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Review Article

COVID-19: Testing Kits and Mechanistic Insights

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ABSTRACT

Novel coronavirus disease (COVID-19) has been spread in 213 countries and created an emergency situation in around the world. Coronavirus is a group of single-stranded RNA enveloped virus which causes severe respiratory infection in the infected individual. Nowadays, coronavirus has become a leading cause of death in the world. Efficient diagnosis is an essential step before starting the best possible treatment. For the diagnosis of coronavirus mainly 3 methods are reported such as RT-PCR method, Regular LAMP-based methods and Serology based tests. Based on the above methods, various diagnostic kits has been developed by different countries. This review contains the list of diagnostic kits approved by various countries, their working mechanism and time taken to give result along with sampling procedure and major precautions which is most important during the diagnosis process. The worldwide R & D (research and development) will definitely lead to find an efficient and rapid diagnostic tool for the treatment of COVID-19.

INTRODUCTION

An outbreak of novel corona virus disease (COVID-19) caused by the novel corona virus (SARS-CoV-2) has caused an emergency situation in around the world. World Health Organisation (WHO) has signified the condition as the global pandemic situation. Up to 21th October 2020, more than 41,050,369 confirmed positive cases of SARS-CoV-2 with almost 1,129,741 death cases were reported in around the world. Starting from the city of Wuhan, China, the epicentre of the disease, the virus has spread in 213 countries, including USA (United States of America), Italy, Spain, Germany, and India. In which, the most SARS-CoV-2cases were reported in USA with a mortality rate 5.31%. The unavailability of the exact anti-viral drug against SARS CoV2 and the mandatory quarantine has made the situation worst (WHO 2020).

There are four types of coronavirus, which include, alpha coronavirus (α-CoVs), beta coronavirus (β-CoVs), gamma coronavirus (γ-CoV) and delta coronavirus (δ-CoV). COVID-19 virus is the largest single stranded RNA enveloped virus and along with SARS CoV (Severe Acute Respiratory Syndrome) & MERS (Middle East Respiratory Syndrome) it belongs to the family betacoronavirus. The α and β coronavirus are able to infect the mammals, whereas, the gamma and delta coronavirus infect the birds (Zhu, Zhang et al. 2020). By previous research work, six types of human coronavirus had been identified. In which α-CoVs , HcoV-NL63 and HcoV-229E , β-CoVs HcoV-OC43 and HcoV-HKU1 causes low pathogenicity and mild respiratory infection. The other two types of beta coronavirus, SARS CoV, MERS causes severe fatal respiratory infection in human body (Kumar, Malviya et al. 2020). In a recent study, it was revealed

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that, the genome sequence of SARS-CoV-2 is 96.2% similar to the genome sequence of bat CoV RaTG13, whereas, the SARS-CoV-2 shares 76.5% similarity with the genomic sequence of SARS CoV. Based on the data of genomic sequence, it was suspected that the bat is the natural host of the SARS-CoV-2 and it might be spread to human body through an unknown intermediated host (Zhou, Yang et al. 2020).

1.1 Epidemiology

The epicentre of COVID-19 was the city of Wuhan, China. The outbreak of COVID-19 was possibly spread from the seafood market of the Wuhan city on 12th December 2019. Several studies revealed that, bat might be the natural host of SARS-CoV-2 (Giovanetti, Benvenuto et al. 2020, Paraskevis, Kostaki et al. 2020). The transmission of the virus in human to human occurs due to the intimate contact with the infected patients cough, droplets, and touches. Direct consumption of the intermediate host or contact with the host is suspected to be the main route of transmission of the SARS-CoV-2 in the human body. However, the sources of transmission are unclear (Bai, Yao et al. 2020).

1.2 Replication and pathogenesis

It has been recognized that the SARS-CoV-2 enters to the host cell of respiratory track by the ACE-2 (angiotensin converting enzyme-2) receptor of the host cell (Zhou, Yang et al. 2020). The spike protein of the virus can attach with the ACE-2 receptor on the host cell surface. The spike protein of the virus has two subunits S1 & S2 (Zhang, Jiang et al. 2014). S1 subunit maintains the cellular tropism with the RBD (receptor binding domain). Whereas, S2 subunit regulates the virus-host cell-membrane fusion by two domains-heptad repeat 1 (HR1) and heptad repeat 2 (HR2) (Yu, Du et al. 2020). After viral fusion, these virus particles were engulfed by the endo-plasm of the host cell. In the endoplasmic acidic pH the virus regulates the release of two polyprotein pp1a and pplab in the cytoplasm and forms16 non-structural proteins (Nsp), by the help of endosomal protein cathepsin L & B (Yu, Du et al. 2020). These non-structural protein forms the replication-transcription complex (RTC), which further release the sub genomic viral RNAs (Hussain, Pan et al. 2005). These sub genomic RNAs encodes the viral structural proteins, which further assemble to form the viral buds and binds with the plasma membrane, thus release the virus into the system of host body. It is also reported that the SARS-CoV-2 can also enters through the tyrosine membrane protease 2 (TMPRSS2) receptor of the host cell, which is endo-lysosome independent pathway and can replicate in the host cell (Millet and Whittaker 2015). This may be a probable mechanism for the multiplication of SARS-CoV-2, because of the 76.2% genome structure similarity between SARS-CoV-2 and SARS CoV, the pathogenesis mechanism of SARS CoV is probably similar with SARS-CoV-2 (Xu, Zhao et al. 2020).

1.3 Clinical symptoms

A recent study revealed that, the initial symptoms of the COVID-19 includes- fever, cough, fatigue, breathing difficulties, sore throat headache, loss of smell and taste sensations. In further, various gastrointestinal problem, kidney problem, CNS (Central Nervous System) failure and multi-organ failure can be observed (Guan, Ni et al. 2020). Breathing difficulties, fever and cough with loss of smell and taste sensations are the major clinical manifestations, which can be differentiated from the other viral infections like SARS CoV, MERS CoV and influenza virus infection (Assiri, Al-Tawfiq et al. 2013).

1.4 Diagnostic process

Clinical diagnosis of COVID-19 is basically manifested by epidemiological history detection, clinical symptoms and due to the symptoms of COVID-19 infection is very much similar to other viral infections that is why the others additional test like nucleic acid detection, immune identification technology by POCT (Point-Of-Care testing) of IgG/IgM antibody which is secreted due the response of SARS-CoV-2, enzyme linked immunosorbent assay (ELISA), CT-scan and also through the blood culture technology has been used to detect the presence of virus (Adhikari, Meng et al. 2020).

METHODS OF DIAGNOSIS

RT-PCR

RT-PCR (Real-Time Polymerase Chain Reaction) is an *in vitro* molecular diagnosis test which is based on amplification technique of nucleic acid. For the qualitative estimation of nucleic acid from the

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sample obtained from the individual showing COVID-19 symptoms can be done by RT-PCR test method. Specimens from upper and lower respiratory like nasopharyngeal swabs, Broncho-alveolar lavage, nasal aspirates and sputum can be used for the testing (Chan, Yip et al. 2020).

