company (BD)	<a href="#">BioGX SARS-CoV-2 Reagents for BD MAX System</a>	Molecular
05/01/2020	Bio-Rad Laboratories, Inc	<a href="#">Bio-Rad SARS-CoV-2 ddPCR Test</a>	Molecular
07/10/2020	Boston Medical Center	<a href="#">BMC-CReM COVID-19 Test</a>	Molecular
07/16/2020	Boston Heart Diagnostics	<a href="#">Boston Heart COVID-19 RT-PCR Test</a>	Molecular
07/07/2020	Access Bio, Inc.	<a href="#">CareStart COVID-19 MDx RT-PCR</a>	Molecular
02/04/2020	Centers for Disease Control and Prevention's (CDC)	<a href="#">CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC)</a>	Molecular
07/01/2020	CENTOGENE US, LLC	<a href="#">CentoFast-SARS-CoV-2 RT-PCR Assay</a>	Molecular
03/12/2020	Roche Molecular Systems, Inc. (RMS)	<a href="#">cobas SARS-CoV-2</a>	Molecular

04/01/2020	Ipsium Diagnostics, LLC	<a href="#">COV-19 IDx assay</a>	Molecular
06/18/2020	Jiangsu Biopertectus Technologies Co., Ltd.	<a href="#">COVID-19 Coronavirus Real Time PCR Kit</a>	Molecular
06/30/2020	TNS Co., Ltd (Bio TNS)	<a href="#">COVID-19 RT-PCR Peptide Nucleic Acid (PNA) kit</a>	Molecular
07/08/2020	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and	<a href="#">CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay</a>	Molecular
04/16/2020	KorvaLabs Inc.	<a href="#">Curative-Korva SARS-Cov-2 Assay</a>	Molecular
06/12/2020	RTA Laboratories Biological Products Pharmaceutical and Machinery Industry	<a href="#">Diagnovital SARS-CoV-2 Real-Time PCR Kit</a>	Molecular
05/21/2020	SolGent Co., Ltd	<a href="#">DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit</a>	Molecular
06/25/2020	Diagnostic Solutions Laboratory, LLC	<a href="#">DSL COVID-19 Assay</a>	Molecular
06/10/2020	Tide Laboratories, LLC	<a href="#">DTPM COVID-19 RT-PCR Test</a>	Molecular
03/19/2020	GenMark Diagnostics, Inc.	<a href="#">ePlex SARS-CoV-2 Test</a>	Molecular
06/08/2020	Euroimmun US, Inc.	<a href="#">EURORealTime SARS-Cov-2</a>	Molecular
06/25/2020	PreciGenome LLC	<a href="#">FastPlex Triplex SARS-CoV-2 detection kit (RT-Digital PCR)</a>	Molecular
04/17/2020	Fosun Pharma USA Inc.	<a href="#">Fosun COVID-19 RT-PCR Detection Kit</a>	Molecular
06/23/2020	University of Alabama at Birmingham Fungal Reference Lab	<a href="#">FRL SARS CoV-2 Test</a>	Molecular
05/05/2020	Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthcare Company)	<a href="#">FTD SARS-CoV-2</a>	Molecular
07/07/2020	Gene By Gene	<a href="#">Gene By Gene SARS-CoV-2 Detection Test</a>	Molecular
04/18/2020	OSANG Healthcare	<a href="#">GeneFinder COVID-19 Plus RealAmp Kit</a>	Molecular
06/23/2020	Gencurix, Inc.	<a href="#">GenePro SARS-CoV-2 Test</a>	Molecular
06/05/2020	Genetron Health (Beijing) Co., Ltd.	<a href="#">Genetron SARS-CoV-2 RNA Test</a>	Molecular
04/06/2020	Gnomegen LLC	<a href="#">Gnomegen COVID-19 RT-Digital PCR Detection Kit</a>	Molecular
05/08/2020	Gnomegen LLC	<a href="#">Gnomegen COVID-19-RT-qPCR Detection Kit</a>	Molecular
06/01/2020	Gravity Diagnostics, LLC	<a href="#">Gravity Diagnostics COVID-19 Assay</a>	Molecular
04/16/2020	GenoSensor, LLC	<a href="#">GS"ç COVID-19 RT-PCR KIT</a>	Molecular
06/09/2020	ChromaCode Inc.	<a href="#">HDPCR SARS-CoV-2 Assay</a>	Molecular
06/23/2020	HealthQuest Esoterics	<a href="#">HealthQuest Esoterics TaqPath SARS-CoV-2 Assay</a>	Molecular
07/23/2020	Helix OpCo LLC (dba Helix)	<a href="#">Helix COVID-19 Test</a>	Molecular
05/22/2020	dba SpectronRX	<a href="#">Hymon SARS-CoV-2 Test Kit</a>	Molecular

