DIAGNOSTIC TESTING FOR COVID-19

Presentation:
Primaryinfo.com

Commercial Testing for COVID-19 Now Available

Physicians and other healthcare providers can now order a 2019 Novel Coronavirus (COVID-19) test through a commercial laboratory for patients who are ill with signs and symptoms consistent with COVID-19, but do not meet the Maricopa County Public Health testing criteria for testing at the Arizona State Public Health Laboratory. **Individuals with symptoms consistent with COVID-19 should see a healthcare provider. DO NOT go to LabCorp or Sonora Quest Laboratory.**

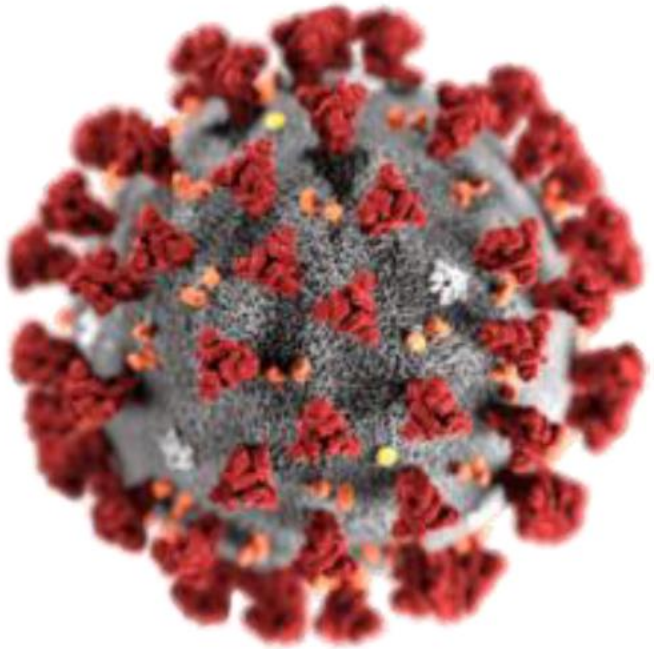
The test detects the presence of the virus that causes COVID-19 and is for use with patients who have signs and symptoms consistent with COVID-19. For additional information on COVID-19, please refer to CDC website, which is available here.

Starting Monday, 3/9/2020, commercial laboratory testing is available at:

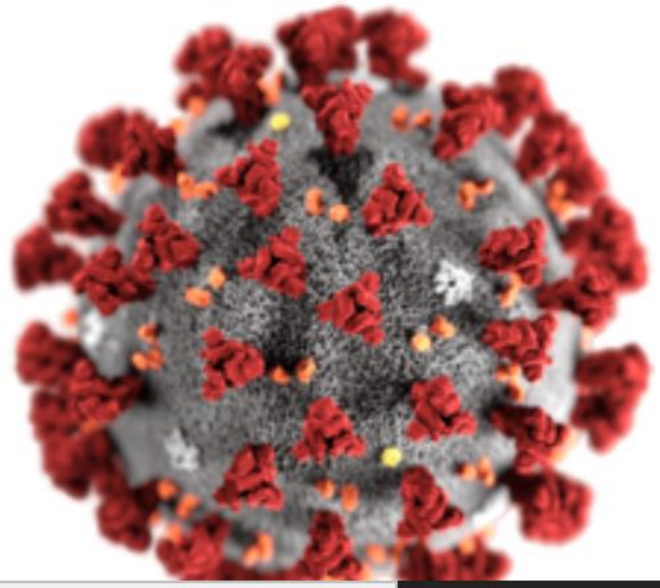
- LabCorp
  https://www.labcorp.com/information-labcorp-about-coronavirus-disease-2019-covid-19

Starting Wednesday, 3/11/2020, commercial laboratory testing is available at:

- Sonora Quest Laboratories
  https://www.sonoraquest.com/our-response-to-coronavirus-disease-2019-covid-19/



COVID-19 Science Report: Containment Measures



COVID-19 Science Report: Diagnostics

pneumonia and 1345 images for viral pneumonia) and 1341 images are from normal subjects. Chest x-ray images for normal and viral pneumonia were used from this database to create the new database.