Principle

In the virus nucleocapsid (N) gene specific oligonucleotide primers and probe (two) of a particular region is selected for the detection of SARS-CoV-2. Human RNase P gene is added as a control sample and clinical sample (specimens) are also incorporated in the panel. Isolated and purified RNA of upper and lower respiratory specimens are reverse transcripted to form cDNA and consequently amplified in Real-Time PCR instrument. Between the forward & reverse primer, the probe anneals at the specific target sequence. In the extension phase of polymerase chain reaction (PCR) the probe is degraded by Taq polymerase which causes the separation of reporter dye from quencher dye, it generates a fluorescent signal during each cycle, from the respective probes the reporter-dye molecules separates and increases intensity of the fluorescence. Applied Bio-systems 7500 Fast Dx RT-PCR System with SDS version 1.40 software is used to identify the fluorescence intensity at each PCR cycle. Results are normally obtainable within few hours to 2 days (CDCAP 2020) . The working of RT-PCR is shown in Fig. 1.

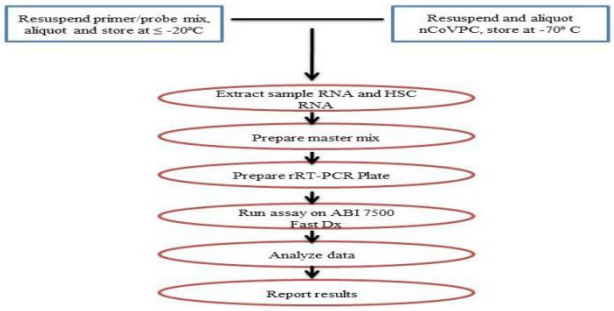

***Fig. 1**. Working mechanism of RT-PCR nCoVPC: Novel coronavirus positive control RNA: Ribonucleic acid*
HSC RNA: Human specimen extraction Ribonucleic acid
ABI 7500: Applied Biosystems 7500 Fast Dx Real-Time PCR System RT-PCR: real-time reverse time transcription polymerase chain reaction

Isothermal nucleic acid amplification-based methods

It is an amplification process of nucleic acid which amplifies the DNA rapidly with more specifically and selectively under the isothermal condition. Due to isothermal reaction time loss for thermal change is negligible. This amplifies the efficiency of the method. This method is further categories into 3 types as mentioned below in detail (Kashir and Yaqinuddin 2020).

Regular LAMP (Loop-mediated isothermal amplification) based methods

It exhibits specificity and high sensitivity due to its prominent amplification feature along with 6 different target sequence identified by 4 different primers at the same time (Notomi, Okayama et al. 2000). Due to its rapidity and less expensive requirements it may help to decrease the cost of corona virus detection (Enosawa, Kageyama et al. 2003). In the individual study it has been shown that RT-LAMP assay is more fold sensitive than conventional one (Poon, Leung et al. 2004, Thai, Le et al. 2004, Pyrc, Milewska et al. 2011).

Sequence-specific LAMP based methods

It is a robust and sequence specific method that monitors LAMP and other isothermal amplification process by separating nonspecific noise from the true signal. Huang *et al* has developed a visualization process for nucleic acid by the combination of RT-LAMP and vertical flow visualization strip. For the detection of MERS-CoV (**Fig. 2**), two primers loop are labelled with fluorescence isothiocyanate (FITC) & Biotin, respectively (**Fig. 2A**). After the amplification, the biotin labelled amplicon binds to colloidal gold particles which are conjugated with streptavidine and form a complex. They are afterward captured by anti-FITC antibody coated on the text line of strip. This process presents a coloured line that can be visible by naked eye (**Fig. 2B**) (Huang, Wang et al. 2018).

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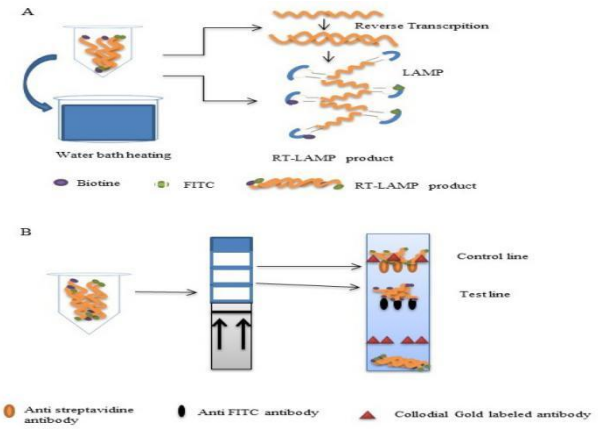

Fig. 2. *Schematics representation of RT-LAMF-VF assay*
A. Amplification reaction for RT-LAMP, B. Detection on visualization strip, RT-LAMP: Reverse transcription Loop-mediated isothermal amplification, LAMP: Loop-mediated isothermal amplification, FITC: Fluorescein isothiocyanate

Rolling circle amplification (RCA)-based methods

RCA method is able to produce 10^9 fold amplification signal of each circle in isotheral condition within 90 min, both in liquid and solid phases. The assay method for the detection of SARS CoV by RCA has been already established. The major benefit of RCA method is that it can work in minimal reagents under isothermal conditions with the avoidance of false-positive result generation (Wang, Potter et al. 2005).

Serology based tests

This method is based on the immune-response obtained by the people who have been exposed to a specific pathogen. It is a blood-based test method which is used to identify antibodies and antigens in the sample. An antibody present against a pathogen in the sample is the indication that the person has been exposed to the pathogen. It mostly involves two types of antibodies i.e. Immunoglobulin-M (IgM) & Immunoglobulin G (IgG). Three types of serology tests are available as discussed in following section (Lee, Lin et al. 2020).

Rapid diagnostic test

It is a qualitative process for the estimation antibodies (IgG and IgM) or viral antigen in the samples like blood from finger prick, saliva or nasal swab fluid of patient. It gives results within 10-30 min. Colour lines are used as indicator for positive or negative result. Qualitative estimation of antibodies can be done by the process as shown in **Fig. 3** (Paradiso, Silvestris et al. 2020).