06/09/2020	Illumina, Inc.	<a href="#">Illumina COVIDSeq Test</a>	Molecular
07/02/2020	Centers for Disease Control and Prevention (CDC)	<a href="#">Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay</a>	Molecular, Multi-analyte
06/26/2020	Inform Diagnostics, Inc.	<a href="#">Inform Diagnostics SARS-CoV-2 RT-PCR Assay</a>	Molecular
06/25/2020	PlexBio Co., Ltd.	<a href="#">IntelliPlex SARS-CoV-2 Detection Kit</a>	Molecular
04/29/2020	LabGenomics Co., Ltd.	<a href="#">LabGun COVID-19 RT-PCR Kit</a>	Molecular
07/06/2020	Laboratorio Clinico Toledo	<a href="#">Laboratorio Clinico Toledo SARS-CoV-2 Assay</a>	Molecular
06/29/2020	LifeHope Labs	<a href="#">LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel</a>	Molecular
07/27/2020	Eli Lilly and Company	<a href="#">Lilly SARS-CoV-2 Assay</a>	Molecular
05/13/2020	Applied DNA Sciences, Inc.	<a href="#">Linea COVID-19 Assay Kit</a>	Molecular
04/03/2020	Co-Diagnostics, Inc.	<a href="#">Logix Smart Coronavirus Disease 2019 (COVID-19) Kit</a>	Molecular
05/18/2020	Quidel Corporation	<a href="#">Lyra Direct SARS-CoV-2 Assay</a>	Molecular
03/17/2020	Quidel Corporation	<a href="#">Lyra SARS-CoV-2 Assay</a>	Molecular
06/24/2020	University of Texas MD Anderson Cancer Center, Molecular Diagnostics	<a href="#">MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay</a>	Molecular
05/14/2020	GeneMatrix, Inc.	<a href="#">NeoPlex COVID-19 Detection Kit</a>	Molecular
03/30/2020	NeuMoDx Molecular, Inc.	<a href="#">NeuMoDx SARS-CoV-2 Assay</a>	Molecular
02/29/2020	Wadsworth Center, New York State Department of Public Health (CDC)	<a href="#">New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel</a>	Molecular
05/04/2020	Sansure BioTech Inc.	<a href="#">Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)</a>	Molecular
07/24/2020	Jiangsu CoWin Biotech Co., Ltd.	<a href="#">Novel Coronavirus (SARS-CoV-2) Fast Nucleic Acid Detection Kit (PCR-Fluorescence Probing)</a>	Molecular
03/27/2020	Luminex Molecular Diagnostics, Inc.	<a href="#">NxTAG CoV Extended Panel Assay</a>	Molecular
06/17/2020	Omnipathology Solutions Medical Corporation	<a href="#">Omni COVID-19 Assay by RT-PCR</a>	Molecular
05/06/2020	OPTI Medical Systems, Inc.	<a href="#">OPTI SARS-CoV-2 RT PCR Test</a>	Molecular
07/17/2020	Access Genetics, LLC	<a href="#">OraRisk COVID-19 RT-PCR</a>	Molecular
06/17/2020	The Ohio State University Wexner Medical Center	<a href="#">OSUWMC COVID-19 RT-PCR test</a>	Molecular
03/16/2020	Hologic, Inc.	<a href="#">Panther Fusion SARS-CoV-2 Assay</a>	Molecular
03/24/2020	PerkinElmer, Inc.	<a href="#">PerkinElmer New Coronavirus Nucleic Acid Detection Kit</a>	Molecular
04/20/2020	Trax Management Services Inc.	<a href="#">PhoenixDx 2019-CoV</a>	Molecular
07/13/2020	Trax Management Services Inc.	<a href="#">PhoenixDx SARS-CoV-2 Multiplex</a>	Molecular

