Laboratory Diagnosis of Covid 19 Infection

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Introduction:

WHO declared an outbreak of febrile respiratory illness of unknown etiology in December 2019 from Wuhan, Hubei province of China. Since its emergence, the disease rapidly spread to neighboring provinces of China as well as to 182 other countries. Infection is spread through droplets of an infected patient generated by coughing and sneezing or through prolonged contact with infected patients.

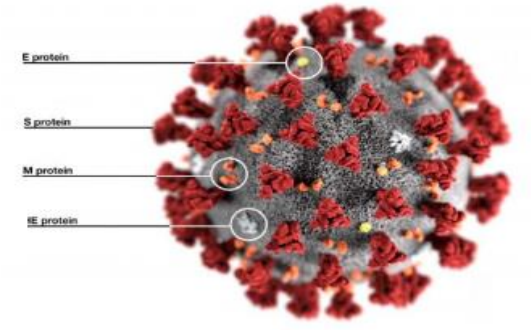
Coronavirus disease 2019 (COVID-19) is a potentially severe acute respiratory infection caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The virus was identified as the cause of an outbreak of pneumonia of unknown cause in Wuhan City, Hubei Province, China, in December 2019. The clinical presentation is that of a respiratory infection with a symptom severity ranging from a mild common cold-like illness, to a severe viral pneumonia leading to acute respiratory distress syndrome that is potentially fatal. The International Committee on Taxonomy of Viruses has confirmed SARS-CoV-2 as the name of the virus owing to the virus's genetic similarity to the SARS-CoV virus, but taking into account that there may be differences in disease spectrum and transmission. The World Health Organization has confirmed COVID-19 (a shortened version of coronavirus disease 2019) as the name of the disease that SARS-CoV-2 infection causes. Prior to this, the virus and/or disease was known by various names including novel coronavirus (2019-nCoV), 2019-nCoV, or variations on this.

Virus: SARS CoV 2

Several coronaviruses can infect humans, the globally endemic human coronaviruses HCoV-229E, HCoV-NL63, HCoV-HKU1 and HCoV-OC43 that tend to cause mild respiratory disease, and the zoonotic Middle East respiratory syndrome coronavirus (MERS-CoV) and severe acute respiratory syndrome coronavirus (SARS-CoV) that have a higher case fatality rate. In December 2019, a cluster of patients with a novel coronavirus was identified in Wuhan, China . Initially tentatively named 2019 novel coronavirus (2019-nCoV), the virus has now been named SARS-CoV-2 by the International Committee of Taxonomy of Viruses (ICTV) . This virus can cause the disease named coronavirus disease 2019 (COVID-19).

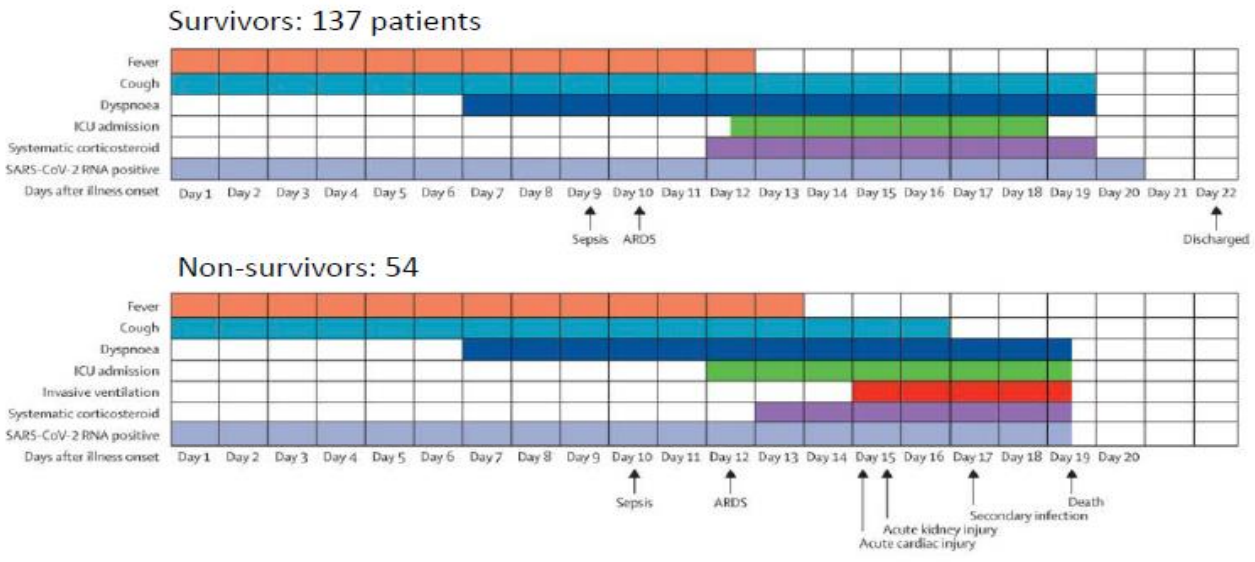
COVID-19

- Closely related to SARS and MERS
- Single stranded-RNA virus
- Enveloped with 4 structural proteins
- Potential receptor is the Angiotensin 2 Converting Enzyme receptor

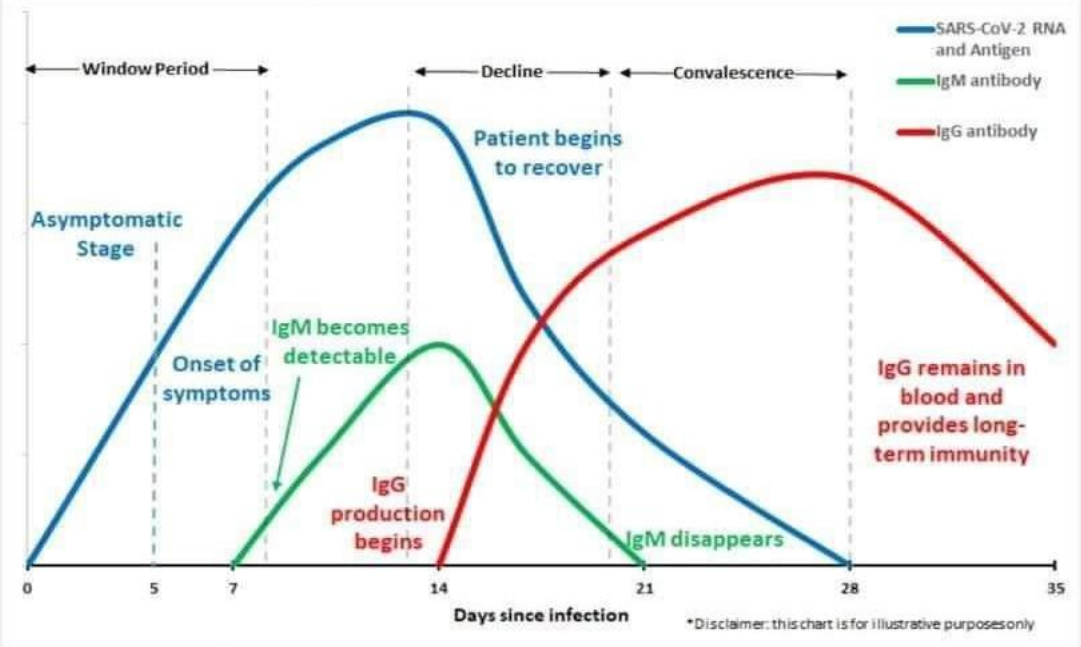


Disease:

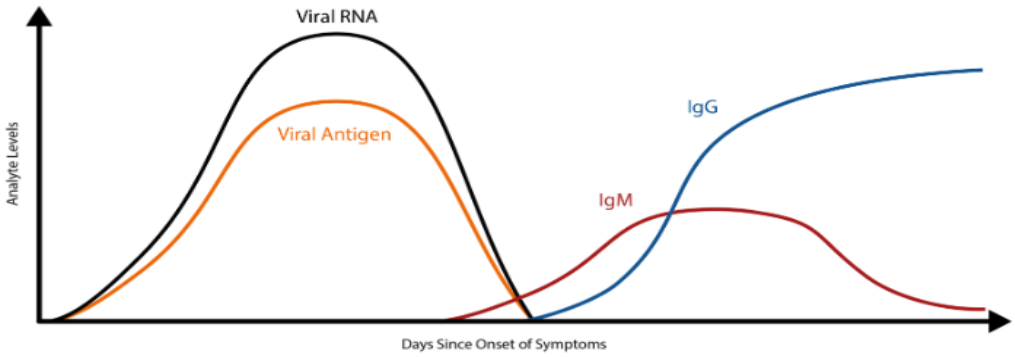
Symptoms	Coronavirus Symptoms range from mild to severe	Cold Gradual onset of symptoms	Flu Abrupt onset of symptoms
Fever	Common	Rare	Common
Fatigue	Sometimes	Sometimes	Common
Cough	Common* (usually dry)	Mild	Common* (usually dry)
Sneezing	No	Common	No
Aches and pains	Sometimes	Common	Common
Runny or stuffy nose	Rare	Common	Sometimes
Sore throat	Sometimes	Common	Sometimes
Diarrhea	Rare	No	Sometimes for children
Headaches	Sometimes	Rare	Common
Shortness of breath	Sometimes	No	No



Diagnostic Analyte Dynamics:



Test results			Clinical Significance
PCR	IgM	IgG	
+	–	–	Patient may be in the window period of infection.
+	+	–	Patient may be in the early stage of infection.
+	+	+	Patient is in the active phase of infection.
+	–	+	Patient may be in the late or recurrent stage of infection.
–	+	–	Patient may be in the early stage of infection. PCR result may be false-negative.
–	–	+	Patient may have had a past infection, and has recovered.
–	+	+	Patient may be in the recovery stage of an infection, or the PCR result may be false-negative.



Estimate of general biomarker levels during the typical timecourse of COVID-19/SARS-CoV-2 infection. Data from Liu et al. and Li et al. Please note that this is purely illustrative and should not be used as a primary reference.

COVID-19 Case Definitions

Suspect Case:
A patient with acute respiratory illness (fever and at least one sign/ symptom of respiratory disease (e.g., cough, shortness of breath) **AND** a history of travel to of residence in a country/area or territory reporting local transmission (See NCDC website for updated list) of COVID-19 disease during the 14 days prior to symptom onset;
OR
A patient / Health care worker with any acute respiratory illness **AND** having been in contact with a confirmed COVID-19 case in the last 14 days prior to onset of symptoms;
OR
A patient with severe acute respiratory infection (fever and at least one sign/symptom of respiratory disease (e.g., cough, shortness breath) AND requiring hospitalization **AND** with no other etiology that fully explains the clinical presentation;
OR
A case for whom testing for COVID-19 is inconclusive
Laboratory Confirmed case: A person with laboratory confirmation of COVID-19 infection, irrespective of clinical signs and symptoms.

Who to test:

Current testing strategy: (ICMR Advisory ver 3 wef 20 March 2020)

i. All asymptomatic individuals who have undertaken international travel in the last 14 days:

- They should stay in home quarantine for 14 days.

- They should be tested only if they become symptomatic (fever, cough, difficulty in breathing)

- All family members living with a confirmed case should be home quarantined

ii. All symptomatic contacts of laboratory confirmed cases.

iii. All symptomatic health care workers.

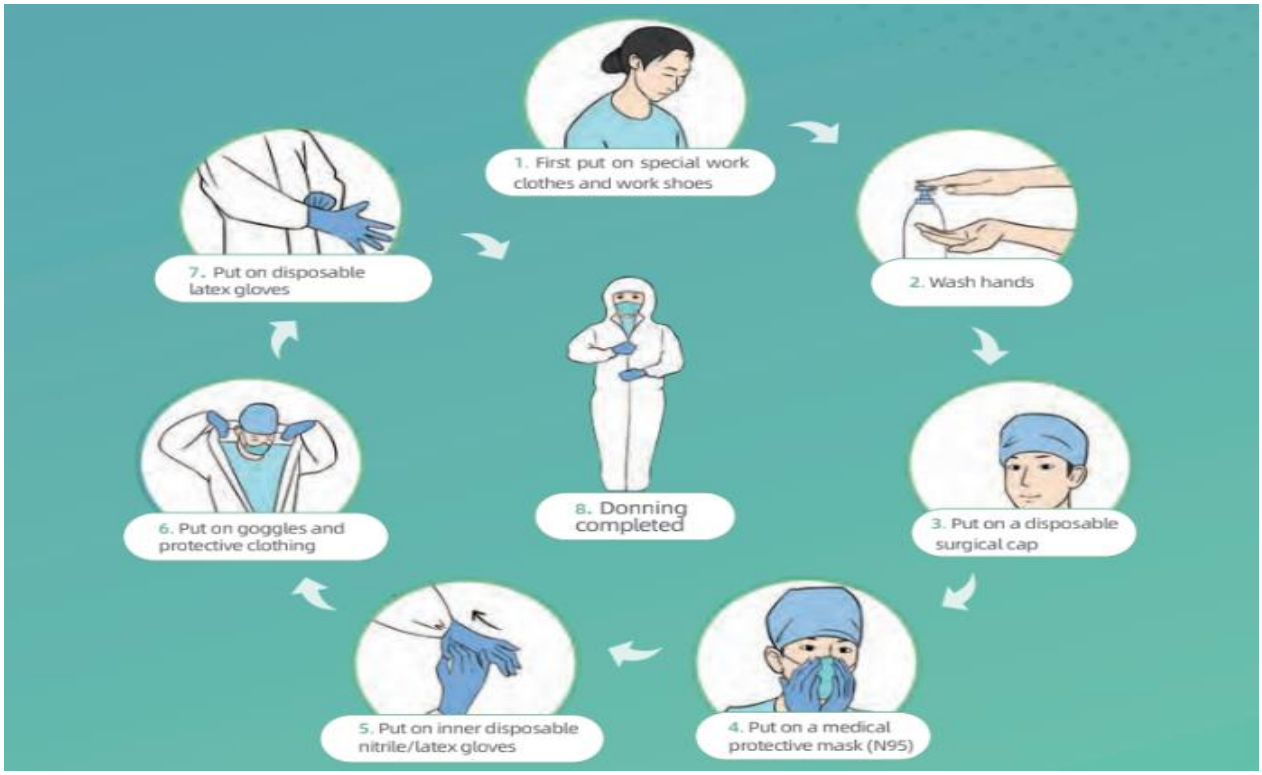
iv. All hospitalized patients with Severe Acute Respiratory Illness (fever AND cough and/or shortness of breath).