Figure 1 shows sample images from the database for normal, COVID-19 pneumonia, and viral pneumonia chest X-ray images.

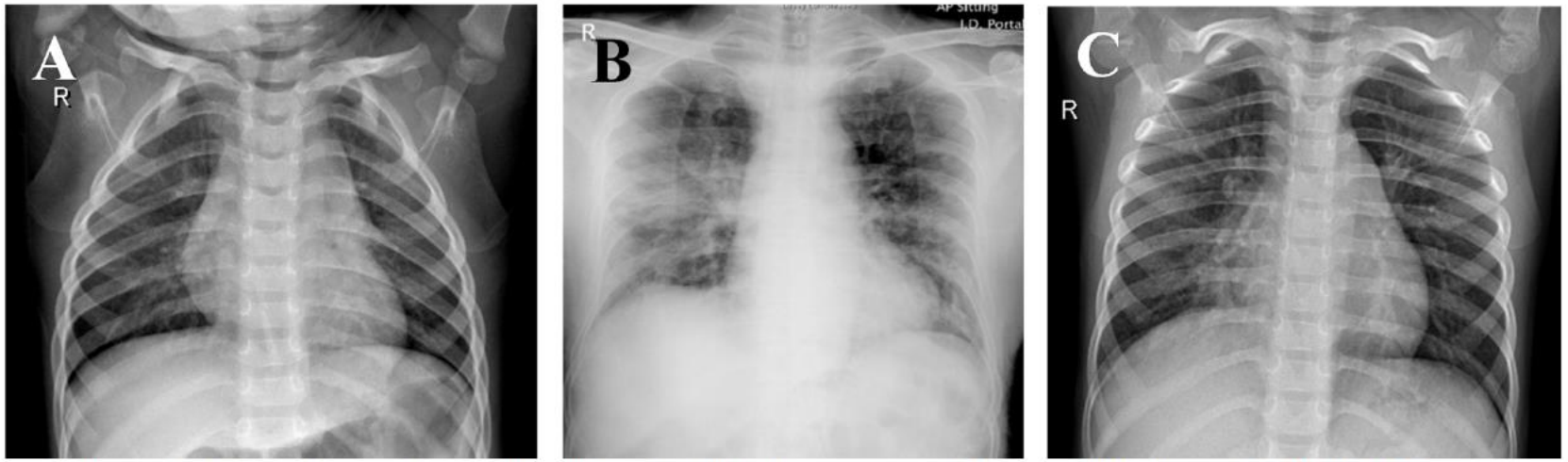


Figure 1: Sample X-ray image from the dataset: (A) shows normal cases, (B) shows COVID-19 cases, and (B) shows Viral Pneumonia case.

Algorithm Selection and Pre-processing: In this study, MATLAB 2019a was utilized to train, evaluate and test four well-known pre-trained deep learning CNNs: AlexNet[24], ResNet18[48], DenseNet201[48] & SqueezeNet[49] to classify the chest x-ray images for two classification problems as mentioned earlier. Figure

Preliminary Stakeholder Engagement Plan (SEP)
March 20, 2020

Sao Tome and Principe COVID-19 Emergency Response Project

1. Introduction/Project Description

An outbreak of coronavirus disease (COVID-19) caused by the 2019 novel coronavirus (SARS-CoV-2) has been spreading rapidly across the world since December 2019, from Wuhan, Hubei Province, China to 65 countries and territories. As of March 15, 2020, 153,517 cases have been confirmed globally (10,982 new cases) and 5,735 deaths (343 new deaths). The number of cases in China has reached 81,048 (27 new) and 3,204 deaths (10 new). Outside of China, 72,469 cases have been confirmed (10,955 new) and 2,531 deaths (33 new) have been reported.

