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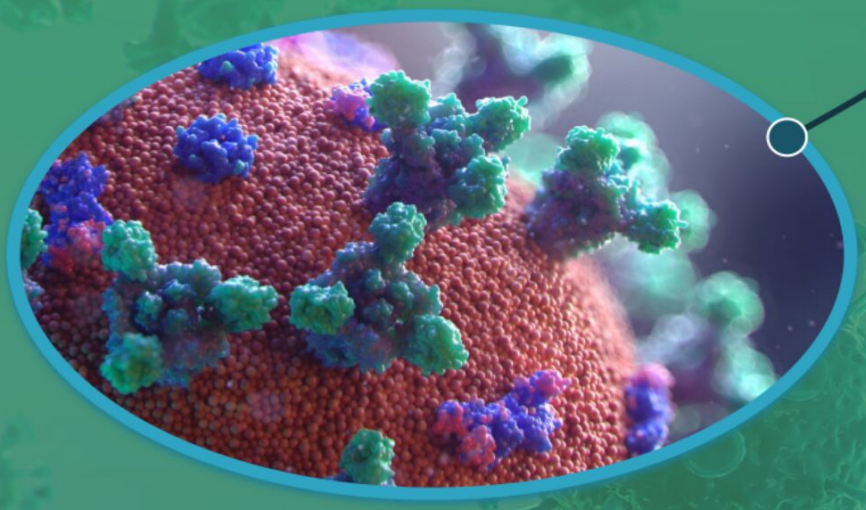
Corona virus special issue



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EDITOR, Lab World Magazine

Registered Office:

F-17, Sarita Vihar,New Delhi-110076,India

Tel : + 91 11 41040630, Cell : +918447195334

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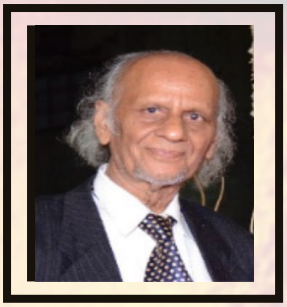
Editor : **Mahesh Chander Gupta**



No Rose without Thorns

Editor's Desk

Today the entire world is passing through a unprecedented hard time. Pandemic created by a small virus-corona virus, has shaken the entire world as it has adversely touched all aspects of life- everywhere globally. Sadly, no treatment/cure is available to combat this ghastly disease. Prevention is the only solution until an effective vaccine is invented. The spread of lethal disease at alarming rate must be supported by screening of doubtful cases . Consequently, the demand for testing laboratories has increased multifold. The role of laboratories for R/D, inventing vaccine, prevention and diagnosis is very crucial to save millions of lives. Establishing corona test laboratory facilities, therefore, is on top priority of every economy that too rapidly.

The beauty of and fragrance of roses cannot be taken away by thorns. Corona virus pandemic has ushered a new world order. The present calamity, has brought all economies together to fight out the dreaded enemy. We are witnessing a new way of life and many innovations.

Vulnerability is the birthplace of innovation, creativity and change [Brene Brown]

Lab World Magazine has understood its obligation. Hence is presenting articles on Corona virus related articles from distinguished authors.

Editor firmly believes that every crisis, doubt or confusion transforms us for betterment. We also found a window of opportunity to reach you instantly no matter where you are.

Besides in print, the magazine will also be published in electronic media to reach you on line. Please send your observations freely.

Mahesh Chander Gupta

Editor

20 July 2020

HAPPY NEWS

A PROUD DAY FOR LABORATORY FRTERNITY AND USERS

COVID-19 Test Facility : Modern Crucial Specific Health Infrastructure is Created

July 27, 2020 New Delhi, PM Modi inaugurated three State of art COVID-19 testing facilities-

The wide outbreak of corona virus pandemic globally compelled every economy to adopt policy to build corona specific diagnostic laboratory facilities on large scale and rapidly. This is because mass screening became unavoidable to combat the deadly enemy.

The Government of India (GOI) adopted “test-track-treat strategy” for early detection and containment of the COVID-19 pandemic.