v. Asymptomatic direct and high-risk contacts of a confirmed case should be tested once between day 5 and day 14 of coming in his/her contact.

- Direct and high-risk contact include those who live in the same household with a confirmed case and healthcare workers who examined a confirmed case without adequate protection as per WHO recommendations

Preanalytic:

PPE: Donning



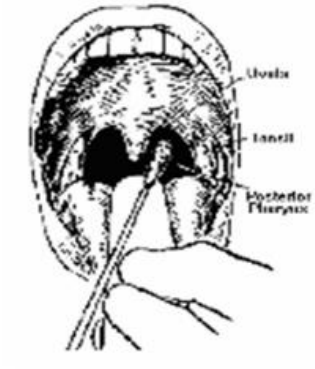
What sample to collect

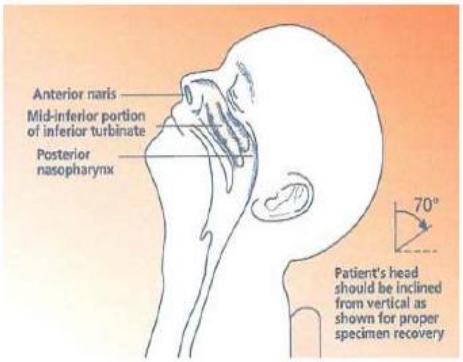
Upper respiratory tract

Oropharyngeal swab (OP swab)
Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media. Refrigerate specimen at 2-8°C and ship to Pathkind Gurgaon Lab with ice pack.

Oropharyngeal swab (e.g., throat swab): Swab the posterior pharynx, avoiding the tongue.

- Insert a thin flexible swab through mouth over the tongue and turn the swab upwards behind the soft palate to reach the nasopharynx.
- Leave the swab in place for a few seconds.
- Slowly remove swab and put the swab with tip downwards into vial containing VTM, breaking the extra portion of the swab stick.

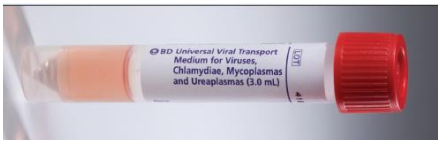




Nasal aspirate

Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C and ship to Pathkind Gurgaon Lab with ice pack. It maybe best to take one throat and one nasal swab and put both into one VTM.

BD Universal Viral Transport Medium (VTM)

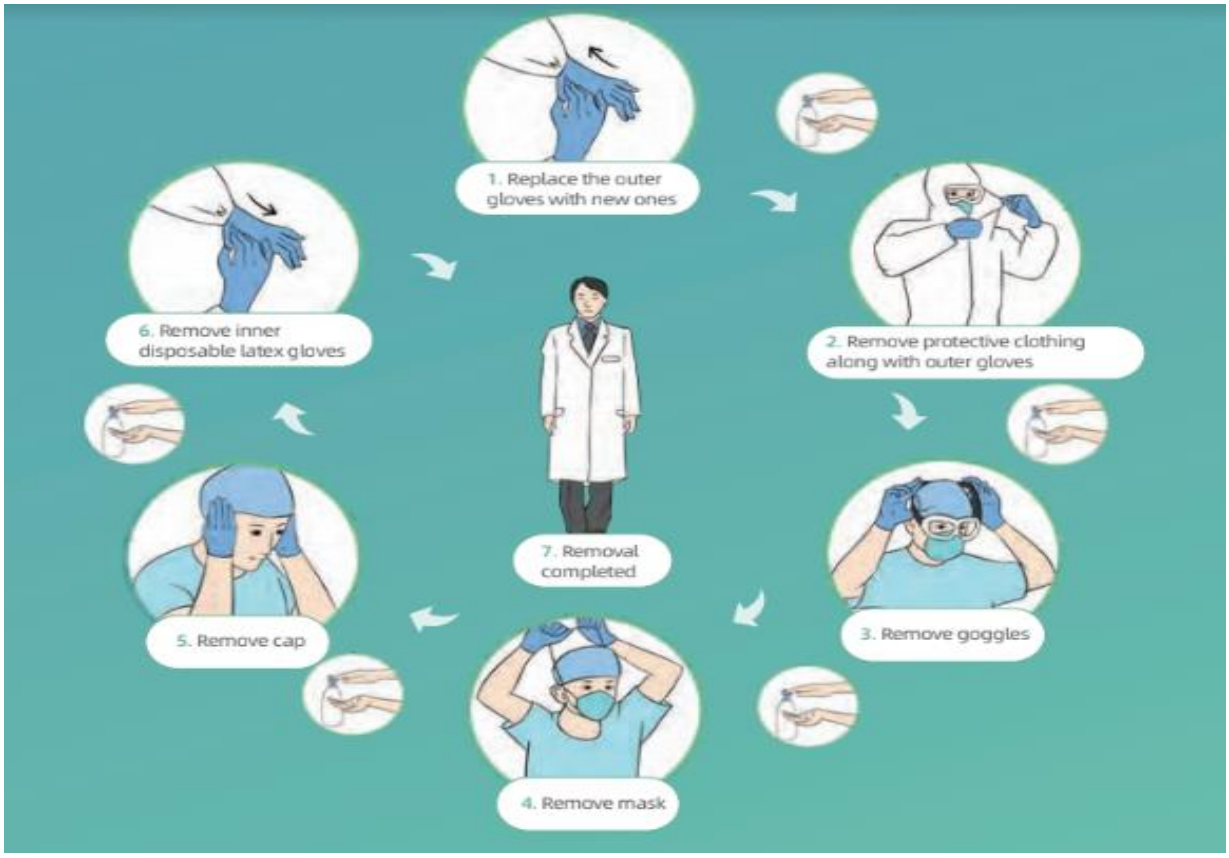


Recovery of SARS CoV 2 from different samples

(JAMA online March 11, 2020)

Specimen	Number tested	Number positive	Percentage positive
Bronchalveolar lavage (BAL)	15	14	93
Brush Biopsy	13	6	46
Sputum	104	75	72
Nasal swab	8	5	63
Pharyngeal swab	398	126	32
Faeces	153	44	29
Blood	307	3	1
Urine	72	0	0

Doffing PPE:



FDA allows self collection of Nasal Swab:

Medical Devices and Tests for COVID-19

Q: Is there a test for COVID-19?

