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Your Tailored Approach to Emerging Markets

Newsletter V

A large, blurred image of an office interior with wooden paneling and a desk, serving as a background for the main title.

# Covid-19 Tests

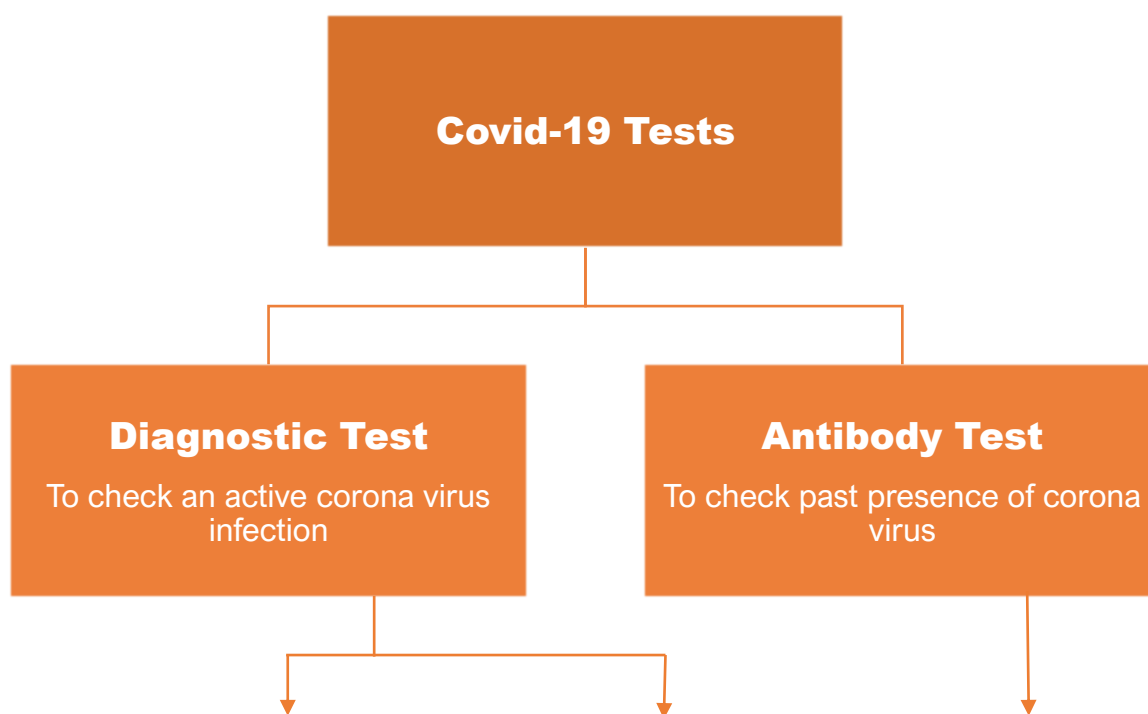
June 2020

Global metric to understand the spread of Corona virus is through number of Confirmed cases i.e. people who have tested positive.

Rate of confirmed cases also depends on the frequency of actual tests taken by the countries.

As of March 2020, no countries were having reliable data to predict the spread of corona virus amongst their population due to limited testing.

By May 2020, according to the testing data published by several countries, number of performed tests are on an average equal to 2.7% of their population, being maximum tested samples not more than 18% of its population.



#	Molecular Test	Antigen Test	Antibody Test
<b>Also Referred as...</b>	Diagnostic test, viral test, molecular test, nucleic acid amplification tests (NAAT), RT-PCR tests	Rapid diagnostic test (Some molecular tests are also rapid tests.)	Serological test, serology, blood test, serology test
<b>Sample collection</b>	Nasal or throat swab (most tests); Saliva (a few tests)	Nasal or throat swab	Finger stick or blood draw
<b>Duration for Result</b>	Same day (some locations) or up to a week	One hour or less	Same day (many locations) or 1-3 days
<b>Another test required?</b>	This test is typically highly accurate and usually does not need to be repeated.	Positive results are usually highly accurate but negative results may need to be confirmed with a molecular test.	Sometimes a second antibody test is needed for accurate results.
<b>Outcome</b>	Diagnoses active coronavirus infection	Diagnoses active coronavirus infection	Shows if infected by coronavirus in the past