It is great pride to lab fraternity that infrastructure of state of art corona testing lab is coming up in public as well as in private sector in compliance to test track strategy Of GOI

The importance of creating corona testing facilities by GOI is evident that, three state of art laboratories were launched by no other than PM Narendra Modi on 27 July 202 via video conferencing at New Delhi. The test facilities have been established with aim to test 10 lakh (1 million) samples per day.

They are set up at three major cities of India – Noida(UP), Mumbai and Kolkata – at the centers of Indian Council of Medical Research (ICMR) viz;

1-ICMR-National Institute of Cancer Prevention and Research, Noida;
2-ICMR-National Institute for Research in Reproductive Health, Mumbai;
3-ICMR-National Institute of Cholera and Enteric Diseases, Kolkata,
Each lab will be able to test over 10,000 samples in a day

All the three testing facilities are high-throughput meaning methods of research/ diagnosis at mass scale availability by using automation, miniaturized assays, and large-scale data analysis

The new facilities set-up at various ICMR labs are expected to help in mass screening early and thus treatment of the deadly infection. Hope they will assist in putting an end to the spread of the pandemic.

PM MODI Launches 3 high throughput covid 19 test facilities.

[Note:the information herein is based on readings from various sources reported by reputed news agencies on web site]

UNVEILING THE NOVEL CORONAVIRUS IN THE LABORATORY: A Review

Arthi Krishna Rao,
Chakravarthy Narasimhachar Srinivas,
Preethii Narayanan

Corresponding author : Arthi Krishna Rao
E mail :arthikrao82@gmail.com
Ph 9841406026

Abstract

Coronavirus outbreak (COVID 19) is threatening the world as a whole currently. A novelbat coronavirus, whose pathogenesis is unknown to the medical fraternity is posing a challenge. The world is left with little option in the absence of a definitive treatment modality. Laboratory diagnosis of the SARS CoV2 virus play sapivotal role in categorising patients for treatment, isolation and quarantine. rtRT-PCR is the main modality of diagnosing the disease complimented by serological methods and biochemical parameters. Repeat testing for suspected cases remains our slogan.

INTRODUCTION

Wuhan, a Hubei province in China saw a cluster of pneumonia cases in December 2019, which was named as the novel coronavirus by the Centres for Disease Control (CDC) in January 2020. SARS CoV 2 was the new name suggested by the International Committee on Taxonomy of Viruses (ICTV) due to its genetic relatedness to the SARS (Severe acute respiratory syndrome) outbreak in 2003.Finally the World Health Organisation (WHO) announced the name COVID 19 (COronaVirus Disease) on 11th February 2020. Coronaviruses are enveloped positive stranded RNA viruses in the order of Nidovirales. They have a crown-like appearance under the electron microscope, which is why the viruses are named after the Latin word corona, meaning ‘crown’ or ‘halo’. Corona viridae is further classified into four genera: Alpha, Beta, Delta and Gamma coronavirus. Common human coronaviruses include Beta coronavirus OC43 and HKU1 and Alpha corona virus 229E which cause common cold; while Alpha corona virus NL63 is considered to be an important cause of (pseudo) croup and bronchiolitis in children. Zoonotic coronaviruses that have emerged and caused outbreaks in humans are the SARS-CoV (2002) which caused the Severe Acute Respiratory Syndrome and MERS-CoV (2012) known as MiddleEast Respiratory Syndrome.[1,2] The primary target for the virus are the epithelial cells of respiratory and intestinal tract and therefore the spread of infection is through droplets or from fomites.The incubation period for the infection varies between 2-14 days with a median Incubation period of 5.2 days.[3] The clinical presentation ranges from mild flu like symptoms to pneumonia leading to severe morbidity and mortality in some cases. Hence it is mandatory to “detect and treat”the affected in order to “protect”the vulnerable. This article is an evidence based review on the laboratory diagnosis of SARS CoV2- the methodologies, challenges and innovations.

METHODS

A thorough and detailed search was made on the internet on Google scholar, National Library of Medicine and Research gate using the keywords, “COVID 19 laboratory diagnosis”, “RT-PCR for COVID 19”, “Gene Xpert for SARS-CoV2”and “Serological tests for COVID 19”

RESULTS

Full free text articles pertaining to the above keywords were included. Non English language articles, downloaded in duplicate and those where only abstracts could be accessed were not taken for reference.