Q. How are people tested for COVID-19?

A. To be tested for COVID-19, a sample is typically collected from your nose and/or throat with a special swab at a designated collection location staffed by health care professionals. Currently, a health care professional swabbing the back of the nasal cavity through the nostril is the preferred choice. Alternatively, the health care professional could may swab the back of your throat, or for patients with symptoms of COVID-19 the sample could may be collected by swabbing the inside of the front of the nose. Depending on, among other things, the type of swab used, a health care professional may collect the sample, or you may be able to collect the sample yourself at the collection site under the supervision of health care personnel.

Specimen Collection

FDA believes that a nasopharyngeal specimen is the preferred choice for swab-based SARS-CoV-2 testing.

If a nasopharyngeal specimen is not available, then any of the following are acceptable:

- oropharyngeal specimen collected by a healthcare professional (HCP);
- mid-turbinate specimen by onsite self-collection or HCP (using a flocked tapered swab); or
- anterior nares specimen by onsite self-collection or HCP (using a round foam swab).

Multiple specimens may be taken with a single swab. If a separate swab is used for collecting specimens from two different locations in the same patient, both swabs may be placed in the same vial in order to conserve collection and assay supplies. At this time, anterior nares and mid-turbinate specimen collection are only appropriate for symptomatic patients and both nares should be swabbed. There is currently not enough information to recommend nasal or mid-turbinate testing for asymptomatic persons.

Other swab specimens (i.e., tongue swabs) may have decreased sensitivity, so caution should be exercised when interpreting negative results.

More data are necessary on the validity of buccal swabs or saliva specimens alone.

For patients with productive cough, a sputum sample is an acceptable lower respiratory specimen.

Due to concerns with specimen stability, transport, and appropriate collection materials, self-collection at home or at sites other than designated collection sites staffed by HCPs is currently not recommended.

FDA believes that sample collection with a flocked swab, when available, is preferred. Collection should be conducted with a sterile swab. If the applicator handle requires additional trimming, the trimming should be performed with a sterile pair of scissors to prevent contamination of the sample. Swab recommendations are based on limited available evidence, and expert opinion suggests further research is needed in this area.

Please be aware that the CDC does not recommend use of calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing.

To avoid specimens being wasted, if a lab is presented with a specimen that was collected or identified in a sub-optimal manner, e.g. with a swab for which there is less evidence of effectiveness, FDA believes that it would still be appropriate for the lab to accept the specimen for analysis and note the circumstances on the report. These specimens may have decreased sensitivity, so caution should be exercised when interpreting negative results.

Transport Media

VTM/UTM remains the preferred transport media.

In the absence of VTM/UTM, alternative transport media can be used to collect and transport patient samples for molecular RT-PCR SARS-CoV-2 assays. These recommendations apply to swab-based specimen collection by healthcare providers (HCP), and to anterior nares (nasal) and mid-turbinate specimen collection onsite by self-collection. The best available evidence indicates that these transport media will stabilize the SARS-CoV-2 RNA without meaningful degradation.

Labs can create their own viral transport media. Refer to CDC's SOP#: DSR-052-01: Preparation of Viral Transport Media. Specimens can be stored for up to 72 hours at 4°C, or frozen for longer storage.

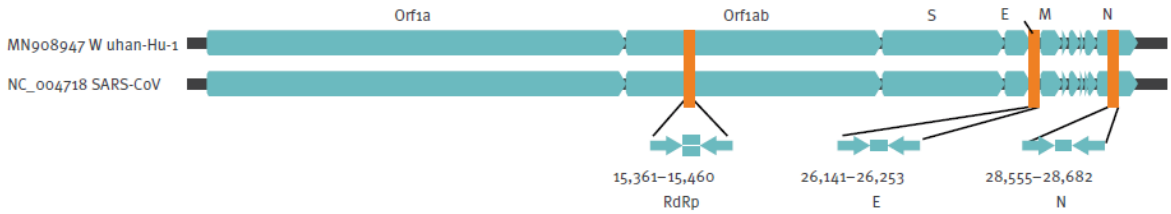
Liquid Amies media may be used for viral transport when universal transport media is not available. Specimens can be stored in liquid Amies media for up to 72 hours at 4°C, or frozen for longer storage. All of the products listed below include a nasopharyngeal (NP) flocked swab unless noted otherwise.

If the above are not available, FDA recommends use of a dry swab in saline to collect and transport samples for molecular RT-PCR SARS-CoV-2 assays. FDA believes that for saline, a sterile glass or plastic vial containing between 1mL and 3mL of phosphate buffered saline is appropriate. Specimens can be stored up to 72 hours at 4°C, or frozen for longer storage.

Analytic:

RT PCR

Relative positions of amplicon targets on the SARS coronavirus and the 2019 novel coronavirus genome

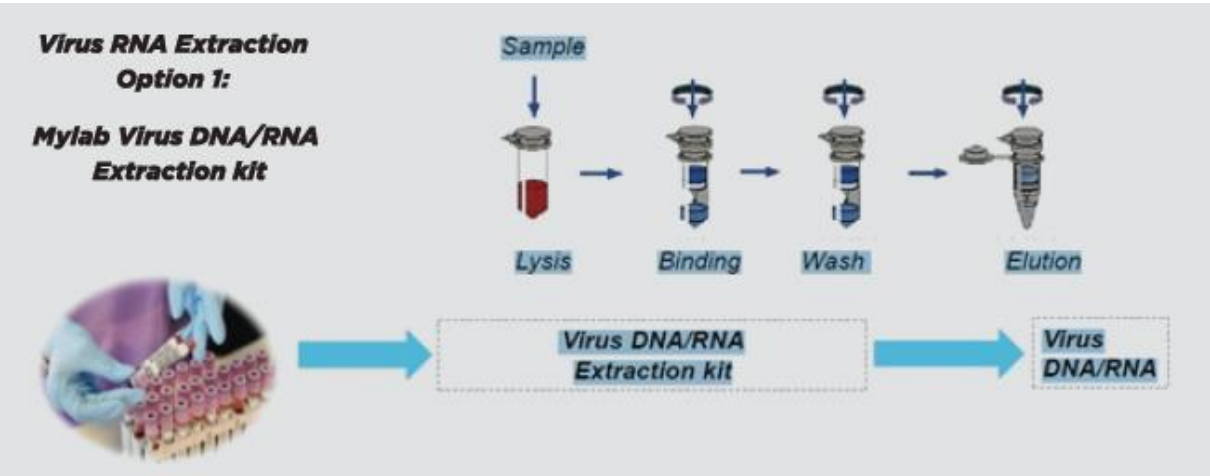


E: envelope protein gene; M: membrane protein gene; N: nucleocapsid protein gene; ORF: open reading frame; RdRp: RNA-dependent RNA polymerase gene; S: spike protein gene.