Over the coming months, the outbreak has the potential for greater loss of life, significant disruptions in global supply chains, lower commodity prices, and economic losses in both developed and developing

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Congress of the United States
House of Representatives
Washington, DC 20515–3211

COMMITTEE ON HOMELAND SECURITY
SUBCOMMITTEES:
INTELLIGENCE AND COUNTERTERRORISM, CHAIRMAN
EMERGENCY PREPAREDNESS, RESPONSE AND RECOVERY

COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEES:
HEALTH
OVERSIGHT AND INVESTIGATIONS

March 18, 2020

Stephen M. Hahn M.D., Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Dr. Hahn,

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11TH DISTRICT, NEW YORK

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COMMITTEE ON HOMELAND SECURITY
SUBCOMMITTEES:
INTELLIGENCE AND COUNTERTERRORISM, *CHAIRMAN*
EMERGENCY PREPAREDNESS, RESPONSE AND RECOVERY

COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEES:
HEALTH
OVERSIGHT AND INVESTIGATIONS

March 16, 2020

Admiral Brett P. Giroir, M.D.
Assistant Secretary for Health
Department of Health and Human Services
200 Independence Avenue, S.W.

Note on COVID-19 Laboratory Preparedness in India

Background

WHO declared an outbreak of febrile respiratory illness of unknown etiology in December 2019 from Wuhan, Hubei province of China. The outbreak has been epidemiologically linked to the Huanan Seafood Wholesale Market involving sale of sea food and live animals. Subsequently the etiological agent was found to be a novel coronavirus which was isolated from the bronchoalveolar lavage of three infected individuals.

Since its emergence, the disease has rapidly spread to neighboring provinces of China as well 72 other countries mainly through International travel.

Infection is spread through droplets of an infected patient generated by coughing and sneezing or through prolonged contact with infected patients.

Virus has been named as SARS-CoV-2 due to its relatedness to the earlier SARS-CoV (2002-03). The WHO has named the disease as COVID-19 and ICTV has named the virus as SARS-CoV-2. Due to the fast spread of virus to neighboring countries, it became critical for all

Guidance document for State Nodal & Testing VRDLs for COVID-19

You have been identified as the State Nodal Laboratory for ensuring collection and transport of suspected COVID-19 sample to ICMR-NIV, Pune. In addition, you are also identified as a testing laboratory for COVID-19.

Your roles and responsibilities are as follows:

- You are supposed to make phone calls to VRDLs in your State (list of VRDLs and contact numbers are attached) and inform them the following:
  - If they collect any suspect samples of COVID-19 directly or through State Health Authorities/IDSP, they should inform you immediately (on real time basis).

Q&A | LABCORP 2019 NOVEL CORONAVIRUS (COVID-19), NAA TEST [139900]

COVID-19 is a respiratory disease caused by infection with a new form of coronavirus (SARS-CoV-2) that has now been detected in multiple locations around the world, including the U.S. LabCorp is supporting the public health response as part of a lab industry consortium that is working very hard to expand the availability of testing.

Below are answers to questions about LabCorp's test for COVID-19, including test methodology, appropriate specimen

Individuals seeking testing for COVID-19 should consult with their physician or healthcare provider, who may order the test if they determine the individual meets testing criteria. Self-ordered testing for COVID-19 is not available.

4. What are acceptable samples types for 2019 Novel Coronavirus (COVID-19), NAA?

A: The following are acceptable sample types, all preferably shipped frozen:

- Nasopharyngeal (NP) swab submitted in viral transport

Testing for COVID-19

Offering our clients state-of-the-art testing is part of CPL's ongoing commitment to excellence.

On **March 11th, 2020**, Clinical Pathology Laboratories began offering testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19).

Clinical Information:

Coronaviruses (CoVs) are a family of enveloped positive-strand RNA viruses that can infect humans and many different species of birds and mammals, including camels, cattle, cats, and bats. The family of viruses can cause respiratory illness ranging from the common cold to more severe respiratory diseases such as Middle East Respiratory Syndrome and Severe Acute Respiratory Syndrome. The most recently identified severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the causative agent of Coronavirus Disease 2019 (COVID-19). Since its emergence at the end of 2019 in Wuhan City, China, the virus has caused an ongoing global outbreak of COVID-19 and a major global public health emergency. The number of patients infected globally by the SARS-CoV-2 virus are increasing rapidly. As of March 25th, 2020, at least 455,000 confirmed cases and more than 20,500 deaths in over 180 countries are reported. In the US, 840 deaths and at least 61,000 confirmed and presumptive cases of COVID-19 have been reported.