07/13/2020	KogeneBiotech Co., Ltd.	<a href="#">PowerChek 2019-nCoV Real-time PCR Kit</a>	Molecular
03/20/2020	Primerdesign Ltd.	<a href="#">Primerdesign Ltd COVID-19 genesig Real-Time PCR assay</a>	Molecular
06/30/2020	Psomagen, Inc.	<a href="#">Psoma COVID-19 RT Test</a>	Molecular
07/21/2020	DiaCarta, Inc.	<a href="#">QuantiVirus SARS-CoV-2 Multiplex Test Kit</a>	Molecular
04/08/2020	DiaCarta, Inc	<a href="#">QuantiVirus SARS-CoV-2 Test kit</a>	Molecular
05/07/2020	Zymo Research Corporation	<a href="#">Quick SARS-CoV-2rRT-PCR Kit</a>	Molecular
07/09/2020	BioSewoom, Inc.	<a href="#">Real-Q 2019-nCoV Detection Kit</a>	Molecular
04/22/2020	altona Diagnostics GmbH	<a href="#">RealStar SARS-CoV02 RT-PCR Kits U.S.</a>	Molecular
03/26/2020	BGI Genomics Co. Ltd	<a href="#">Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2</a>	Molecular
04/29/2020	Rheonix, Inc.	<a href="#">Rheonix COVID-19 MDx Assay</a>	Molecular
04/15/2020	Maccura Biotechnology (USA) LLC	<a href="#">SARS-CoV-2 Fluorescent PCR Kit</a>	Molecular
05/06/2020	BioMérieux SA	<a href="#">SARS-COV-2 R-GENE</a>	Molecular
04/03/2020	ScienCell Research Laboratories	<a href="#">ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit</a>	Molecular
03/19/2020	DiaSorin Molecular LLC	<a href="#">Simplexa COVID-19 Direct assay</a>	Molecular
04/07/2020	InBios International, Inc	<a href="#">Smart Detect SARS-CoV-2 rRT-PCR Kit</a>	Molecular
07/27/2020	Sandia National Laboratories	<a href="#">SNL-NM 2019 nCoV Real-Time RT-PCR Diagnostic Assay</a>	Molecular
04/23/2020	SD Biosensor, Inc.	<a href="#">STANDARD M nCoV Real-Time Detection Kit</a>	Molecular
03/13/2020	Thermo Fisher Scientific, Inc.	<a href="#">TaqPath COVID-19 Combo Kit</a>	Molecular
06/18/2020	3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.	<a href="#">TRUPCR SARS-CoV-2 Kit</a>	Molecular
04/27/2020	SEASUN BIOMATERIALS	<a href="#">U-TOP COVID-19 Detection Kit</a>	Molecular
03/20/2020	Cepheid	<a href="#">Xpert Xpress SARS-CoV-2 test</a>	Molecular

**TRAVELERS FROM EUROPE ACCEPTABLE TESTS Ministère Santé France : Tests moléculaires RT-PCR validés CNR**

	Mobidiag France	<a href="#">Amplidiag COVID-19 kit</a>	
	3D BIOMEDCINE - Wiratech Europe	<a href="#">3DMed 2019-nCoV par RT-qPCR</a>	
	3D BIOMEDCINE - Wiratech Europe	<a href="#">ANDIS SARS-CoV-2</a>	
	BIOMERIEUX	<a href="#">ARGENE SARS-COV-2 R-GENE</a>	

	Hologic	<a href="#">Aptima SARS-CoV-2 Assay</a>	
	JIANGSU BIOPERFECTUS TECHNOLOGIES - MIDAS PHARMA	<a href="#">COVID-19 Coronavirus Real Time PCR kit</a>	
	ROCHE MOLECULAR SYSTEMS	<a href="#">Cobas SARS-CoV-2</a>	
	FAST TRACK DIAGNOSTICS - Siemens Diagnostics	<a href="#">FTD SARS-CoV-2</a>	
	Sansure Biotech - BlueDNACompanion	<a href="#">Novel Coronavirus (2019-nCoV) Nucleic acid diagnostic kit (PCR Fluorescence probing)</a>	
	Shanghai Fosun Long March Medical Science ( TRIDEM Pharma	<a href="#">Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit - Fosun 2019-nCoV qPCR</a>	
	LifeRiver BIOSYNEX	<a href="#">Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 Genes)</a>	
	Mobidiag	<a href="#">Novodiag COVID-19</a>	
	BioSewoom BizConsulting	<a href="#">Real-Q 2019-nCoV Detection Kit</a>	
	BGI Europe	<a href="#">Real-Time Fluorescent RT-PCR Kit for detecting 2019-nCoV</a>	
	VIRCELL - ORGENTEC	<a href="#">SARS-COV-2 REALTIME PCR KIT</a>	
	DIASORIN MOLECULAR	<a href="#">Simplexa COVID-19 Direct</a>	
	LIFE TECHNOLOGIES THERMOFISHER SCIENTIFIC	<a href="#">TaqPath COVID-19 CE-IVD RT-PCR Kit v2</a>	
	Certest Orgentec	<a href="#">VIASURE SARS-CoV-2 Real Time PCR Detection</a>	
	VITASSAY HEALTHCARE SERVBIO	<a href="#">Vitassay qPCR SARS-CoV-2</a>	
	CEPHEID	<a href="#">Xpert Xpress SARS-CoV-2</a>	