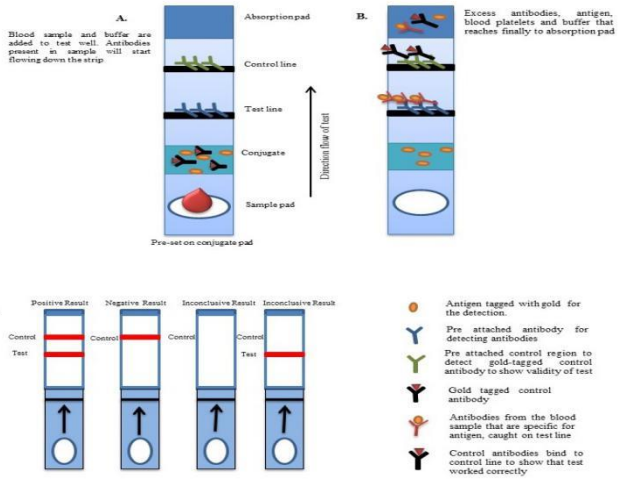

Fig. 3. *Schematic representation of rapid diagnostic test*

Enzyme-linked immunosorbent assay (ELISA)

Qualitative and quantitative estimation of the antibodies can be done by this process. Whole blood, plasma or serum can be used as sample for testing. In a plate, virus protein of interest is coated with spike proteins such as S1 Receptor-Binding Domain (S1RBD). Followed by incubation of patient's sample with protein (S1RBD). If the sample has antibodies against the viral protein, they bind together to form a complex. Antibody and protein complex can be detected after washing the antibodies that leads to production of colour or fluorescence. Time required for obtaining result is 1-5 hours. The complete mechanism for the detection of viral infection is shown in **Fig. 4** (Xiang, Yan et al. 2020).

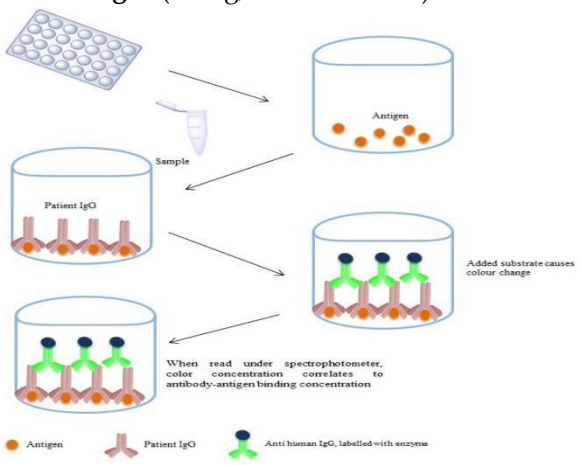

Fig. 4*. Schematic representation of ELISA*

Neutralization assay

These tests help to find the patient's antibodies that are effective & active against the virus. Patient's blood, serum or plasma can be used as sample for the test. Cell culture that allows the

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SARS-CoV-2 growth is used in this assay. While growing virus and cells with reducing concentrations of patient antibodies, researchers are able to visualize and measure how many antibodies in the patient's serum are capable to block virus replication. Visualization and quantification of antibodies of patient is analyzed further. 3-5 days are required to obtain the result. Antibodies present in patient serum which are able to inhibit virus growth in *ex vivo* condition is the indication that the patient is potentially protected against future infection **Fig. 5** (Shen, Wang et al. 2020).

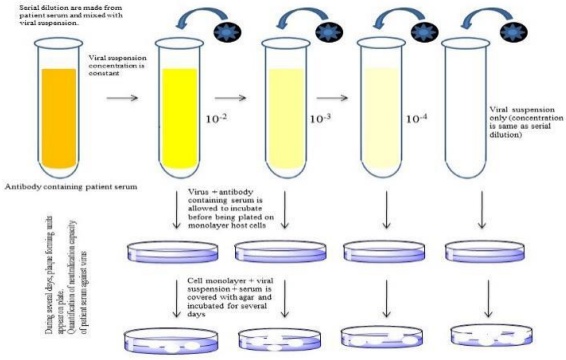

Fig. 5. *Schematic representation of neutralization assay PRNT50 is the dilution in which the antibody can reduce plaque formation by 50%. This indicates that the patient antibody can reduce the viral activity.*

Classification of analysing kits

The testing kits can be classified on the basis of the time frame within which results of the specific test can be obtained. As the most prominent COVID-19 test is RT-PCR and it is primarily carried out in central or national laboratories, research protocols require extensive facilities, reagents and skills, and are mostly performed under strict supervision. Delays in sample delivery and samples returned to the originator indicate that the average test period frequently consumes 48 hours (2 Days) (Control and Prevention 2020). And thus, this test is categorized as slow analysing procedure. On the other hand, various serological test are available which can produce results within a matter of few minutes to few hours, and hence these testing kits can be categorized as rapid diagnosis test or fast analysing kits (Xiang, Yan et al. 2020). The category wise distinction of various testing kits approved by different countries is outlined within **Table 1** and **2**.

Rapid analysing kits

Due to shortage of reagents and laboratory capacity, various devices/kits are being developed by manufacturers for smooth testing of COVID-19 outside of laboratory. They are easy to use and rapid to provide results. These test kits are either based on detection of antibodies which are generated due to response of infection, from blood/serum or detection of antigen (protein) from the virus of COVID-19 or from respiratory samples (throat swab/ sputum) (WHO 2020). Antigen-antibody based tests are less accurate however they are easy to use and provide results in 20–60 minutes (Sheridan 2020).

Rapid diagnostic tests based on antigen detection

In a sample collect from respiratory tract of patients one type of RDT (rapid diagnostic test) detects the presence of antigens (viral proteins), which are expressed by COVID-19 virus. If the target antigen (viral protein) is present in appropriate concentrations in the sample then it will be bind to specific antibodies which already fixed on a paper strip enclosed in plastic casing and gives visually, detectable signal within 30 minutes. This test is best used to identify early/acute infection because antigens detected are expressed only during active replication of virus. Testing ability of kits are how much effective it depends on factors such as concentration of virus, time from starting of infection, quality of sample collected from patients, processing method of collected sample and quality of reagents used in test kits (WHO 2020).

Rapid diagnostic tests based on host antibody detection

Another test for COVID-19 that detects the existence of antibodies in the blood sample collected from patients. Over time goes (from days to weeks) antibodies are produced after infection. The strength of response of antibody depends on factors such as patient's age, diet of patients, diseases severity and other disease or infections of patients like HIV (WHO 2020). Rapid analysing kits developed and approved by the different countries are shown in **Table 1**.

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Table 1. Rapid analyzing kits

Test kits approved under emergency use of authorization (EUA) by FDA, USA As of April 25, 2020, the EUA listed on its website: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov

Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/Slow
VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack (379KB)	Ortho Clinical Diagnostics, Inc.	Serology Total Antibody	14/04/2020	Rapid
DPP COVID-19 IgM/IgG System (369KB)	Chembio Diagnostic System, Inc.	Serology IgM and IgG	14/04/2020	Rapid
qSARS-CoV-2 IgG/IgM Rapid Test (328KB)	Cellex Inc.	Serology IgM and IgG	01/04/2020	Rapid

Test kits approved by Therapeutic Goods Administration (TGA), Australia As of April 25, 2020, the TGA listed on its website "https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia"

Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
COVID-19 IgG/IgM Rapid Test Cassette	Zhejiang Orient Gene Biotech Co Ltd (China)	Lateral Flow IgG/IgM	24/04/2020	Rapid
Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)	Zhuhai Livzon Diagnostics Inc (China)	Lateral Flow IgG/IgM	23/04/2020	Rapid
2019-nCoV Ab Test (Colloidal Gold)	Innovita (Tangshan) Biological Technology Co Ltd (China)	Lateral Flow IgG/IgM	20/04/2020	Rapid
SARS-CoV-2 Antibody Test (Lateral Flow Method)	Guangzhou Wondfo Biotech Co Ltd (China)	Lateral Flow IgG/IgM	17/04/2020	Rapid
2019-nCOV/COVID-19 IgG/IgM Rapid Test Device	Hangzhou Realy Tech Co Ltd (China)	Lateral Flow IgG/IgM	16/04/2020	Rapid
COVID-19 IgG/IgM Rapid Test Cassette	Zhejiang Orient Gene Biotech Co Ltd (China)	Lateral Flow IgG/IgM	14/04/2020	Rapid
SARS-CoV-2 IgM/lgG Antibody Rapid Test	Qingdao Hightop Biotech Co Ltd (China)	Lateral Flow IgG/IgM	7/04/2020	Rapid
VivaDiag™ COVID-19 IgM/IgG Rapid Test	VivaChek Biotech (Hangzhou) Co Ltd (China)	Lateral Flow IgG/IgM	6/04/2020	Rapid
Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)	Hangzhou Laihe Biotech Co Ltd (China)	Lateral Flow IgG/IgM	6/04/2020	Rapid
COVID-19 IgG/IgM Rapid Test Cassette	Hangzhou Clongene Biotech Co Ltd (China)	Lateral Flow IgG/IgM	4/04/2020	Rapid
Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test kit	CellexInc (USA)	Lateral Flow IgG/IgM	31/03/2020	Rapid
Wantai SARS-CoV-2 Ab Rapid Test kit	Beijing WantaiBiologicalpharmacy Enterprise Co Ltd (China)	Lateral Flow IgG/IgM	27/03/2020	Rapid
OnSite COVID-19 IgG/IgM Rapid Test	CTK Biotech Inc (USA)	Lateral Flow IgG/IgM	19/03/2020	Rapid

Test kits approved by Health Sciences Authority (HSA), Singapore As of April 25, 2020, the HSA listed on its website "https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation"

Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
Grit Overseas Pte Ltd	DiagnoSure COVID-19 IgG/ IgM Rapid Test Cassette	Lateral Flow IgG/IgM	24/04/2020	Rapid
SkyQuest Pte Ltd	Wondfo SARS-CoV-2 Antibody Test	Lateral Flow IgG/IgM	9/04/2020	Rapid
Camtech Diagnostics Pte Ltd	Camtech COVID-19	Lateral Flow	9/04/2020	Rapid

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	IgM/IgG	IgG/IgM		
Biolidics Limited	Nanjing Vazyme 2019-nCoV IgG/IgM Detection Kit, also marketed as Biolidics 2019-nCoV IgG/IgM Detection Kit	Serology IgM and IgG	20/03/2020	Rapid

Test kits approved by National Medical Products Administration (NMPA), China As of April 25, 2020, the NMPA listed on its website: https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg

Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ Slow
Antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	Guangzhou Wondfo Biotech Co., Ltd.	Lateral Flow IgG/IgM	Approved till 02/04/2020	Rapid
Antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	INNOVITA(Tangshan) Biological Technology Co., Ltd.	Lateral Flow IgG/IgM		Rapid
IgM Antibody test kit for novel coronavirus 2019-nCoV (magnetic particle-based chemiluminescence immunoassay)	Bioscience (Chongqing) Diagnostic Technology Co., Ltd.	Lateral Flow IgG/IgM		Rapid
Antibody test kit for novel coronavirus 2019-nCoV (chemiluminescencemicroparticle immunoassay)	Xiamen Innodx Biotech Co., Ltd.	Lateral Flow IgG/IgM		Rapid
IgM antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	Hecin Scientific, Inc.	Lateral Flow IgG/IgM		Rapid
IgM/IgG antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	Nanjing Vazyme Medical Technology Co., Ltd.	Lateral Flow IgG/IgM		Rapid
IgM/IgG antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	Zhuhai Livzon Diagnostics Inc.	Lateral Flow IgG/IgM		Rapid

Test kits approved by Federal Service for Surveillance in Healthcare, Russia As of April 25, 2020, the Federal Service for Surveillance in Healthcare listed on its website: https://www.roszdravnadzor.ru/services/misearch

Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
Rapid test COVID-19 IgG / IgM (Whole blood / serum / plasma)	LLC "BIOTEK"	Lateral Flow IgG/IgM	24/04/2020	Rapid

Test kits approved by National Health Surveillance Agency (ANVISA), Brazil As of April 25, 2020, the ANVISA listed on its website: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus

Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
TR DPP® COVID-19 IGM/IGG – Bio Manguinhos	OSWALDO CRUZ FOUNDATION	Serology IgM and IgG	22/04/2020	Rapid
Anti-SARS-CoV-2 ELISA IgA	EUROIMMUN BRASIL MEDICINA DIAGNOSTICA LTDA	ELISA IgA	10/04/2020	Rapid
Anti-SARS-CoV-2 IgG ELISA	EUROIMMUN BRASIL MEDICINA DIAGNOSTICA LTDA	ELISA IgG	10/04/2020	Rapid
COVID-19 IgG/IgM LF	ADVAGEN BIOTECH LTDA	Lateral Flow IgG/IgM	03/04/2020	Rapid
TesteRápidoOnSite™ COVID-19 IgG/IgM	BIO ADVANCE DIAGNOSTICOS LTDA	Lateral Flow IgG/IgM	03/04/2020	Rapid
COVID-19 IgG/IgM	CEPALAB LABORATÓRIOS LTDA	Serology IgM and IgG	03/04/2020	Rapid
Smart Test Covid-19 Vyttra	VYTTRA DIAGNOSTICOS IMPORTACAO E EXPORTACAO S.A.	Serology IgM and IgG	31/03/2020	Rapid

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DPP® COVID-19 IgM/IgG System	CHEMBIO DIAGNOSTICS BRAZIL LTDA.	Serology IgM and IgG	25/03/2020	Rapid
LUMIRATEK COVID-19 (IgG/IgM)	LUMIRADX HEALTHCARE LTDA	Serology IgM and IgG	25/03/2020	Rapid
One Step COVID-2019 Test	CELER BIOTECNOLOGIA S/A	Serology IgM and IgG	24/03/2020	Rapid
CORONAVÍRUS RAPID TEST	DIAGNÓSTICA INDÚSTRIA E COMÉRCIO LTDA	Serology IgM and IgG	24/03/2020	Rapid
COVID-19 IgG/IgM ECO Teste	Eco DiagnosticaLtda	Serology IgM and IgG	24/03/2020	Rapid
Anti COVID-19 IgG/IgM Rapid Test	LABTEST DIAGNOSTICA S/A	Serology IgM and IgG	24/03/2020	Rapid
MedTesteCoronavírus (COVID-19) IgG/IgM (TESTE RAPIDO)	MEDLEVENSOHN COMÉRCIO E REPRESENTAÇÕES DE PRODUTOS HOSPITALARES LTDA	Serology IgM and IgG	24/03/2020	Rapid
Family Rapid Test Cassette 2019-nCoV IgG / IgM (whole blood / serum / plasma)	QR Consulting, Import and Distribution of Medical Products Ltda	Lateral Flow IgG/IgM	24/03/2020	Rapid
CORONAVÍRUS IgG/IgM (COVID-19)	EBRAM PRODUTOS LABORATORIAIS LTDA	Serology IgM and IgG	20/03/2020	Rapid