Some alternative testing that are being used by a few countries are:

- **Rapid, point of care diagnostic care:** Mucus sample from nose or throat can be collected and diagonalized at doctor's clinic and can gives result in minutes. These can be Molecular or Antigen test.
- **At-home collection test:** Doctor can prescribe then patient can take sample at home and send directly to the laboratory for analysis.
- **Saliva test:** Spiting in a tube instead of nose or throat swab. It can be easy for patient and safer for healthcare worker to maintain distance while sample collection.

Testing and actions taken by a few countries are discussed below:

## CHINA

Corona virus intiated in late 2019, adversely affecting China and creating Covid-19 pandemic. Although the effect of this pandemic on their people is still a mystery.

Currently, while other countries are in exponential progression of Covid-19 cases, China is generally said to have this pandemic largely under control.

As this pandemic started showing its high impact on other countries world wide, China lifted its export ban and started supplying Covid-19 test kits, PPE, ventilators, etc. which also resulted in increased fraudulent companies, offers supplying false & damaged products.

## UNITED STATES

Testing in the US began and started publishing from mid-March which increased rapidly causing more than 100,000 tests per day by end of March.

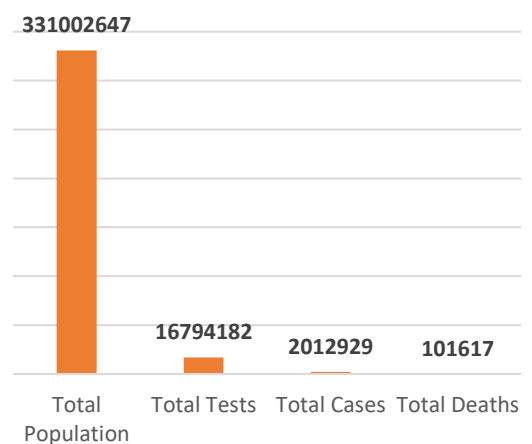
Number of cases kept ascending, but large number of tests were not vastly available until late April, when first time number of tests per confirmed cases began to rise.

CDC (Center for Disease Control and Prevention) issued guidance for who should be tested, but decisions about testing can be taken by state and local health departments and/or individual clinicians.

To combat Covid-19 pandemic, FDA has also issued Emergency Use Authorization (EUA) that authorizes Emergency use of products used to test or fight against Covid-19.

Templates for these EUA submissions are available which helps in the preparation, submission, and authorization of an EUA:

- [Molecular Diagnostic Template for Manufacturers](#)
- [Molecular Diagnostic Template for Laboratories](#)
- [Serology Template for Manufacturers](#)
- [Serology Template for Laboratories](#)



- Antigen Template for Manufacturers
- Home Specimen Collection Molecular Diagnostic Template

List of Manufacturers and Laboratories authorised under EUA is regularly updated by FDA on their website.

Latest List of EUA Authorized Manufacturer & Commercial Laboratory is as follows:

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology
05/29/2020	Healgen Scientific LLC	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	Serology IgM and IgG
05/29/2020	Siemens Healthcare Diagnostics Inc.	Atellica IM SARS-CoV-2 Total (COV2T)	Total Antibody
05/29/2020	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur SARS-CoV-2 Total (COV2T)	Total Antibody
05/28/2020	PrivaPath Diagnostics, Inc.	LetsGetChecked Coronavirus (COVID-19) Test	Molecular
05/22/2020	dba SpectronRx	Hymon SARS-CoV-2 Test Kit	Molecular
05/21/2020	BioCore Co., Ltd.	BioCore 2019-nCoV Real Time PCR Kit	Molecular
05/21/2020	SolGent Co., Ltd.	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	Molecular
05/21/2020	Seasun Biomaterials, Inc.	AQ-TOP COVID-19 Rapid Detection Kit	Molecular
05/21/2020	P23 Labs, LLC.	P23 Labs TaqPath SARS-CoV-2 Assay	Molecular
05/18/2020	Quidel Corporation	Lyra Direct SARS-CoV-2 Assay	Molecular
05/15/2020	Everlywell, Inc.	Everlywell COVID-19 Test Home Collection Kit	Home Collection Kit
05/15/2020	Fulgent Therapeutics, LLC	Fulgent COVID-19 by RT-PCR Test	Molecular
05/15/2020	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel	Molecular
05/14/2020	Hologic, Inc.	Aptima SARS-CoV-2 assay	Molecular
05/14/2020	GeneMatrix, Inc.	NeoPlex COVID-19 Detection Kit	Molecular
05/13/2020	Applied DNA Sciences, Inc.	Linea COVID-19 Assay Kit	Molecular
05/11/2020	1drop Inc.	1copy COVID-19 qPCR Multi Kit	Molecular
05/11/2020	Abbott Molecular Inc.	Alinity m SARS-CoV-2 assay	Molecular
05/08/2020	Quidel Corporation	Sofia 2 SARS Antigen FIA	Antigen
05/08/2020	Gnomegen LLC	Gnomegen COVID-19-RT-qPCR Detection Kit	Molecular
05/07/2020	Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics - Rutgers University	Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2-Assay	Molecular
05/07/2020	Zymo Research Corporation	Quick SARS-CoV-2rRT-PCR Kit	Molecular
05/06/2020	OPTI Medical Systems, Inc.	OPTI SARS-CoV-2 RT PCR Test	Molecular
05/06/2020	Sherlock BioSciences, Inc.	Sherlock CRISPR SARS-CoV-2 Kit	Molecular
05/06/2020	BioMérieux SA	SARS-COV-2 R-GENE	Molecular
05/05/2020	Fast Track Diagnostics Luxembourg S.à.r.l. (a Siemens Healthineers Company)	FTD SARS-CoV-2	Molecular
05/04/2020	EUROIMMUN US Inc.	Anti-SARS-CoV-2 ELISA (IgG)	Serology IgG
05/04/2020	Sansure BioTech Inc.	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	Molecular
05/02/2020	Roche Diagnostics	Elecsys Anti-SARS-CoV-2	Serology Antibody
05/01/2020	Bio-Rad Laboratories, Inc	Bio-Rad SARS-CoV-2 ddPCR Test	Molecular
05/01/2020	BioFire Diagnostics, LLC	BioFire Respiratory Panel 2.1 (RP2.1)	Molecular
04/30/2020	Wadsworth Center, New York State Department of Health	New York SARS-CoV Microsphere Immunoassay for Antibody Detection	Serology Total Antibody
04/29/2020	LabGenomics Co., Ltd.	LabGun COVID-19 RT-PCR Kit	Molecular
04/29/2020	Rheonix, Inc.	Rheonix COVID-19 MDx Assay	Molecular
04/29/2020	Bio-Rad Laboratories, Inc	Platelia SARS-CoV-2 Total Ab assay	Serology Total Antibody
04/27/2020	SEASUN BIOMATERIALS	U-TOP COVID-19 Detection Kit	Molecular
04/26/2020	Abbott Laboratories Inc.	SARS-CoV-2 IgG assay	Serology IgG only
04/24/2020	DiaSorin Inc.	LIAISON SARS-CoV-2 S1/S2 IgG	Serology IgG only
04/24/2020	Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack	Serology IgG only
04/24/2020	Autobio Diagnostics Co. Ltd.	Anti-SARS-CoV-2 Rapid Test	Serology IgM and IgG
04/23/2020	SD Biosensor, Inc.	STANDARD M nCoV Real-Time Detection Kit	Molecular
04/22/2020	altona Diagnostics GmbH	RealStar SARS-CoV02 RT-PCR Kits U.S.	Molecular
04/21/2020	Seegene, Inc.	Allplex 2019-nCoV Assay	Molecular
04/20/2020	Trax Management Services Inc.	PhoenixDx 2019-CoV	Molecular
04/18/2020	OSANG Healthcare	GeneFinder COVID-19 Plus RealAmp Kit	Molecular
04/17/2020	Fosun Pharma USA Inc.	Fosun COVID-19 RT-PCR Detection Kit	Molecular
04/16/2020	KorvaLabs Inc.	Curative-Korva SARS-Cov-2 Assay	Molecular
04/16/2020	GenoSensor, LLC	GS™ COVID-19 RT-PCR KIT	Molecular
04/15/2020	Maccura Biotechnology (USA) LLC	SARS-CoV-2 Fluorescent PCR Kit	Molecular
04/15/2020	Mount Sinai Laboratory	COVID-19 ELISA IgG Antibody Test	Serology IgG
04/14/2020	Chembio Diagnostic System, Inc	DPP COVID-19 IgM/IgG System	Serology IgM and IgG
04/14/2020	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack	Serology Total Antibody
04/10/2020	Atila BioSystems, Inc.	iAMP COVID-19 Detection Kit	Molecular
04/08/2020	DiaCarta, Inc	QuantiVirus SARS-CoV-2 Test kit	Molecular
04/08/2020	Becton, Dickinson & Company	BD SARS-CoV-2Reagents for BD MAX System	Molecular