DISCUSSION

Diagnostic methods for detection of SARS CoV2 can be broadly classified as Molecular and Serological. WHO has recommended the real time Reverse Transcriptase-Polymerase Chain Reaction (rtRT-PCR) for detection of this RNA virus.RT-PCR is a molecular test that amplifies a tiny amount of viral genetic material in a sample and is considered to be the gold standard for identification of SARS-CoV-2 virus. Deep sequencing molecular methods such as next-generation sequencing and meta genomic next-generation sequencing may be needed in future to determine the mutations in SARS-CoV-2 but are currently impractical for diagnosing COVID-19. Laboratory diagnosis begins from collecting the right sample to issuing the right report.

Samples collected:

Upper respiratory tract samples

1. Nasopharyngeal/Oropharyngeal swab

2. Nasal swab

Lower respiratory tract samples

1. Sputum

2. Bronchoalveolar lavage(BAL)

3. Endotracheal aspirate (ETA)

Patients have demonstrated high viral loads in the respiratory tract within 5-6 days of onset of symptoms. Nasopharyngeal swabs show better recovery of the RNA(63%) compared to the oropharyngeal swabs (32%). Similarly lower respiratory tract samples showed better yield and are collected at the time of intubation. Some studies have also isolated the virus from stool samples, however stool PCR is not done routinely.[3] Asingle Nasopharyngeal(NP) swab can be preferred for testing as it is tolerated better by the patient and is safer to the operator Compared to the throat swab. NP swabs have an inherent quality, that they usually reach the Correct area to be tested in the nasal cavity. CDC recommends the use of synthetic swabs with plastic or wire shafts as calcium alginate swabs or those with wooden shafts may contain inhibitory substances that may inactivate the virus.[4] Donning of appropriate personal protective gear is mandatory for collection of samples.

How to collect a Nasopharyngeal swab specimen?

1. Label the specimen container with the patient's details2. Nasal swab
2. Don appropriate PPE
3. Seat the patient comfortably and explain the procedure
4. Tilt the patient's head back slightly, so that the nasal passages become more accessible.
5. Gently insert the swab along the nasal septum, just above the floor of the nasal passage, to the nasopharynx, until resistance is felt.
6. Leave the swab in place for several seconds to absorb secretions and slowly remove the swab while rotating it. [5]