Test kits approved by Indian Council of Medical Research (ICMR), India As of April 25, 2020, the ICMR listed on its website: https://icmr.nic.in/sites/default/files/upload_documents/Antibody_based_tests_16042020.pdf

Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
SARS-CoV-2 Antibody test	Guangzhou Wondfo Biotech	Lateral Flow IgG/IgM	Approved Till 16/04/2020	Rapid
COVID-19 IgM/IgG Rapid Test	BioMedomics (CE-IVD)	Serology IgM and IgG		Rapid
COVID-19 IgM/IgG Antibody Rapid Test	ZHUHAI LIVZON DIAGNOSTICS (CEIVD)	Serology IgM and IgG		Rapid
New Coronavirus (COVID-19) IgG/IgM Rapid Test	Voxtur Bio Ltd, India	Serology IgM and IgG		Rapid
COVID-19 IgM/IgG Antibody Detection Card Test	VANGUARD Diagnostics, India	Serology IgM and IgG		Rapid
Makesure COVID-19 Rapid test	HLL Lifecare Limited, India	Serology IgM and IgG		Rapid
YHLO iFlash-SARS-CoV-2 IgM and IgG detection kit	CPC Diagnostics	Serology IgM and IgG		Rapid
ACCUCARE IgM/IgG Lateral Flow Assay kit	LAB-CARE Diagnostics (India Pvt. Ltd)	Serology IgM and IgG		Rapid
Abchek COVID-19 IgM/IgG Antibody Rapid Test	NuLifecare	Serology IgM and IgG		Rapid
One Step Corona Virus (COVID-19) IgM/IgG Antibody Test	ALPINE BIOMEDICALS	Serology IgM and IgG		Rapid
COVID-19 IgM/IgG Rapid Test Kit	Medsource Ozone Biomedicals	Serology IgM and IgG		Rapid
Immuno Quick Rapid Test for Detection of Novel Coronavirus (COVID-19) IgM/IgG Antibodies	Immuno Science India Pvt. Ltd	Serology IgM and IgG		Rapid
Standard Q COVID-19 IgM/IgG Duo test – One Step Rapid Antibody test	SD Biosensors	Serology IgM and IgG		Rapid
COVID-19 IgG/IgM Rapid Test Kit Rafael Diagnostic	BMT Diagnostics	Serology IgM and IgG		Rapid

*Rapid denotes the time frame for testing which produces results within few minutes to few hours.

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Slow analysing kits

For the diagnosis of existing disease several protocols are published by WHO. The test of choice RT-PCR. This test is performed on blood/respiratory sample (La Urbana 2020). PCR test is several decades old and based on science. It provides highly accurate results, but they are complex to use, and provides results slowly (Sheridan 2020). For the identification and laboratory confirmation of COVID-19 disease, respiratory tract sample is recommended method (WHO 2020). List of slow analysing kits are shown in Table 2.

Table 2. Slow analyzing kits

Test kits approved by Canada (Health Canada) As of April 25, 2020, the Health Canada listed on its website "https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html"				
Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
Genefinder COVID-19 Plus Realamp Kit	Osang Healthcare Co., Ltd. (South Korea)	Nucleic Acid Test	21/04/2020	Slow
BD SARS-CoV-2 Reagents For BD Max System	BD Integrated Diagnostic Solutions (Canada)	Nucleic Acid Test	19/04/2020	Slow
Spartan Cube COVID-19 System	Spartan Bioscience Inc. (Canada)	Nucleic Acid Test	11/04/2020	Slow
DiaSorinSimplexa COVID-19 Direct Molecular Assay on the LIAISON MDX Instrument	DiaSorin Molecular LLC (United States)	Nucleic Acid Test	09/04/2020	Slow
Allplex 2019-NCoV Assay	Seegene Inc. (Korea)	Nucleic Acid Test	09/04/2020	Slow
PerkinElmer New Coronavirus Nucleic Acid Detection Kit	PerkinElmer, Inc. (United States)	Nucleic Acid Test	06/04/2020	Slow
DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	Life Sciences Research Institute (South Korea)	Nucleic Acid Test	05/04/2020	Slow
1copy COVID-19 QPCR Kit	1DROP INC. (imported by Luminarie Canada Inc.) (South Korea)	Nucleic Acid Test	30/03/2020	Slow
NxTAG COV Extended Panel	Luminex Molecular Diagnostics, Inc. (Canada)	Nucleic Acid Test	26/03/2020	Slow
Abbott Realtime SARS-CoV-2	Abbott Molecular Inc. (United States)	Nucleic Acid Test	25/03/2020	Slow
LYRA SARS-CoV-2 ASSAY	Diagnostic Hybrids, Inc. - Also trading as Quidel Corporation (United States)	Nucleic Acid Test	25/03/2020	Slow
SARS-CoV-2 Assay (Panther Fusion System)	Hologic (United States)	Nucleic Acid Test	25/03/2020	Slow
Xpert Xpress SARS-CoV-2	Cepheid (United States)	Nucleic Acid Test	24/03/2020	Slow
TaqPathTM COVID-19 Combo Kit	Thermo Fisher (United States)	Nucleic Acid Test	18/03/2020	Slow
cobas SARS-CoV-2	Roche (United States)	Nucleic Acid Test	18/03/2020	Slow
Test kits approved under emergency use of authorization (EUA) by FDA, USA As of April 25, 2020, the EUA listed on its website "https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov"				
Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
STANDARD M nCoV Real-Time Detection Kit (129KB)	SD Biosensor, Inc.	Nucleic Acid Test	23/04/2020	Slow
RealStar SARS-CoV-2 RT-PCR Kits U.S. (130KB)	altona Diagnostics GmbH	Nucleic Acid Test	22/04/2020	Slow
Allplex 2019-nCoV Assay (124KB)	Seegene, Inc.	Nucleic Acid Test	21/04/2020	Slow
PhoenixDx 2019-CoV (134KB)	Trax Management Services Inc.	Nucleic Acid Test	20/04/2020	Slow
GeneFinder COVID-19 Plus RealAmp Kit (320KB)	OSANG Healthcare	Nucleic Acid Test	18/04/2020	Slow