04/07/2020	InBios International, Inc	Smart Detect SARS-CoV-2 rRT-PCR Kit	Molecular
04/06/2020	Gnomegen LLC	Gnomegen COVID-19 RT-Digital PCR Detection Kit	Molecular
04/03/2020	Co-Diagnostics, Inc.	Logix Smart Coronavirus Disease 2019 (COVID-19) Kit	Molecular
04/03/2020	ScienCell Research Laboratories	ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit	Molecular
04/03/2020	Luminex Corporation	ARIES SARS-CoV-2 Assay	Molecular
04/02/2020	Becton, Dickinson & Company (BD)	BioGX SARS-CoV-2 Reagents for BD MAX System	Molecular
04/01/2020	Ipsium Diagnostics, LLC	COV-19 IDx assay	Molecular
04/01/2020	Cellex Inc.	qSARS-CoV-2 IgG/IgM Rapid Test	Serology IgM and IgG
03/30/2020	QIAGEN GmbH	QIAstat-Dx Respiratory SARS-CoV-2 Panel	Molecular
03/30/2020	NeuMoDx Molecular, Inc.	NeuMoDx SARS-CoV-2 Assay	Molecular
03/27/2020	Luminex Molecular Diagnostics, Inc.	NxTAG CoV Extended Panel Assay	Molecular
03/27/2020	Abbott Diagnostics Scarborough, Inc.	ID NOW COVID-19	Molecular
03/26/2020	BGI Genomics Co. Ltd	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2	Molecular
03/25/2020	Avellino Lab USA, Inc.	AvellinoCoV2 test	Molecular
03/24/2020	PerkinElmer, Inc.	PerkinElmer New Coronavirus Nucleic Acid Detection Kit	Molecular
03/23/2020	Mesa Biotech Inc.	Accula SARS-Cov-2 Test	Molecular
03/23/2020	BioFire Defense, LLC	BioFire COVID-19 Test	Molecular
03/20/2020	Cepheid	Xpert Xpress SARS-CoV-2 test	Molecular
03/20/2020	Primerdesign Ltd.	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	Molecular
03/19/2020	GenMark Diagnostics, Inc.	ePlex SARS-CoV-2 Test	Molecular
03/19/2020	DiaSorin Molecular LLC	Simplexa COVID-19 Direct assay	Molecular
03/18/2020	Abbott Molecular	Abbott RealTime SARS-CoV-2 assay	Molecular
03/17/2020	Quest Diagnostics Infectious Disease, Inc.	Quest SARS-CoV-2 rRT-PCR	Molecular
03/17/2020	Quidel Corporation	Lyra SARS-CoV-2 Assay	Molecular
03/16/2020	Laboratory Corporation of America (LabCorp)	COVID-19 RT-PCR Test	Molecular
03/16/2020	Hologic, Inc.	Panther Fusion SARS-CoV-2 Assay	Molecular
03/13/2020	Thermo Fisher Scientific, Inc.	TagPath COVID-19 Combo Kit	Molecular
03/12/2020	Roche Molecular Systems, Inc. (RMS)	cobas SARS-CoV-2	Molecular
02/29/2020	Wadsworth Center, New York State Department of Public Health's (CDC)	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel	Molecular
02/04/2020	Centers for Disease Control and Prevention's (CDC)	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC)	Molecular