The World Assciation of Societies of Pathology and Laboratory Medicine (WASPaLM) is present in the complex world of information on COVID-19, and specifically trying to give the correct information to stakeholders and public concerning the actual real power of diagnostics.

The main questions concerning the laboratory diagnosis of COVID-19 disease to which we should answer are:

1) RT-PCR is the main method to detect the presence of the virus. Is it possible to measure the number of virus copies by RT-PCR or it is only a qualitative assay? If yes, did someone correlate the number of copies with the seriousness of the disease?

2) Antibodies anti COVID-19 have been isolated. Do we know the time of appearance of IgM and IgG after the infection and how long they last? IgG antibodies are neutralizing and give immunity? For how long?

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சுகாதார மற்றும் சுதேச வைத்திய சேவைகள் அமைச்சு
Ministry of Health and Indigenous Medical Services

Director/ Medical Superintendent

Teaching Hospital/ Provincial General Hospital/ District General Hospital/ Base Hospital

.....

PCR TESTING FOR COVID-19

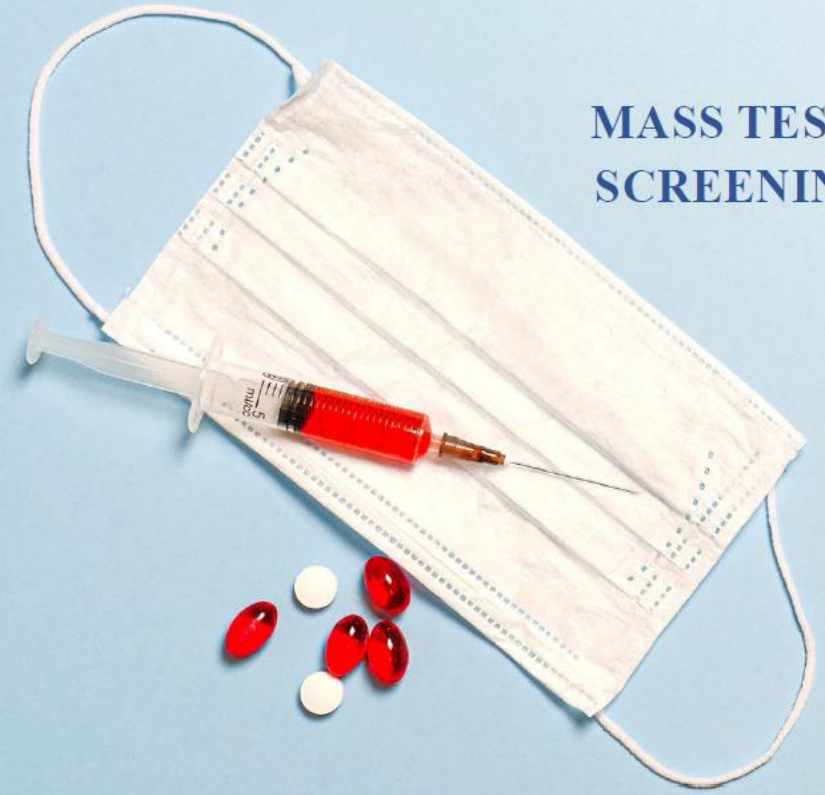
Please note that in addition to the Medical Research Institute, PCR testing for COVID-19 infection has been established at virology laboratories at National Hospital Kandy and Teaching Hospitals Karapitiya and Anuradhapura. Accordingly, it is decided to assign each of the following hospitals to one of these facilities, decentralizing PCR testing for COVID-19.

Hereafter, all samples for this testing should be sent to the designated laboratory only. Sending duplicate