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Fosun COVID-19 RT-PCR Detection Kit (317KB)	FosunPharma USA Inc.	Nucleic Acid Test	17/04/2020	Slow
GS COVID-19 RT-PCR KIT (317KB)	GenoSensor, LLC	Nucleic Acid Test	16/04/2020	Slow
Curative-Korva SARS-CoV-2 Assay (280KB)	KorvaLabs Inc.	Nucleic Acid Test	16/04/2020	Slow
SARS-CoV-2 Fluorescent PCR Kit (154KB)	Maccura Biotechnology (USA) LLC	Nucleic Acid Test	15/04/2020	Slow
iAMP COVID-19 Detection Kit (124KB)	AtilaBioSystems, Inc.	Nucleic Acid Test	10/04/2020	Slow
BD SARS-CoV-2Reagents for BD MAX System (212KB)	Becton, Dickinson & Company	Nucleic Acid Test	08/04/2020	Slow
QuantiVirus SARS-CoV-2 Test kit (319KB)	DiaCarta, Inc.	Nucleic Acid Test	08/04/2020	Slow
Smart Detect SARS-CoV-2 rRT-PCR Kit (128KB)	InBios International, Inc.	Nucleic Acid Test	07/04/2020	Slow
Gnomegen COVID-19 RT-Digital PCR Detection Kit (320KB)	Gnomegen LLC	Nucleic Acid Test	06/04/2020	Slow
ARIES SARS-CoV-2 Assay (125KB)	Luminex Corporation	Nucleic Acid Test	03/04/2020	Slow
ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (319KB)	ScienCell Research Laboratories	Nucleic Acid Test	03/04/2020	Slow
Logix Smart Coronavirus Disease 2019 (COVID-19) Kit (317KB)	Co-Diagnostics, Inc.	Nucleic Acid Test	03/04/2020	Slow
BioGX SARS-CoV-2 Reagents for BD MAX System (154KB)	Becton, Dickinson & Company (BD)	Nucleic Acid Test	02/04/2020	Slow
COV-19 IDx assay (288KB)	Ipsum Diagnostics, LLC	Nucleic Acid Test	01/04/2020	Slow
NeuMoDx SARS-CoV-2 Assay (127KB)	NeuMoDx Molecular, Inc.	Nucleic Acid Test	30/03/2020	Slow
QIAstat-Dx Respiratory SARS-CoV-2 Panel (128KB)	QIAGEN GmbH	Nucleic Acid Test	30/03/2020	Slow
ID NOW COVID-19 (356KB)	Abbott Diagnostics Scarborough, Inc.	Nucleic Acid Test	27/03/2020	Slow
NxTAGCoV Extended Panel Assay (318KB)	Luminex Molecular Diagnostics, Inc.	Nucleic Acid Test	27/03/2020	Slow
Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV (131KB)	BGI Genomics Co. Ltd	Nucleic Acid Test	26/03/2020	Slow
AvellinoCoV2 test (284KB)	Avellino Lab USA, Inc.	Nucleic Acid Test	25/03/2020	Slow
PerkinElmer New Coronavirus Nucleic Acid Detection Kit (319 KB)	PerkinElmer, Inc.	Nucleic Acid Test	24/03/2020	Slow
BioFire COVID-19 Test (317 KB)	BioFireDefense, LLC	Nucleic Acid Test	23/03/2020	Slow
Accula SARS-CoV-2 Test (322 KB)	Mesa Biotech Inc.	Nucleic Acid Test	23/03/2020	Slow
Primerdesign Ltd COVID-19 genesig Real-Time PCR assay (132KB)	Primerdesign Ltd	Nucleic Acid Test	20/03/2020	Slow
Xpert Xpress SARS-CoV-2 test (140 KB)	Cepheid	Nucleic Acid Test	20/03/2020	Slow
Simplexa COVID-19 Direct (103KB)	DiaSorin Molecular LLC	Nucleic Acid Test	19/03/2020	Slow
ePlex SARS-CoV-2 Test (126KB)	GenMark Diagnostics, Inc.	Nucleic Acid Test	19/03/2020	Slow
Abbott Real*Time* SARS-CoV-2 assay (324KB)	Abbott Molecular	Nucleic Acid Test	18/03/2020	Slow
Lyra SARS-CoV-2 Assay (294KB)	Quidel Corp.	Nucleic Acid Test	17/03/2020	Slow
Quest SARS-CoV-2 rRT-PCR (297KB)	Quest Diagnostics Infectious Disease, Inc.	Nucleic Acid Test	17/03/2020	Slow
Panther Fusion SARS-CoV-2 (290KB)	Hologic, Inc.	Nucleic Acid Test	16/03/2020	Slow

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COVID-19 RT-PCR Test (296KB) (reissued April 20, 2020)	Laboratory Corporation of USA	Nucleic Acid Test	16/03/2020	Slow
TaqPath COVID-19 Combo Kit (105KB)	Thermo Fisher Scientific, Inc.	Nucleic Acid Test	13/03/2020	Slow
cobas SARS-CoV-2 (111KB)	Roche Molecular Systems, Inc. (RMS)	Nucleic Acid Test	12/03/2020	Slow
New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel (312KB) (Reissued 03/10/2020)	Wadsworth Center, NYSDOH	Nucleic Acid Test	29/02/2020	Slow
CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (286KB) (Reiussed 03/15/2020)	CDC	Nucleic Acid Test	04/02/2020	Slow
Test kits approved by Ministry of Health, Labour and Welfare (MHLW), Japan As of April 25, 2020, the MHLW listed on its website "https://www.who.int/diagnostics_laboratory/200408_imdrf_collated_table_8_april_2020.pdf?ua=1"				
Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
2019-nCoV Fluorescence Detection Real-time RT-PCR Kit	Sysmex Corporation	Nucleic Acid Test	27/03/2020	Slow
Loopamp Novel Coronavirus 2019 (SARS-CoV-2) Detection Kit	Eiken Chemical Co., Ltd.	Nucleic Acid Test	31/03/2020	Slow
cobas SARSCoV-2	Roche Diagnostics K.K.	Nucleic Acid Test	31/03/2020	Slow
List of test kits approved by Therapeutic Goods Administration (TGA), Australia As of April 25, 2020, the TGA listed on its website "https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia"				
Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
Aridia COVID-19 Real-Time PCR Test	CTK Biotech Inc (USA)	Nucleic Acid Test	24/04/2020	Slow
EasyNat Diagnostic Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay)	Ustar Biotechnologies (Hangzhou) Co Ltd (China)	Nucleic Acid Test	23/04/2020	Slow
BD SARS-CoV-2 Reagents for BD MAX™ System	Becton Dickinson and Company (USA)	Nucleic Acid Test	17/04/2020	Slow
Abbott RealTime SARS-CoV-2	Molecular Division Abbott Molecular Inc (USA)	Nucleic Acid Test	17/04/2020	Slow
PowerChekTM 2019-nCoV Real-time PCR Kit	Kogene Biotech Co Ltd (Korea - Republic of)	Nucleic Acid Test	16/04/2020	Slow
EasyScreen™ SARS-CoV-2 Detection Kit	Genetic Signatures Ltd (Australia)	Nucleic Acid Test	13/04/2020	Slow
Real-time fluorescent RT-PCR kit for detecting SARS-CoV-2	BGI Europe A/S (Denmark)	Nucleic Acid Test	10/04/2020	Slow
VIASURE SARS-CoV-2 Real Time PCR Detection Kit	CerTestBiotec SL (Spain)	Nucleic Acid Test	31/03/2020	Slow
Allplex™ 2019-nCoV Assay	SeegeneInc (Korea - Republic of)	Nucleic Acid Test	27/03/2020	Slow
TaqPath COVID-19 Combo Kit	Life Technologies Corporation (USA)	Nucleic Acid Test	24/03/2020	Slow
Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 genes)	Shanghai ZJ Bio-Tech Co Ltd (China)	Nucleic Acid Test	22/03/2020	Slow
Xpert® Xpress SARS-CoV-2	Cepheid (USA)	Nucleic Acid Test	22/03/2020	Slow
VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit	CerTestBiotec SL (Spain)	Nucleic Acid Test	21/03/ 2020	Slow
Panther Fusion® SARS-CoV-2 Assay (Panther Fusion® System)	HologicInc (USA)	Nucleic Acid Test	20/03/2020	Slow
cobas® SARS-CoV-2	Roche Molecular Systems Inc (USA)	Nucleic Acid Test	20/03/2020	Slow
AusDiagnostics respiratory virus panel (including SARS-CoV-2) test	AusDiagnostics Pty Ltd (Australia)	Nucleic Acid Test	19/03/2020	Slow
Test kits approved under emergency use of authorization (EUA) by the Ministry of Food and Drug Safety (MFDS), South				