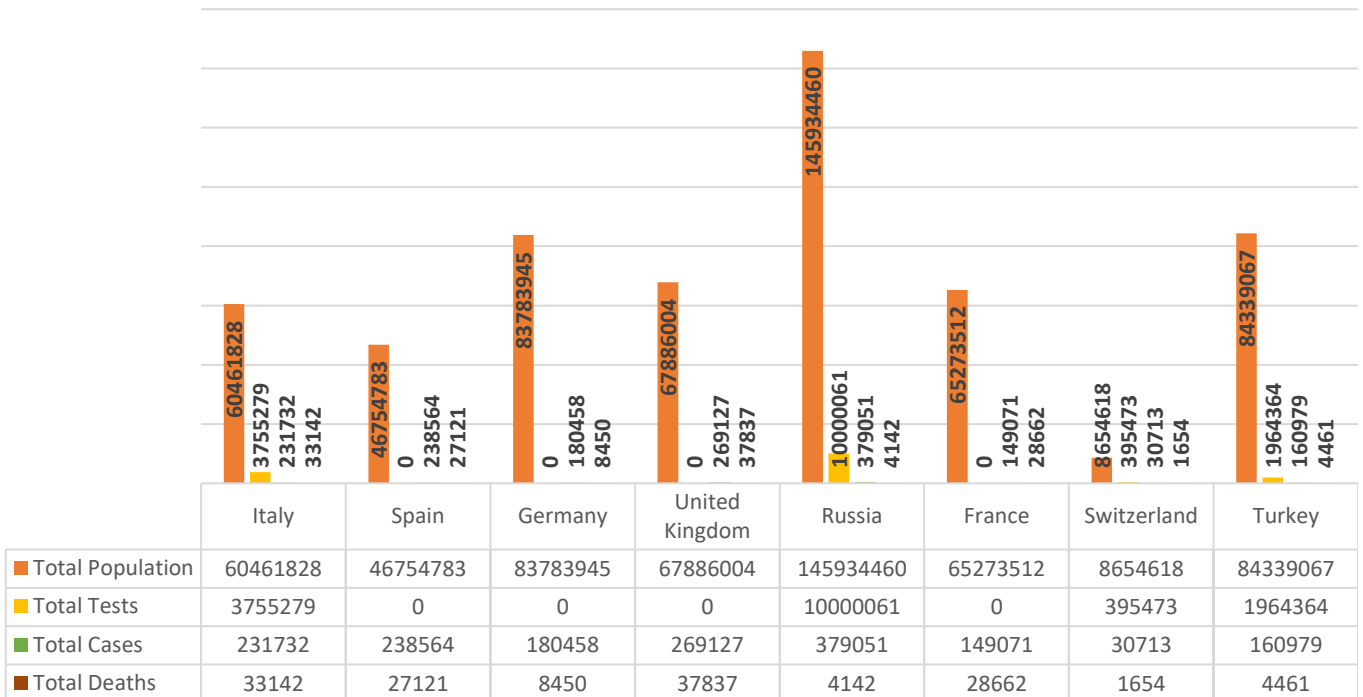
Date EUA Issued	Laboratory	Letter Granting Inclusion under EUA
05/22/2020	Exact Sciences Laboratories	<a href="#">Exact Sciences SARS-CoV-2 (N gene detection) Test</a>
05/22/2020	Express Gene LLC (dba Molecular Diagnostics Laboratory)	<a href="#">Express Gene 2019-nCoV RT-PCR Diagnostic Panel</a>
05/22/2020	Avera Institute for Human Genetics	<a href="#">Avera Institute for Human Genetics SARS-CoV-2 Assay</a>
05/18/2020	Color Genomics, Inc.	<a href="#">Color SARS CoV-2 Diagnostic Assay</a>
05/13/2020	One Health Laboratories, LLC	<a href="#">SARS-CoV-2 Real-Time RT-PCR-Test</a>
05/13/2020	Cedars-Sinai Medical Center, Department of Pathology and Laboratory Medicine	<a href="#">SARS-CoV-2-Assay</a>
05/12/2020	Columbia University Laboratory of Personalized Genomic Medicine	<a href="#">Triplex CII-CoV-1 rRT-PCR Test</a>
05/07/2020	Biocollections Worldwide, Inc.	<a href="#">Biocollections Worldwide SARS-CoV-2 Assay</a>
05/03/2020	UTMG Pathology Laboratory	<a href="#">UTHSC/UCH SARS-CoV-2-RT-PCR Assay</a>
04/30/2020	Altru Diagnostics, Inc.	<a href="#">Altru Dx SARS-CoV-2 RT-PCR assay</a>
04/28/2020	Biocerna	<a href="#">SARS-CoV-2 Test</a>
04/27/2020	Nationwide Children's Hospital	<a href="#">SARS-CoV-2 Assay</a>
04/24/2020	Ultimate Dx Laboratory	<a href="#">UDX SARS-CoV-2 Molecular Assay</a>
04/24/2020	AIT Laboratories	<a href="#">SARS-CoV-2 Assay</a>
04/23/2020	Southwest Regional PCR Laboratory LLC. dba MicroGen DX	<a href="#">COVID-19 Key</a>
04/22/2020	Diatherix Eurofins Laboratory	<a href="#">SARS-CoV-2 PCR Test</a>