Government of the People's Republic of Bangladesh

National Preparedness and Response Plan for COVID-19, Bangladesh

Version 5, March 2020

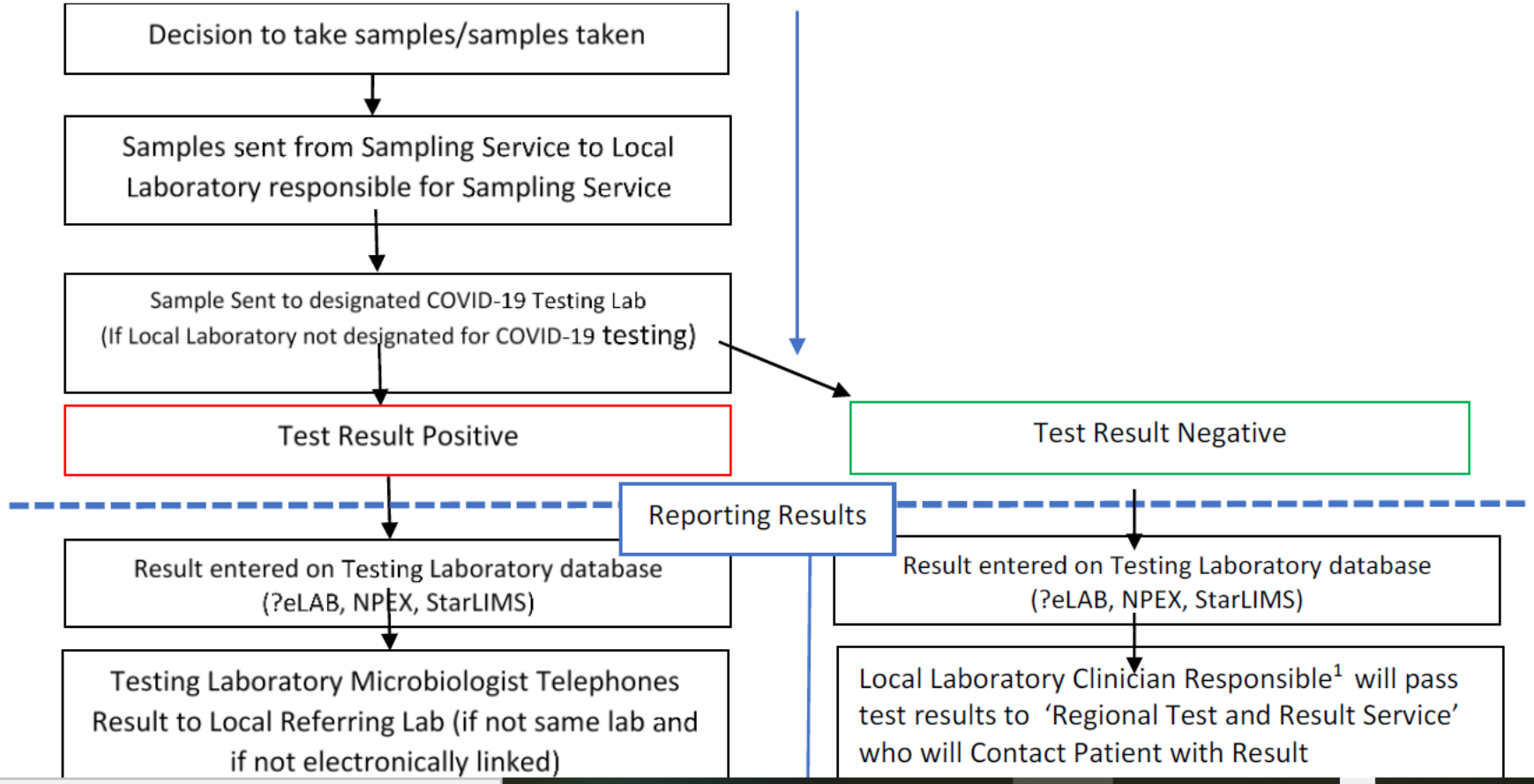


MASS TESTING PREPARATION FOR COVID-19 SCREENING IN INDIA WITH RECOMMENDED SWADESH-PROTOCOL

RAJU VENKATRAMAN,
DR. RAMA KRISHNAN,
ROSHNI RAJU PALEPU

31.03.2020

5.5 Notification of Presumptive Positive/ Positive Results and Negative Results



Opinion

2019 Novel Coronavirus Disease (COVID-19): Paving the Road for Rapid Detection and Point-of-Care Diagnostics

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[1] Department of Biotechnology and Biomedicine, Technical University of Denmark, 2800 Kongens Lyngby, Denmark; tring@dtu.dk
[2] Laboratory of Applied Micro and Nanotechnology (LAMINATE), Division of Microbiology and Production, National Food Institute, Technical University of Denmark. Kemitorvet, Building 204, 2800 Lyngby Denmark; ddba@food.dtu.dk
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Received: 26 February 2020; Accepted: 11 March 2020; Published: 14 March 2020

Abstract: We believe a point-of-care (PoC) device for the rapid detection of the 2019 novel Coronavirus (SARS-CoV-2) is crucial and urgently needed. With this perspective, we give sugges potential candidate for the rapid detection of the coronavirus disease 2019 (COV factors for the preparedness and response to the outbreak of the COVID-19.

