

Listes de tests de diagnostic du SARS-Cov-2 à l'intention des voyageurs embarquant pour la Polynésie française

Tests moléculaires RT-PCR conformes à la législation Pf

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

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

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

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

2. Ministère Santé France : Tests moléculaires RT-PCR validés CNR

	Mobidiag France	Amplidiag COVID-19 kit	
	3D BIOMEDCINE - Wiratech Europe	3DMed 2019-nCoV par RT-qPCR	
	3D BIOMEDCINE - Wiratech Europe	ANDIS SARS-CoV-2	
	BIOMERIEUX	ARGENE SARS-COV-2 R-GENE	

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

Tests moléculaires non conformes à la législation Pf

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

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

Autres tests non conformes

Antigen Diagnostic tests - Tests antigéniques

Serology tests - Tests sérologiques