### Non-Approved Tests

06/13/2020	Kaiser Permanente Mid-Atlantic States	<a href="#">KPMAS COVID-19 Test</a>	Molecular, Home Collection,
07/30/2020	Clinical Reference Laboratory, Inc.	<a href="#">CRL Rapid Response</a>	Molecular, Home Collection,
07/15/2020	Quest Diagnostics Infectious Disease, Inc.	<a href="#">Quest Diagnostics PF SARS-CoV-2 Assay</a>	Molecular, Home Collection,
07/15/2020	Quest Diagnostics Infectious Disease, Inc.	<a href="#">Quest Diagnostics RC SARS-CoV-2 Assay</a>	Molecular, Home Collection,
07/15/2020	Quest Diagnostics Infectious Disease, Inc.	<a href="#">Quest Diagnostics HA SARS-CoV-2 Assay</a>	Molecular, Home Collection,
06/04/2020	Phosphorus Diagnostics LLC	<a href="#">Phosphorus COVID-19 RT-qPCR Test</a>	Molecular, Home Collection,
03/30/2020	QIAGEN GmbH	<a href="#">QIAstat-Dx Respiratory SARS-CoV-2 Panel</a>	Molecular, Multi-analyte
07/13/2020	Compass Laboratory Services, LLC	<a href="#">Compass Laboratory Services SARS-CoV2 Assay</a>	Molecular, Home Collection,
05/28/2020	PrivaPath Diagnostics, Inc.	<a href="#">LetsGetChecked Coronavirus (COVID-19) Test</a>	Molecular, Home Collection,

06/30/2020	The Kroger Co.	<a href="#">Kroger Health COVID-19 Test Home Collection Kit</a>	Home Collection Kit
05/21/2020	P23 Labs, LLC.	<a href="#">P23 Labs TaqPath SARS-CoV-2 Assay</a>	Molecular, Home Collection
03/17/2020	Quest Diagnostics Infectious Disease, Inc.	<a href="#">Quest SARS-CoV-2 rRT-PCR</a>	Molecular, Home Collection
05/18/2020	Color Genomics, Inc.	<a href="#">Color SARS Cov-2 Diagnostic Assay</a>	Molecular, Home Collection
05/15/2020	Fulgent Therapeutics, LLC	<a href="#">Fulgent COVID-19 by RT-PCR Test</a>	Molecular, Home Collection
05/15/2020	Everlywell, Inc.	<a href="#">Everlywell COVID-19 Test Home Collection Kit</a>	Molecular, Home Collection Kit
05/15/2020	Assurance Scientific Laboratories	<a href="#">Assurance SARS-CoV-2 Panel</a>	Molecular, Home Collection
05/07/2020	Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biosciences, Rutgers University	<a href="#">Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2-Assay</a>	Molecular, Home Collection
07/09/2020	UCSF Health Clinical Laboratories, UCSF Clinical Labs at China Basin	<a href="#">SARS-CoV-2 RNA DETECTR Assay</a>	Molecular
06/10/2020	Cue Health Inc.	<a href="#">Cue COVID-19 Test</a>	Molecular
06/10/2020	TBG Biotechnology Corp.	<a href="#">ExProbe SARS-CoV-2 Testing Kit</a>	Molecular
05/21/2020	Seasun Biomaterials, Inc.	<a href="#">AQ-TOP COVID-19 Rapid Detection Kit</a>	Molecular
05/06/2020	Sherlock BioSciences, Inc.	<a href="#">Sherlock CRISPR SARS-CoV-2 Kit</a>	Molecular
04/10/2020	Atila BioSystems, Inc.	<a href="#">iAMP COVID-19 Detection Kit</a>	Molecular
03/23/2020	Mesa Biotech Inc.	<a href="#">Accula SARS-Cov-2 Test</a>	Molecular
03/27/2020	Abbott Diagnostics Scarborough, Inc.	<a href="#">ID NOW COVID-19</a>	Molecular

### Additional non-approved tests

Antigen Diagnostic tests - Tests antigéniques

Serology tests - Tests sérologiques