04/20/2020	Mayo Clinic Laboratories, Rochester, MN	<a href="#">SARS-CoV-2 Molecular Detection Assay</a>
04/15/2020	Hackensack University Medical Center (HUMC) Molecular Pathology Laboratory	<a href="#">CDI Enhanced COVID-19 Test</a>
04/15/2020	CirrusDx Laboratories	<a href="#">CirrusDx SARS-CoV-2 Assay</a>
04/14/2020	Infectious Diseases Diagnostics Laboratory (IDDL), Boston Children's Hospital	<a href="#">Childrens-Altona-SARS-CoV-2 Assay</a>
04/14/2020	Exact Sciences Laboratories	<a href="#">SARS-CoV-2 Test</a>
04/13/2020	Integrity Laboratories	<a href="#">SARS-CoV-2 Assay</a>
04/13/2020	Pathology/Laboratory Medicine Lab of Baptist Hospital Miami	<a href="#">COVID-19 RT-PCR Test</a>
04/10/2020	Orig3n, Inc.	<a href="#">Orig3n 2019 Novel Coronavirus (COVID-19) Test</a>
04/10/2020	Specialty Diagnostic (SDI) Laboratories	<a href="#">SDI SARS-CoV-2 Assay</a>
04/10/2020	University of North Carolina Medical Center	<a href="#">UNC Health SARS-CoV-2 real-time RT-PCR test</a>
04/08/2020	Stanford Health Care Clinical Virology Laboratory	<a href="#">Stanford SARS-CoV-2 assay</a>
04/06/2020	Viracor Eurofins Clinical Diagnostics	<a href="#">Viracor SARS-CoV-2 assay</a>
04/03/2020	Massachusetts General Hospital	<a href="#">MGH COVID-19 qPCR assay</a>
04/02/2020	Diagnostic Molecular Laboratory – Northwestern Medicine	<a href="#">SARS-Cov-2 Assay</a>
04/02/2020	Infectious Disease Diagnostics Laboratory - Children's Hospital of Philadelphia	<a href="#">SARS-CoV-2 RT-PCR test</a>
03/31/2020	Yale New Haven Hospital, Clinical Virology Laboratory	<a href="#">SARS-CoV-2 PCR test</a>