Rapid Detection of Novel Coronavirus (COVID-19) by Reverse Transcription-Loop-Mediated Isothermal Amplification

--Manuscript Draft--

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Corresponding Author:	Laura Elaine Lamb, Ph.D. Beaumont Health Royal Oak, MI United States
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Order of Authors:	Laura Elaine Lamb, Ph.D.
	Sarah N. Bartolone
	Elijah Ward
	Michael B. Chancellor
Manuscript Region of Origin:	UNITED STATES
Abstract:	Novel Corona virus (COVID-19 or 2019-nCoV) is an emerging global health concern that requires a rapid diagnostic test. Quantitative reverse transcription PCR (qRT-PCR) is currently the standard for COVID-19 detection; however, Reverse Transcription

Rapid Detection of Novel Coronavirus (COVID-19) by Reverse Transcription-Loop-Mediated Isothermal Amplification

Laura E. Lamb[1,2*], Sarah N. Bartolone[1], Elijah Ward[1], Michael B. Chancellor[1,2]

[1] Department of Urology, Beaumont Health System, Royal Oak, MI, United States of America

[2] Oakland University William Beaumont School of Medicine, Rochester Hills, MI, United States of America

Serology testing for COVID-19

February 28, 2020

This is up to date as of February 21, 2020

Background

Serology tests are blood-based tests that can be used to identify whether people have been exposed to a particular pathogen. Serology-based tests analyze the serum component of whole blood. The serum includes antibodies to specific components of pathogens, called antigens. These antigens are recognized by the immune system as foreign and are targeted by the immune response. These types of tests are often used in viral infections to see if the patient has an immune response to a pathogen of interest, such as influenza. The tests can be used to diagnose infection.

There are several types of serology tests.

1. Neutralization tests can indicate whether the patient has active, functional antibodies to the pathogen in question by measuring how much the patient antibodies can inhibit viral growth in the lab.

COVID-19 detection and serology

Serology testing for COVID-19 is attractive because of the relatively short time to diagnosis and the ability to test for an active immune response against the virus. Currently, however, no serology tests are available for COVID-19. The CDC uses and currently recommends a PCR method to diagnose infection based on the presence of viral RNA. While PCR is a very sensitive assay, combining PCR with serology would theoretically increase sensitivity of testing. Having 2 tests would allow confirmation of infection, rather than relying on a single test.

The 2 potential serology tests for COVID-19 would be (1) a test for viral proteins (likely a Western blot), with antibodies raised in animals that would allow for detection; or, more commonly, (2) an ELISA that detects the patient's antibodies to the virus. These would allow for rapid detection of viral proteins, or antibodies to those proteins, using serum alone.

Accelerated infection testing at scale: a proposal for inference with single test on multiple patients

March 30, 2020

Tarun Jain, Indian Institute of Management Ahmedabad, Email: tj9d@virginia.edu

Bijendra Nath Jain, Indraprastha Institute of Information Technology Delhi and Indian Institute of Technology Delhi, Email: bnjain@iiitd.ac.in

1. Introduction

In pandemics or epidemics, public health authorities need to rapidly test a large number of individuals, both to determine the line of treatment as well as to know the spread of infection to plan containment, mitigation and future responses. However, the lack of adequate testing kits could be a bottleneck, especially in the case of unanticipated new diseases, such as COVID-19, where the testing technology