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Korea As of April 25, 2020, the MFDS listed on its website "(https://www.mfds.go.kr/eng/brd/m_52/view.do?seq=74424&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1"				
Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
Real-Q 2019-nCoV Detection Kit	BioSewoom Inc.	Nucleic Acid Test	13/03/2020	Slow
DiaPlexQ TM N Coronavirus Detection kit	Solgent Co, Ltd.	Nucleic Acid Test	27/02/2020	Slow
STANDARD TM nCoV RT Detection kit	SD BIOSENSOR	Nucleic Acid Test	27/02/2020	Slow
Allplex TM 2019-nCoV Assay	Seegene	Nucleic Acid Test	12/02/2020	Slow
PowerCheck TM 2019-nCoV RT PCR kit	kogenebiotech	Nucleic Acid Test	4/02/2020	Slow
List of test kits approved by Health Sciences Authority (HSA), Singapore As of April 25, 2020, the HSA listed on its website "https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation"				
Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
Medicell Pharmaceutical (S) Pte Ltd	Sansure Biotech Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit	Nucleic Acid Test	23/04/2020	Slow
BioWalker Pte Ltd	BioWalker SARS-CoV-2 Assay	Nucleic Acid Test	20/04/2020	Slow
PerkinElmer Singapore Pte Ltd	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay	Nucleic Acid Test	20/04/2020	Slow
Vela Operations Singapore Pte Ltd	ViroKey SARS-CoV-2 RT-PCR Test	Nucleic Acid Test	15/04/2020	Slow
Acumen Research Laboratories Pte Ltd	Acu-Corona 3.0	Nucleic Acid Test	13/04/2020	Slow
All Eights (Singapore) Pte Ltd	SeegeneAllplex™ 2019-nCoV Assay	Nucleic Acid Test	2/04/2020	Slow
Abbott Laboratories (Singapore) Pte Ltd	Abbott RealTime SARS-CoV-2 assay	Nucleic Acid Test	1/04/2020	Slow
Credo Diagnostics Biomedical Pte Ltd	VitaPCR™ SARS-CoV-2 Assay	Nucleic Acid Test	1/04/2020	Slow
Acumen Research Laboratories	Acu-Corona™ 2.0	Nucleic Acid Test	31/03/2020	Slow
MiRXES Pte Ltd	MiRXES FORTITUDE KIT 2.0	Nucleic Acid Test	30/03/2020	Slow
SPD Scientific Pte Ltd	Cepheid® Xpert® Xpress SARS-CoV-2	Nucleic Acid Test	26/03/2020	Slow
Biowalker Pte Ltd	Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay)	Nucleic Acid Test	24/03/2020	Slow
Life Technologies Holdings Pte Ltd	TaqPath™ COVID-19 Combo Kit	Nucleic Acid Test	20/03/2020	Slow
JN Medsys Pte Ltd	ProTect™ COVID-19 RT-qPCR Kit	Nucleic Acid Test	19/03/2020	Slow
Roche Diagnostics Asia Pacific Pte Ltd	Cobas® SARS-CoV-2	Nucleic Acid Test	19/03/2020	Slow
DSO National Laboratories	Real-Time PCR Assay for the Detection of SARS-CoV-2 Virus	Nucleic Acid Test	10/03/2020	Slow
AITbiotech Pte Ltd	abTES™ COVID-19 qPCR I Kit	Nucleic Acid Test	5/03/2020	Slow
Veredus Laboratories Pte Ltd	VereCoV™ Detection Kit	Nucleic Acid Test	18/02/2020	Slow
FORTITUDE KIT 2.0	Diagnostics Development Hub (DxD)	Nucleic Acid Test	7/02/2020	Slow

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Test kits approved by National Medical Products Administration (NMPA), China As of April 25, 2020, the NMPA listed on its website "https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg"				
Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Shanghai ZJ Bio-Tech Co., Ltd.	Nucleic acid test	Approved till 02/04/2020	Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Shanghai GeneoDx Biotechnology Co., Ltd.	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	BGI Biotechnology (Wuhan) Co., Ltd.	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Da An Gene Co., Ltd. of Sun Yat-sen University	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Sansure Biotech Inc.	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Shanghai BioGerm Medical Biotechnology Co., Ltd.	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Beijing Applied Biological Technologies Co., Ltd.	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Maccura Biotechnology Co., Ltd.	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Wuhan Easy Diagnosis Biomedicine Co., Ltd.	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (Isothermal amplification-real time fluorometric PCR)	Ustar Biotechnologies (Hangzhou) Ltd.	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (hybridization capture immunofluorescence)	Anbio (Xiamen) Biotechnology Co., Ltd.	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Shanghai Fosun Long March Medical Science Co., Ltd.	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (RNA capture probe method)	Shanghai Rendu Biotechnology Co., Ltd.	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (Dual amplification)	Wuhan Zhongzhi Biotechnologies INC.	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (RNA isothermal amplification lateral flow assay)	Wuhan Zhongzhi Biotechnologies INC.	Nucleic acid test		Slow
Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (combinatorial probe-anchor synthesis sequencing)	BGI Biotechnology (Wuhan) Co., Ltd.	Nucleic acid test (next generation sequencing)		Slow
Nucleic Acid reagent test kit for six respiratory viruses (constant temperature amplification chip)	Chengdu CapitalBio Biotechnology Co., Ltd.	Nucleic acid test		Slow
Test kits approved by Federal Service for Surveillance in Healthcare, Russia As of April 25, 2020, the "https://www.roszdravnadzor.ru/services/misearch"				
Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
Coronavirus RNA Reagent Kit	OOO "AVIVIR"	Nucleic acid test	23/04/2020	Slow