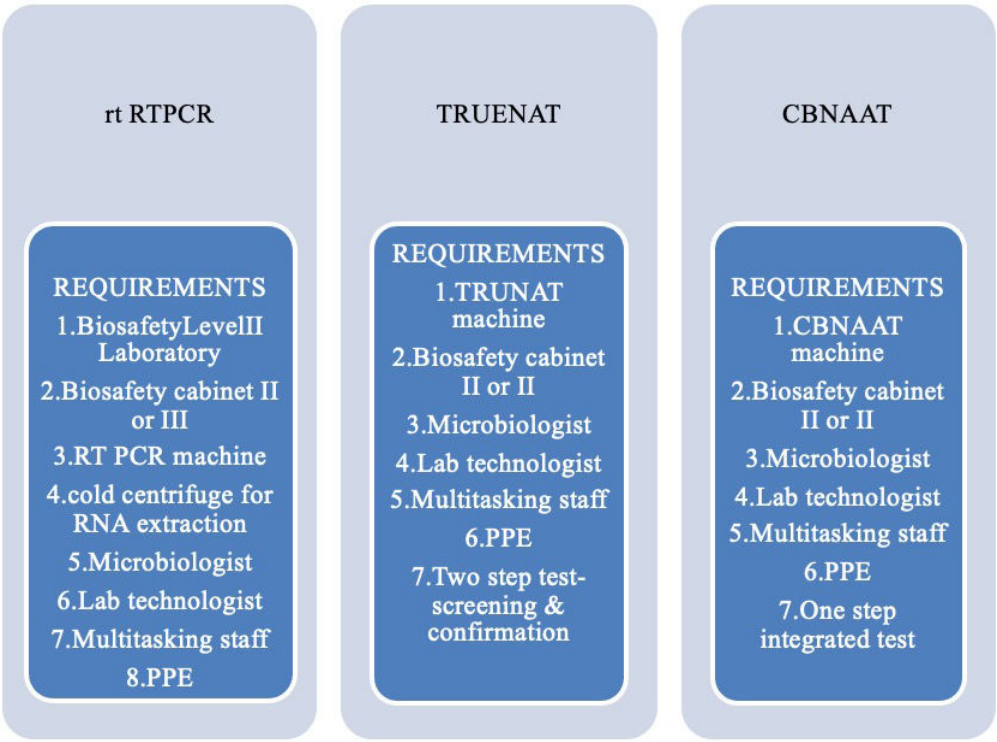
Transport of samples

After collection the swabs are laced in a viral transport medium (VTM) to preserve the integrity of the nucleic acid and is transported to the testing facility.Lower respiratory tract samples may be sent in a sterile container.All samples should be transported to the testing laboratory at 2-8°C or may be frozen to -20°C if a delay is anticipated.[6]

Processing of samples

Current diagnostic tests to identify the SARS CoV2 RNA include real time RT-PCR, and automated self containedinvitro diagnostic assays such as the TRUENAT and CBNAAT.Molecular methods that are under evaluation are Loop-mediated isothermal amplification(RT-LAMP), multiplex is othermal amplification followed by microarray detection, and CRISPR (clustered regularly interspaced short palindromic repeats)-based assays. Laboratories should be equipped with a level II or III biosafety cabinet in a negative pressure room. The technologist involved in processing of samples should also wear N95 mask, googles/face shield, gloves, cap and a disposable gown. There are a number of coronaviruses that cause respiratory and intestinal infections in humans. Among these coronaviruses are a group of SARS-like bat coronaviruses, including both SARS-CoV and SARS-CoV-2, that are categorised under the subgenus Sarbecovirus. Coronaviruses have a number of molecular targets within their positive-sense, single-stranded RNA genome that can be used for PCR assays. These include genes encoding structural proteins, including envelope glycoproteins spike (S), envelope (E), transmembrane (M), helicase (Hel), and nucleocapsid (N). Also there are species-specific accessory genes required for viral replication which include RNA-dependent RNA polymerase (RdRp), hemagglutinin-esterase (HE), and open reading frame 1a (ORF1a) and ORF1b. In the United States, the CDC recommends two nucleocapsid protein targets (N1 and N2) while WHO recommends first-line screening with an E gene assay followed by a confirmatory assay using the RdRp gene.[7]

MOLECULAR TESTING METHODS



Merits And Demerits Of Different Molecular Methods

RTPCR requires expensive equipment and the turn around time may vary from 3-24 hours. Extraction of nucleic acid is performed separately, after which the extracted material is amplified and detected real time in a thermal cycler.A study by J-L He et al reported a sensitivity of 79% and specificity of 100%, for RT-PCR. The RT-PCR testing accuracy may be affected by a number of factors including viral load in the respiratory tract, specimens source, sampling procedures and timing, quality control of the test, and inherent performance of the testing kits[8] The TRUENAT is a Nucleic acid detection assay in which two steps are employed. The first one is to screen for the E gene common to Sarbecoviruses followed by use of a second cartridge to detect the RdRp gene only when the screening test is positive. [9] The GeneXpert is a Cartridge Based Nucleic Acid Amplification Test (CBNAAT) that automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real-time PCR assays.. The systems require the use of single-use disposable cartridges that hold the RT-PCR reagents and host the RT-PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized.The results are given out in a short time span of 45 minutes compared to RTPCR.[10] Interpretationof Molecular test results In individuals with symptomatic COVID-19 infection, viral RNA in the nasopharyngeal swab is measured by the cycle threshold (Ct). RNA becomes detectable as early as day 1 of symptoms and peaks within the first week of symptom onset. The Ct is the number of replication cycles required to produce a fluorescent signal. Lower Ct values represent higher viral RNA loads. A Ct value less than 40 is clinically reported as PCR positive. This positivity starts to decline by week 3 and subsequently becomes undetectable. It has to be remembered that a “positive” PCR result reflects onlythe detection of viral RNA and does not necessarily indicate presence of viable