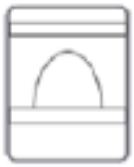
Numbers below amplicons are genome positions according to SARS-CoV, GenBank NC_004718.

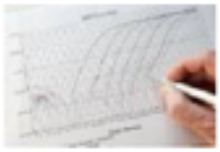
PathoDetect™

COVID-19
Qualitative PCR kit



Work Flow





sample | Extraction of Nucleic Acid | Real Time PCR Run | Result Analysis

30~50min | 120min | 5min

	Stage	Cycles	Temperature	Time
Reverse Transcription	Hold	1	45°C	15 minutes
Initial Denaturation	Hold	1	95°C	2 minutes
Amplification	Cycling	50	95°C	3 seconds
			55°C	32 seconds

Target	Detector Name	Reporter	Quencher
COVID-19 specific RNA	COVID-19	FAM™	BHQ® - 1
RNaseP specific DNA (IPC)	RNaseP	CAL Flour® Red 610	BHQ® - 2

Control Type	Control Name	Purpose of Control	COVID-19 FAM channel	Internal Control (RNaseP) CF610 channel
COVID-19 Positive Control	COVID-19 (FAM™)	Verifies the performance of the master mix	+	+
	RNaseP (CF®610)			
No Template Control	Master Mix + Water	Verifies the reagents are free of contamination	-	-

	Sample Result		Logix Smart™ COVID-19 Positive Control	No Template Control (NTC) (Master Mix + Water)	Interpretation of Results
	COVID-19 (SARS-CoV-2)	Internal Positive Control (RNaseP) CF610 channel			
Instrument Reading	+	+	+	-	COVID-19 +
	-	+	+	-	COVID-19 -
	Any Result (+/-)	-	+	-	Inconclusive: See Troubleshooting
		+	-	-	
		+	+	+	

Anything before 45 cycles is considered a positive reading (+). Anything after 45 cycles is considered a negative reading (-). When possible, always check that the medical history and/or symptoms match with the final result prior to treatment.

Pathkind Lab's Dummy Report:

Name	: **Mr. DUMMY**		Billing Date	:	01/04/202015:19:21
Age	: 45 Yrs		Sample Collected on	:	01/04/2020 15:20:00
Sex	: Male		Sample Received on	:	01/04/2020 15:20:03
P. ID No.	: P100085669		Report Released on	:	01/04/2020 15:24:32
Accession No	: **100020000014**		Barcode No.	:	4012203
Referring Doctor	: Self				
Referred By	:				

Report Status - Final

Test Name	Result	Biological Ref. Interval	Unit
MOLECULAR DIAGNOSTIC			
COVID-19 Virus Qualitative PCR			
Method: rRT - PCR			
Covid - 19	**Detected**	Not Detected	

COVID-19 Virus Qualitative PCR

Clinical Significance :

RESULT	Interpretation
DETECTED	RNA specific to SARS-CoV-2 Detected
NOT DETECTED	RNA specific to SARS-CoV-2 NOT detected
INCONCLUSIVE	This could be due to low viral load in the sample. A repeat testing on fresh sample is recommended

Note

1. Negative result does not rule out the possibility of Covid-19 infection. Presence of inhibitors, mutations & insufficient specific to SARS-CoV-2 can influence the test result. Kindly correlate the results with clinical findings.
2. Test conducted on Nasal & Throat Swab Smples
3. Lower respiratory tract samples like Sputum, BAL, ET aspirate are appropriate samples especially in severe and progressive lung disease.
4. Kindly consult referring Physician / Authorized hospitals for appropriate follow up.
5. Covid-19 Test conducted as per kits approved by ICMR / CE-IVD / USFDA.
6. LOD of assay : 10 GCE (Genomic copy equivalants)/Reaction
7. Target genes specific for SARS -CoV-2 included in the assay are : ORF 1ab, N protein & S protein

Serology: Not Yet Recommended by ICMR

Benefits

- Rapid testing for nCoV antibodies within 10 minutes
- Just 10ul of specimen : Whole blood, serum , plasma
- Suitable for Point of Care Testing. No need for extra equipment.

Specification

Information	Detail
Time to result	10 minutes
Storage and operating conditions	2-40℃/36-104℉
Shelf life	24 months
Sample type	Whole blood/Serum/plasma
Specificity	95%(95/100)

Simple Test Procedure

The test procedure for COVID-19 IgG

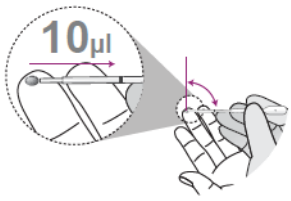
The test procedures for both COVID-19 IgM and IgG are the same.

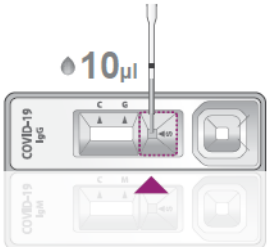
1 Collecting of Sample
Using an STANDARD Ezi Tube+, collect the 10µl of serum/plasma/whole blood to the black line of the STANDARD Ezi Tube+.

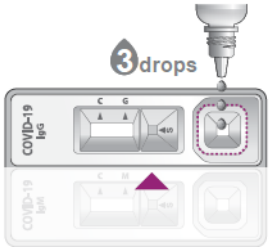
2 Adding of Sample
Add the collected serum/plasma/whole blood to the sample well of the test device.
Discard the Ezi tube+into the disposal bag after use.

3 Dropping of Assay diluent
Add 3 drops (90µl) of assay diluent into the assay diluent well of the test device.

4 Reading Time
Read test result at 10~15 minutes.
Discard the test device into the disposal bag after use.

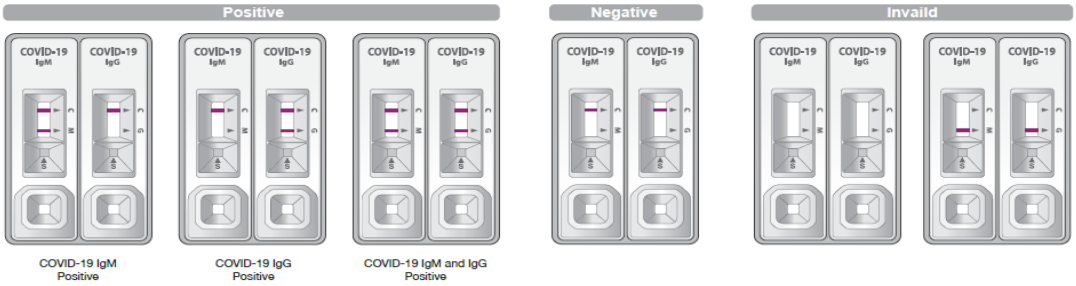






CAUTION Do not read test results after 15 minutes. It may give false results.