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Coronavirus RNA Reagent Kit	FSBI "TsSP" Ministry of Health of Russia	Nucleic acid test	21/04/2020	Slow
Coronavirus RNA Reagent Kit	FSBI "TsSP" Ministry of Health of Russia	Nucleic acid test	27/03/2020	Slow
Coronavirus RNA Reagent Kit	FBUN SSC WB "Vector" Rospotrebnadzor	Nucleic acid test	14/02/2020	Slow

Test kits approved by National Health Surveillance Agency (ANVISA), Brazil As of April 25, 2020, the ANVISA listed on its website "https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus"

Device name	Manufacturer	Mechanism/ Technology	Date authorized	Rapid/ slow
Kit MOLECULAR SARS-CoV-2 (E/P1) - Bio-Manguinhos	OSWALDO CRUZ FOUNDATION	Nucleic acid test	06/04/2020	Slow
Abbott Real Time SARS-CoV-2 EUA	ABBOTT LABORATÓRIOS DO BRASIL LTDA	Nucleic acid test	03/04/2020	Slow
SARS-CoV-2 S gene for BD Max	BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS LTDA.	Nucleic acid test	03/04/2020	Slow
VIASURE SARS-CoV-2 Real-Time PCR Detection Kit	BIOMÉDICA EQUIPAMENTOS E SUPRIMENTOS HOSPITALARES LTDA	Nucleic acid test	24/03/2020	Slow
ECO F COVID-19 Ag	Eco Diagnostica Ltda	Nucleic acid test	24/03/2020	Slow
COVID-19 Ag ECO Teste	Eco Diagnostica Ltda	Nucleic acid test	24/03/2020	Slow
cobas® SARS-CoV-2	Roche Molecular System, Inc	Nucleic acid test	24/03/2020	Slow

**Slow denotes the time frame for testing procedure in which the procurement of results took more than 48 hours.*

Procedure for sampling

According to ICMR guidelines at April 25, 2020 **As of April 25, 2020, the ICMR listed on its website** "https://www.mohfw.gov.in/pdf/NotificationofICMguidelinesforCOVID-19testinginprivatelaboratoriesiIndia.pdf" laboratory test of COVID-19 should be done only after the prescription of a qualified physician and only RT-PCR based assay are suggested. Conventional PCR and Antibody /Antigen tests are not recommended. Specimen collection, storage, packaging and transport should be done by trained staff with the proper regulation of Standard operating procedures. Collection of respiratory material should be in minimum quantity. Upper respiratory specimens like nasopharyngeal and oropharyngeal swab or wash, lower respiratory specimens like sputum, endotracheal aspirate or bronchoalveolar lavage can be collected as samples (Zhang, Jiang et al. 2014, Linton, Kobayashi et al. 2020). Additional clinical specimens like blood and stool can also be collected. In decreased patients autopsy material including tissues of lung can be collected.

Packaging and shipment of the sample should be done as soon as possible after the collection. Specimen during delivery to laboratory should be stored at 2-8^{o}C up to 72 hours. In case of delay, the specimen should be stored in viral transport medium. Specimen should be frozen to -20^{o}C to -70^{o}C ideally and shipped on dry ice (WHO 2020). Transport of specimen at national and International border should be complying according to national regulation and UN model regulation, respectively. WHO has issued a guideline for the transport of infectious substances (WHO 2020).

Precautions taken during sampling (As of April 25, 2020, the ICMR listed on its website https://www.mohfw.gov.in/pdf/NotificationofICMguidelinesforCOVID19testinginprivatelaboratoriesiIndia.pdf) During collecting the sample from a suspected patient all precautions should be ensured.

- COVID-19 testing staff should be properly trained in performing RT-PCR and good laboratory practices.
- Private laboratories should do home collection of samples in order to avoid the local travel of the suspect.
  - Government ID for the current address, contact name of suspect patient should be recorded when sample is collected
  - Sample opening should be done only in biosafety cabinet class II A2
  - Disposing off the biomedical waste should be according to the national guidelines. Sample in

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virus transport media with swab should be discarded in biohazard bag containing 2% lyzol and 5% hypochlorite solution (freshly prepared). Bag should be sealed with plastic bag and disposed off according to national guideline.

Future perspectives

Various prospective *in vitro* diagnosis assay formats, such as those based on multiplex detection, microfluidics, lab-on-a-chip and reverse transcription loop-mediated isothermal amplification (RT-LAMP) are currently on the pipeline segment of their development and being investigated by researchers. It is most essential need of the current time to develop an automated and fully integrated point of care *in vitro* diagnosis assay that can perform both immunological and molecular testing on a single analytical platform.

Ideally *in-vitro* diagnosis assay for the detection of SARS CoV-2 soon would be based on smartphone mediated point of care electrochemical test for detection of SARS-CoV-2 biomarkers, like that of iHealth Align device developed by iHealth, USA, for monitoring the blood glucose level using a smartphone-based application As of April 26, 2020, the ICMR listed on its website https://ihealthlabs.com/glucometer/ihealth-align. Smartphones are ubiquitous, powered by internal battery and having a display screen. Also, they are global positioning system (GPS) enabled for tagging of data along with potential to store the compiled results in the internal memory as well as to a secure the date in Cloud. Hence, smartphone-based point of care electrochemical device for the diagnosis of SARS-CoV-2 biomarkers could be a breakthrough for the large-scale rapid testing of COVID-19 suspects (Vashist 2020).

CONCLUSIONS

The proper diagnosis of people infected with the SARS-CoV-2 is essentially needed to break the chain of global spread of COVID-19. In the current scenario RT-PCR based diagnostic assays can be performed only by highly skilled analysts in central laboratories. Hence, their utility gets minimized which restricts its wide deployment, such as in remote locations and villages.

The major contributing factor for global spread of COVID-19 is the delay in diagnosis of peoples until they have spread the disease onto many others. The automated chemiluminescence immunoassay and rapid lateral flow immunoassay tests for IgM/IgG could supplement the existing COVID-19 testing by RT-PCR. However, there must be a quality check for the clinical performance of the test kits before their actual deployment for the diagnosis of COVID-19. One of the most remarkable achievement in the field of *in vitro* diagnostic kit is the recently developed Abbott ID Now^{TM}COVID-19 test that claims to detect SARS-CoV-2 within 5 min (Point-of-Care 2020) and may upgrade COVID-19 diagnosis. The ongoing rigorous research and development will surely lead to effective and reliable *in vitro* diagnosis assays for COVID-19.

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