SSHSPH COVID-19 Science Report: Therapeutics (30 Mar) - Adobe Acrobat Reader DC

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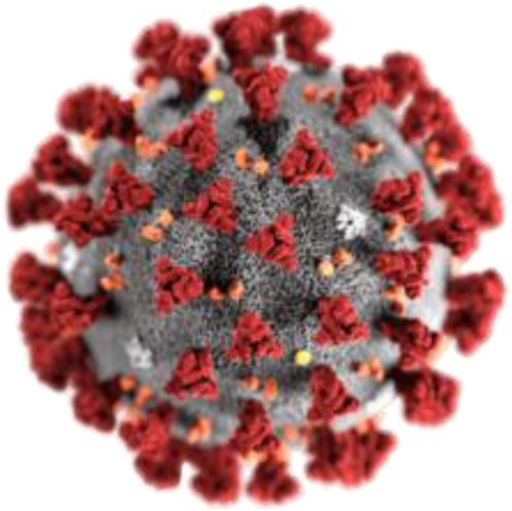

COVID-19 Science Report: Therapeutics

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Q&A

Covid-19: W

Gareth Iacobucci

The BMJ

What tests are currently available in the UK?

The NHS is using polymerase chain reaction (PCR) testing to determine which people currently have covid-19. This involves extracting RNA from a nose or throat swab sample through laboratory analysis. It has a high level of accuracy, and results take around a day to come through. But once a person has recovered the test can no longer tell if they have been infected. The other type of test, which Public Health England (PHE) says could be available to UK residents to use at home "within days," subject to testing, detects antibodies in the blood. This test is designed to detect whether someone previously had the virus

Why is the UK's testing capacity so low?

David Farren, a consultant in medical microbiology and an infection control doctor in Northern Ireland, believes that the UK-wide consolidation in the number of pathology laboratories resulting from a review in 2006 left the UK less equipped to deal with a pandemic of this scale.[1] He said, "A lot of laboratories were centralised, and each hospital now wouldn't necessarily have a fully functioning lab. So we weren't in as good a position as we might have been 10-15 years ago, where we might have had more staff and more laboratory footprint. But we have to work with what we have . . . and if there's

SSHSPH COVID-19 Science Report: What's New (30 Mar) - Adobe Acrobat Reader DC

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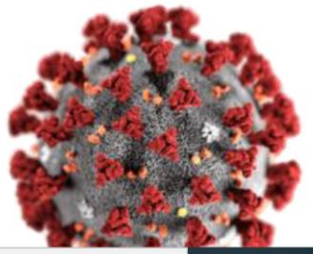

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What's New

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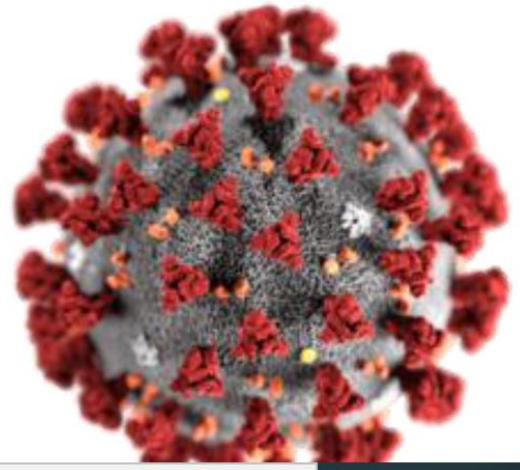

COVID-19 Science Report: Vaccines

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Laboratory testing for coronavirus disease 2019 (COVID-19) in suspected human cases.

Interim guidance
2 March 2020

World Health Organization

1. Introduction

Several coronaviruses can infect humans, the

The decision to test should be based on clinical and epidemiological factors and linked to an assessment of the likelihood of infection. PCR testing of asymptomatic or mildly symptomatic contacts can

Laboratory testing for coronavirus disease (COVID-19) in suspected human cases

Interim guidance
19 March 2020

World Health Organization

Background

This document provides interim guidance to laboratories and stakeholders involved in COVID-19 virus laboratory testing of patients.

It is based in part on the interim guidance on laboratory testing for Middle East Respiratory Syndrome (MERS) coronavirus.[1-6] Information on human infection with the

If case management requires, patients should be tested for other respiratory pathogens using routine laboratory procedures, as recommended in local management guidelines for community-acquired pneumonia. Additional testing should not delay testing for COVID-19. As co-infections can occur, all patients that meet the suspected case definition should be tested for COVID-19 virus regardless of whether another respiratory pathogen is found.