Interpretation



1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is control line (C).
2. A colored band will appear in the lower section of the result window. These bands are test line of IgM/IgG (M, G).
3. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.

*** Positive results should be considered in conjunction with the clinical history and other data available to the physician.**
*** STANDARD Q COVID-19 IgM/IgG Duo Test may cross-react with SARS antibodies.**

ICMR Guidance on Rapid antibody kits for COVID-19

Not recommended for diagnosis of COVID-19 infection

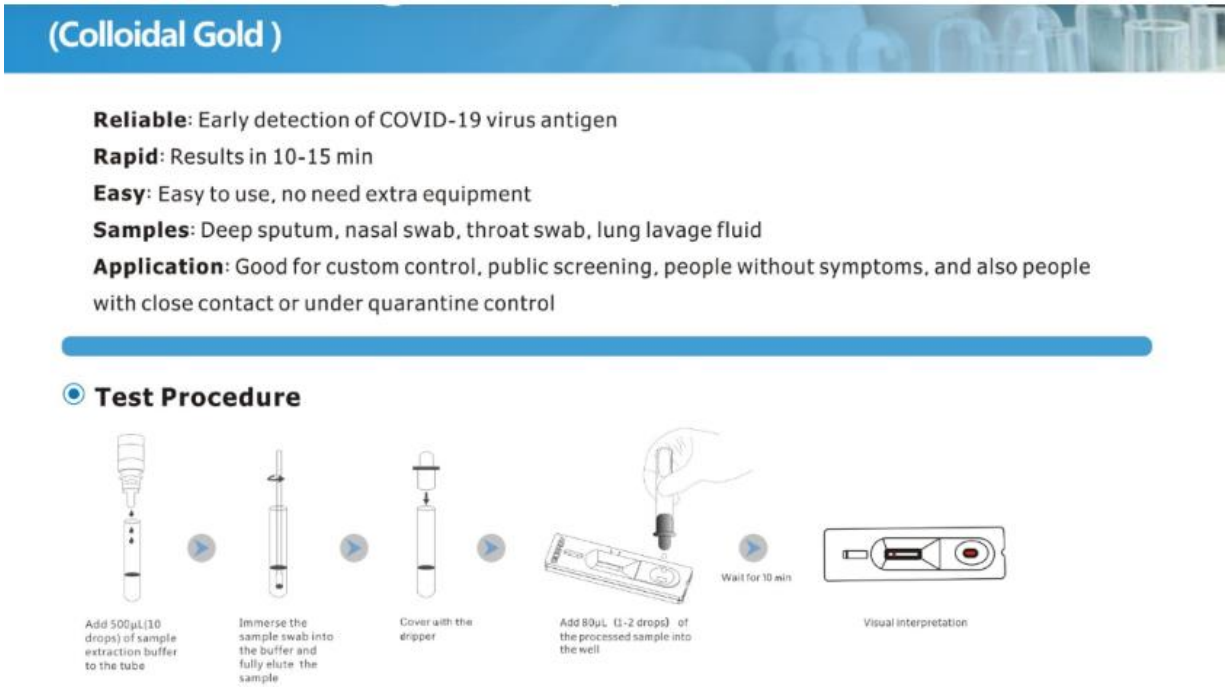
- Can be done on blood/serum/plasma samples
- Test result is available within 30 minutes
- Test comes positive after 7-10 days of infection
- The test remains positive for several weeks after infection
- Positive test indicates exposure to SARS-CoV-2
- Negative test does not rule out COVID-19 infection

ICMR has approved a number of Antibody Rapid tests, but these tests are not recommended for diagnosis of COVID-19 infection. Antigen detection may be useful

Covid 19 Ag GICA Rapid: Not Yet Available in India

Two Biotechnology companies in China and South Korea have constructed Antigen detection tests using monoclonal antibodies constructed using phage display technology.

Covid 19 Ag GICA Rapid



2 April 2020

Interim advisory for use of rapid antibody test for COVID-19 in hotspot areas

Population in hotspot areas may be tested using rapid antibody test, and

- Antibody positives to be confirmed by RT-PCR using throat/nasal swab
- Antibody negatives to be quarantined at home

Disposal of waste:

Keep separate color coded bins/ bags / containers in collection area and maintain proper segregation of waste as per BMWM Rules, 2016 as amended and CPCB guidelines for implementation of BMW Management Rules.

As precaution double layered bags (using 2 bags) should be used for collection of waste from COVID – 19 isolation wards so as to ensure adequate strength and no-leaks;

Collection and store biomedical waste separately prior to handing over the same CBWTF.

Use a dedicated collection bin labelled as “COVID – 19” to store COVID – 19 waste. In addition to mandatory labelling, bags/ containers used for collecting biomedical waste from COVID – 19 wards, should be labelled as “COVID – 19 Waste”. This marking would enable CBWTFs to identify the waste easily for priority treatment and disposal immediately upon the receipt.

General waste not having contamination should be disposed as solid waste as per BMW Rules 2016;

Maintain separated record of waste generated from COVID-19 isolation wards.

Use dedicated trolleys and collection bin in collection area. A label “COVID-19 Waste” to be pasted on these items also.

The (inner and outer) surface of container/ bins/ trolleys used for storage of COVID – 19 waste should be disinfected with 1% sodium hypochlorite solution. Finally waste must be autoclaved before being handed over to the authorized vendor for final disposal.

Infection Prevention:

IPC strategies to prevent or limit infection transmission in health-care settings include the following:

1. Early recognition and source control
2. Application of Standard Precautions for all patients
3. Implementation of empiric additional precautions (droplet and contact and whenever applicable airborne precautions) for suspected cases
4. Administrative controls
5. Environmental and engineering controls

Personal protection steps:

Johns Hopkins University has sent this detailed note on avoiding the contagion:

* The virus is not a living organism, but a protein molecule (DNA) covered by a protective layer of lipid (fat), which, when absorbed by the cells of the ocular, nasal or buccal mucosa, changes their genetic code. (mutation) and convert them into aggressor and multiplier cells.

* Since the virus is not a living organism but a protein molecule, it is not killed, but decays on its own. The disintegration time depends on the temperature, humidity and type of material where it lies.