Developers can approach FDA to discuss any alternative technology for validation through [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov)

As of now for the treatment of Covid-19, there is no FDA-Approved drugs, according to NIH (National Institutes of Health) Covid-19 Treatment Guidelines.

## EUROPE

Italy, Spain, Germany, France, United Kingdom, Switzerland, Turkey, Russia are in the list of countries highly affected by Covid-19 pandemic.



Here 0 indicates information not available

European Commission presented [guidelines](#) on coronavirus testing methodologies on 15 April 2020, in order to support Member States to effectively use high-quality testing tools during different stages of this pandemic with their national strategies.

Currently, [EU legislation](#) lays down a number of requirements for tests. The manufacturer of a test must prepare a technical file, which demonstrates that the test is safe and performs as intended.

Currently for Covid-19 tests, Directive 98/79/EC on in vitro diagnostic medical devices (IVD) is applicable.

To place these tests in EU market, manufacturer must comply with relevant provisions of the Directives along with technical file showing tests are safe and performs as intended, by demonstrating compliance with the requirement in Annexure I of the Directive and verification with Notified Body.

In early April 2020, numbers of CE-marked Covid-19 test devices under Directive 98/79/EC are approximately as following:

- 78 for RT-PCR Tests

- 13 Rapid Antigen Tests
- 101 Antibody Tests (mostly rapid)

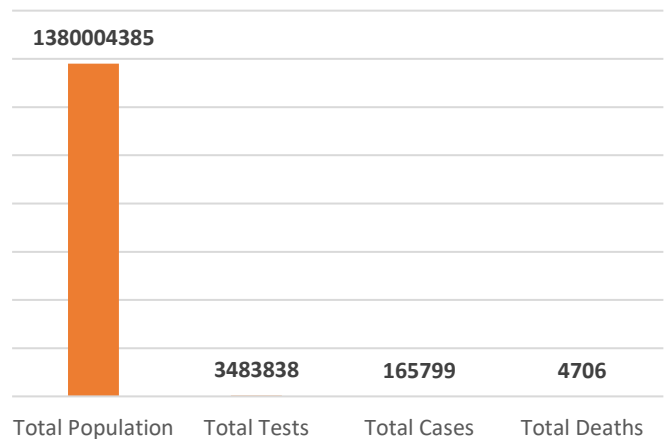
26 May 2022 onwards, the Directive will be replaced by Regulation (EU) 2017/746 on IVD which is already in transitional period from May 2017 during which conformity of IVD medical devices can be assessed either under the Regulation or under the Directive.

## INDIA

India is testing 75,000 to 80,000 samples a day through RT-PCR in latest.

Until end of April, India procured 90% of its RT-PCR tests from USA, China, Germany, South Korea, France, Israel, UK, etc

India based Mylab became the 1<sup>st</sup> Indian company with Covid-19 diagnostic test kits (RT-PCR) to receive validation by National Institute of Virology. Other Indian companies followed suit and received validation and started supplying number of kits to the healthcare firms in the country. National Institute of Virology (NIV) developed India's first indigenous antibody testing kit named ELISA (enzyme-linked immunosorbent assay) which is claimed to be more reliable and economical.



There are no 100% accurate tests available anywhere in the World till date. However, a huge demand of test kits has resulted in many fraudulent or inaccurate testing kits in the market.



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