COVID-19 Testing Laboratories

Apex Laboratory
ICMR-National Institute of Virology, Pune

Testing VRDLs for 2019-nCoV:

1. AIIMS, Delhi
2. KGMU, Lucknow
3. SMS, Jaipur
4. NICED, Kolkata
5. IGGMC, Nagpur

Guidelines for COVID-19 testing in private laboratories in India

The test to be conducted by a laboratory which has NABL accreditation for real-time PCR assay for RNA virus.

Whom to test:

Laboratory test should only be offered when prescribed by a qualified physician as per the ICMR guidleines for COVID-19 testing. Since the guidance evolves periodically, the latest revised version should be followed (link below).

(https://icmr.nic.in/sites/default/files/upload_documents/2020-03-20_covid19_test_v3.pdf)/ www.mohfw.gov.in.

Sample collection and Testing guidelines:

- Appropriate biosafety and biosecurity precautions should be ensured while collecting respiratory samples (oropharnygeal and nasal swab) from a suspect patient. Alternatively, a COVID-19 specific separate sample collection site may be created.

TRAINING RESOURCES FOR COVID 19 MANAGEMENT

S.No	Roles	Category of Health care professionals.	TRAINING RESOURCE
1	Field Surveillance (younger persons to be deployed)	ANM, ASHA, Anganwadi workers Ayush students NCC cadets NSS volunteers NYKS volunteers IRCS volunteers CPSE workers All officers generally deployed as micro observers during general elections, including teachers	1. COVID-19 FACILITATOR GUIDE https://www.mohfw.gov.in/pdf/FacilitatorGuideCOVID19_27%20March.pdf
2	Field Supervision (comparatively older persons may be deployed)	PHC doctors Ayush doctors Dental doctors Physiotherapists All officers generally deployed as micro observers during general	1. COVID-19 FACILITATOR GUIDE https://www.mohfw.gov.in/pdf/FacilitatorGuideCOVID19_27%20March.pdf

FACT SHEET FOR HEALTHCARE PROVIDERS

CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel

Updated: March 15, 2020

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Centers for Disease Control and Prevention (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

Testing is to be conducted on specimens from people who meet Coronavirus Disease 2019 (COVID-19) clinical and/or epidemiological criteria for testing.

What are the symptoms of COVID-19?
Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information

This test is to be performed only using respiratory specimens collected from individuals who meet COVID-19 clinical and/or epidemiological criteria for testing.

- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel should be ordered for the detection of the virus that causes COVID-19 in individuals who meet the COVID-19 clinical and/or epidemiological criteria for testing.

COVID-19 Guidance on Sample Collection and Testing as of March 15, 2020 at 7 pm

Please ensure that you are using the latest guidance document, available at
http://www.bccdc.ca/health-professionals/clinical-resources/coronavirus-(novel)

PHSA Laboratories

BCCDC Public Health Laboratory

A service of the Provincial Health Services Authority

As you are aware, COVID-19 has been declared a global pandemic. Testing is available, but a limited resource. Testing should be performed **ONLY** on symptomatic patients. Please note that infants and children may manifest very minor symptoms.

Who *should* be tested for COVID-19?	Who *does not need* to be tested for COVID-19?
Patients **with respiratory symptoms** who are: 1. Hospitalized, or likely to be hospitalized 2. Health Care Workers 3. Residents of long term care facilities	1. Patients without symptoms. The exception is health care workers with COVID-19 infection who require a negative test after symptom resolution to

Stanford HEALTH CARE

COVID-19 Specimen Collection & Handling

Lab Customer Service
(877) 717-3733

NOTE: This guidance covers testing performed at the Stanford Virology Lab for SARS CoV-2 and is only intended for FACILITIES OUTSIDE OF STANFORD (including UHA).

Check CDC guidelines for testing: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical specimens.html

SPECIMEN COLLECTION INSTRUCTIONS FOR SARSCOV2 TESTING

Upper Respiratory Swab Specimens

Preferred Source: Nasopharyngeal (NP) swab in individual Viral or Universal Transport Medium

Acceptable Source: Oropharyngeal swab

Upper Respiratory Collection Guidelines

Questions?


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