* The virus is very fragile; the only thing that protects it is a thin outer layer of fat. That is why any soap or detergent is the best remedy, because the foam CUTS the FAT (that is why you have to rub so much: for 20 seconds or more, to make a lot of foam). By dissolving the fat layer, the protein molecule disperses and breaks down on its own.

* HEAT melts fat; this is why it is so good to use water above 25 degrees Celsius for washing hands, clothes and everything. In addition, hot water makes more foam and that makes it even more useful.

* Alcohol or any mixture with alcohol over 65% DISSOLVES ANY FAT, especially the external lipid layer of the virus.

* Any mix with 1 part bleach and 5 parts water directly dissolves the protein, breaks it down from the inside.

* Oxygenated water helps long after soap, alcohol and chlorine, because peroxide dissolves the virus protein, but you have to use it pure and it hurts your skin.

* NO BACTERICIDE SERVES. The virus is not a living organism like bacteria; they cannot kill what is not alive with anthobiotics, but quickly disintegrate its structure with everything said.

* NEVER shake used or unused clothing, sheets or cloth. While it is glued to a porous surface, it is very inert and disintegrates only between 3 hours (fabric and porous), 4 hours (copper, because it is naturally antiseptic; and wood, because it removes all the moisture and does not let it peel off and disintegrates).), 24 hours (cardboard), 42 hours (metal) and 72 hours (plastic). But if you shake it or use a feather duster, the virus molecules float in the air for up to 3 hours, and can lodge in your nose.

* The virus molecules remain very stable in external cold, or artificial as air conditioners in houses and cars. They also need moisture to stay stable, and especially darkness. Therefore, dehumidified, dry, warm and bright environments will degrade it faster.

* UV LIGHT on any object that may contain it breaks down the virus protein. For example, to disinfect and reuse a mask is perfect. Be careful, it also breaks down collagen (which is protein) in the skin, eventually causing wrinkles and skin cancer.

* The virus CANNOT go through healthy skin.

* Vinegar is NOT useful because it does not break down the protective layer of fat.

* NO SPIRITS, NOR VODKA, serve. The strongest vodka is 40% alcohol, and you need 65%.

* LISTERINE IF IT SERVES! It is 65% alcohol.

* The more confined the space, the more concentration of the virus there can be. The more open or naturally ventilated, the less.

* This is super said, but you have to wash your hands before and after touching mucosa, food, locks, knobs, switches, remote control, cell phone, watches, computers, desks, TV, etc. And when using the bathroom.

* You have to HUMIDIFY HANDS DRY from so much washing them, because the molecules can hide in the micro cracks. The thicker the moisturizer, the better.

* Also keep your NAILS SHORT so that the virus does not hide there.

This is a cut & Paste version of various relevant information available from reliable sources on Covid 19 disease and SARS CoV 2 virus. The information is evolving and may change over time.

COVID-19 CLINICAL INFORMATION FORM

AFFIX BARCODE

(ICMR NO: _____)

Patient Details			
Name of patient:			
Age: Gender: Date of Birth: ___/___/_____			
Permanent Address:			
Current Address: Same as above ☐			
Nationality: Mobile / Phone:			
Email:			
Date of sample collection:			
Ref. Hospital / Doctor name & contact details:			
Exposure History			
Is the patient quarantined? Y/N **International Travel History: Y/N**			
If yes, Travel place: _____ & Stay / travel duration with date from: ___/___/_____ to ___/___/_____			
Health care worker working in hospital/ lab involved in managing patients: Y/N Hospitalization date ___/___/_____ Discharge date ___/___/_____			
Status of clinical symptoms - Symptomatic / Asymptotic			
If Symptomatic date of onset of symptom:_____			
Symptoms	**Please tick whichever is applicable**	**Symptoms**	**Please tick whichever is applicable**
Fever (<7 days)		Vomiting	
Fever (>7 days)		Muscle pain	
Cough		Abdominal pain	
Difficulty in Breathing		Headache	
Nausea		Diarrhoea	
Any other symptom (please mention with date onset):_____			
If any other tests done (please provide details)			
Specimen Information			
Type of sample: Nasal and Throat swab Any other (please mention):			
Valid Govt. ID attached showing address proof : _____ (Specify: Aadhar/Voter ID/Driving License /Passport			

National Accreditation Board for Testing and Calibration Laboratories

(A Constituent Board of Quality Council of India)

NABL / M-1629

01.04.2020

AMIT PRUTHI
Pathkind Diagnostics Pvt ltd
PLOT NO 55 - 56, PHASE 4, UDYOG VIHAR
SEC-18
GURGAON,HARYANA-122015
Mobile: 9818548428
E-mail: amit.pruthi@pathkindlabs.com

Subject: **Scope Extension**

Dear Sir/Ma'am,

NABL is pleased to grant of accreditation in accordance with ISO 15189:2012 in the field of Medical testing for the discipline of Molecular Testing as per the scope recommended by the assessment team.

Dr. Arpeeta and Dr. Ashok Rattan nominated by the laboratory to review the results and authorize the release of reports are accepted.

The certificate number for your laboratory is MC-3055 with Issue date 07.12.2018 valid till 06.12.2020, Amended date:01.04.2020

NABL is now allowing its accredited CAB's (Testing, calibration and Medical) to use NABL accredited CAB combined ILAC MRA Mark on their Test/ Calibration reports through a valid agreement. For more details please refer NABL-133 which is available on our website www.nabl-india.org.

NABL-133 should also be followed for using NABL Symbol.

Yours faithfully,
Syed Tahira Rizvi
syedtahira@nabl.qcin.org

National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name	PATHKIND DIAGNOSTICS PVT LTD, PLOT NO 55 - 56, PHASE 4, UDYOG VIHAR SEC-18, GURGAON, HARYANA, INDIA		
Accreditation Standard	ISO 15189:2012		
Certificate Number	MC-3055	Page No. :	33 / 33
Validity	07/12/2018 to 06/12/2020	Last Amended on	01/04/2020

S.No	Discipline	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used	%CV
245	MOLECULAR TESTING	EDTA PLASMA	HBV DNA QUANTITATIVE	RT PCR	6.1
246	MOLECULAR TESTING	EDTA PLASMA	HCV RNA QUANTITATIVE	RT PCR and Genexpert	9.9
247	MOLECULAR TESTING	EDTA PLASMA	HIV-1 RNA QUANTITATIVE	Genexpert	NA
248	MOLECULAR TESTING	NASAL SWAB, NASOPHARYNGEAL SWAB	H1N1	RT PCR	NA

INDIAN COUNCIL OF MEDICAL RESEARCH
DEPARTMENT OF HEALTH RESEARCH

Date: 02/04/2020

List of Private Laboratories to test COVID-19

Total Labs: 52

S. No.	Names of States	Names of Laboratory and Address
3.	Haryana (6)	1. Strand Life Sciences, A-17, Sector 34, Gurugram 2. SRL Limited, GP26, Sector 18, Gurugram 3. Modern Diagnostic & Research Centre-Lab, 363-364/4, JAwahar Nagar. Gurgaon 4. Core Diagnostics Pvt Ltd, Udyog Vihar Phase-3, Gurgaon 5. MolQ Laboratory, Plot 28,29; Sector 18(P), Electronic city, Udyog Vihar, Phase IV, Gurgaon 6. Pathkind Diagnostics Pvt Ltd, Plot 55-56, Phase 4, Udyog Vihar, Sec 18, Gurgaon

Question & Answers:

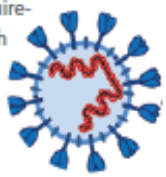
Q. 1: Who should get tested?

Ans. As per current guidelines, if you develop the acute onset of fever and symptoms of respiratory illness, such as cough or shortness of breath, you should visit your nearest health facility and the doctor will decide if you need to be tested for 2019-novel Coronavirus (SARS-CoV-2) depending upon your history oftravel to affected countries or contact with any suspects.

- **All asymptomatic individuals who have undertaken international travel in the last 14 days:**
  - They should be tested only if they become symptomatic (fever, cough, difficulty in breathing)
  - All family members living with a confirmed case should be home quarantined
- **All symptomatic contacts of laboratory confirmed cases.**
- **All symptomatic health care workers.**
- **All hospitalized patients with Severe Acute Respiratory Illness (fever AND cough and/or shortness of breath).**
- **Asymptomatic direct and high-risk contacts of a confirmed case should be tested once between day 5 and day 14 of coming in his/her contact.**
  - Direct and high-risk contact include those who live in the same household with a confirmed case and healthcare workers who examined a confirmed case without adequate protection as per WHO recommendations.

Q. 2: What documents are to be presented for getting tested for 2019-novel Coronavirus (SARS-CoV-2)?

Ans. Duly filled COVID -19 (Clinical Information Form) along with the referring doctor's prescription, also Govt. photo-id (Aadhaar card/ VoterId/ Passport) to support the current address and contact number of the suspect patient to be provided at the time of sample collection. These are mandatory requirements defined by Govt. of India without which testing of 2019-novel Coronavirus (SARS-CoV-2) is not allowed. You may download Clinical Information Form www.pathkindlabs.com.



Q. 3: If I have symptoms and my doctor prescribes the test, in that case can I get my family also tested?

Ans. Family member's testing will be subject to availability of referring doctor's prescription and Clinical Information Form. **As per ICMR current guidelines (20-03-20) Asymptomatic direct and high-risk contacts of a confirmed case should be tested once between day 5 and day 14 of coming in his/her contact.** Direct and high-risk contacts include those who live in the same household with a confirmed case and healthcare workers who examined a confirmed case without adequate protection as per WHO recommendations.

Q. 4: What are the ways to book 2019-novel Coronavirus (SARS-CoV-2) testing?

Ans. You can register yourself by visiting Pathkind Labs website www.pathkindlabs.com or else you can call at our customer care no. 782-784-4444. We will reconfirm the sample pickup after conforming the availability of your Clinical Information Form and Prescription.

Q. 5: What is the current recommended method for testing and what kind of samples can be tested?

Ans. As of now, RT-PCR is the recommended method. The Nasal and Throat swab will be collected by taking due precaution.

Q. 6: Can I visit any of the nearest centres/Labs to book the test or give the samples?

Ans. You are advised to book the test online via Pathkind Labs website www.pathkindlabs.com or else you can call at our customer care no. 782-784-4444. The sample will be collected from your home by an expert sample collection agent only.

Q. 7: What kind of precautions will be taken by Phlebotomist who collects the sample?

Ans. Phlebotomist will use **Disposable (single use)** Personal Protective Equipment(PPE)- which comprises of a long sleeved fluid repellent disposable gown, gloves, mask, N95 mask, goggles, hair cover and shoe cover.

Q. 8: What's the sample transportation process?

Ans. The sample will be collected in a viral transport medium (VTM) to maintain the stability of the sample. This will further get transported in a cold chain.

Q. 9: What are sample packaging guidelines?

Ans. Triple packaging to be carried out The packaging consists of three layers as follows.

1. Primary receptacle: A labelled primary watertight, leak-proof receptacle containing the specimen. The receptacle is wrapped in enough absorbent material to absorb all fluid in case of breakage and placed in zip lock bag.

2. Secondary receptacle: A second durable, watertight, leak-proof receptacle to enclose and protect the primary receptacle(s). Several wrapped primary receptacles may be placed in one secondary receptacle i.e thermocool box. Secondary receptacle should have sufficient Ice packs to maintain the temperature.

3.Outer shipping package: The secondary receptacle is placed in an outer shipping package with clear marking of sample type. Outer shipping package should be packed in Red Biohazard bag so that courier boys or lab personnel can easily identify the sample.

Q. 10: - What are the guidelines on test report sharing with the Govt.?

Ans. We will share all the patient's report with defined Govt bodies through online portal created by ICMR

Q. 11: - By when can I get my report?

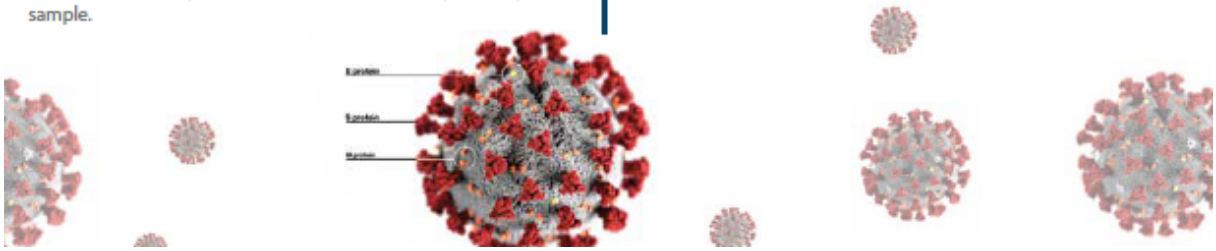
Ans. All the samples reported within 48 hours of sample reaching the lab, subject to Govt Rules and Regulations.*

Q. 12: -How do I access my report?

Ans. You can access your report from our website www.pathkindlabs.com with the provided login id & password.

Q. 13: -How do I interpret my report?

Ans. You are advised to visit your referring doctor with the report for the final interpretation.



Rational use of personal protective equipment (PPE) for coronavirus disease (COVID-19)

Interim guidance
19 March 2020

World Health Organization

Table 1. Recommended personal PPE during the outbreak of COVID-19 outbreak, according to the setting, personnel, and type of activity[a]

Setting	Target personnel or patients	Activity	Type of PPE or procedure
Health care facilities			
Inpatient facilities			
Laboratory	Lab technician	Manipulation of respiratory samples	Medical mask Gown Gloves Eye protection (if risk of splash)