virus. Some patients have tested positive for SARS CoV2, by RT-PCR even beyond week 6 following the first positive test and some have also been reported positive after 2 consecutive negative PCR tests performed 24 hours apart. There is no clarity if this is a testing error, reinfection,or reactivation.[11,12]. In a study of 205 patients with confirmed COVID-19 infection, RT-PCR positivity was highest in bronchoalveolar lavage specimens (93%), followed by sputum (72%), nasal swab (63%), and pharyngeal swab (32%).[13]

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Issues affecting results

An important issue we face with the real-time RT-PCR test is the risk of false-negative and false-positive results. Studies have reported that many ‘suspected’ cases with typical clinical characteristics of COVID-19 and features of atypical pneumonia on computed tomography

(CT) Chest images were not diagnosed positive .Thus, a negative result does not exclude the possibility of COVID-19 infection and should not be used as the only criterion for treatment or patient management decisions. It is always safe to consider a combination of real-time RT-PCR and clinical features for the management of SARS-CoV-2 outbreak.[14]False positives may occur occasionally due to

- reagent contamination with previously amplified DNA,
- cross contamination during collection, transportation and aliquoting and
- technical errors.

Liberal use of negative control samples in each assay and a well-designed plan for confirmatory testing can help ensure that laboratory contamination is detected and that specimens are not in appropriately labeled as SARS-CoV positive.[15] False negative reports may be due to

- Improperly collected sample

- Type of specimen- Lower respiratory tract samples yielded the highest recovery followed by nasopharyngeal swab (NP).• technical errors.

- Stage of disease- The viral load is highest in the first 5 days after symptoms onset and wanes gradually. However in severe disease BAL and sputum may be positive but the virus may not be isolated from nasopharyngeal swabs., whereas the yield is good from a NP swab in mild to moderate cases.[12]

- Error in storage and transport- Prompt transport to testing laboratory and maintenance of cold chain incase of anticipated delay is mandatory.[16]

- Prolonged nucleic acid conversion- A study reported that 21% of its patients turned positive by RTPCR after 2 consecutive negatives. They have taken a longer time for conversion and may have been detected negative in the early stage of disease. Such group of patients require longer period of observation.[17] Clinical correlation along with radiological features suggestive of an atypical pneumonia may be helpful in pointing out the diagnosis in some of the patients.[18]

SEROLOGICAL TESTS

Serology testing for COVID-19 is defined as analysis of plasma, serum, or whole blood for the detection of antibodies, especially immunoglobulin G (IgG), immunoglobulinM (IgM), and immunoglobulin A (IgA), that are specific for SARS-CoV-2 antigens.[19] Two SARS CoV2 proteinsthat are notably important antigenic targets include the S and N genes S proteins are from the coronavirus spikes for receptor binding and fusion and N protein, a structural component of the helical nucleocapsidplays an important role in viral pathogenes is,replication, and RNA packaging.

SEROLOGICAL TESTS

Antibodies to the N protein have been frequently detected inCOVID-19 patients and hence ,maybe one of the immuno dominantantigens in the early diagnosis of disease[7]. Seroconversion occurs approximately 7–14 days after symptom onset. Generally in classical immune response to viruses,IgM is produced first, accompanied by IgA, and then followed by a shift toward IgG specificity challenges associated with high false-positive rates . IgG is a longer lasting antibody with potential viral neutralizing activity. Many manufacturers have therefore focused theire fforts on developing immunoassays against IgG rather than IgM.[19]. The antibody tests

- Can be done on blood/serum/plasma samples
- Test result is available within 30 minutes
- Test may come positive after 7-10 days of infection
- The test may remain positive for several weeks after infection
- Positive test indicates exposure to SARS-CoV-2
- Negative test does not rule out COVID-19 infection.[20]

The Indian Council for Medical Research has validated and approved an indigenous IgG ELISA for sero-surveys and surveillance in high risk population such as healthcare workers, immunocompromised persons and frontline workers.[21]

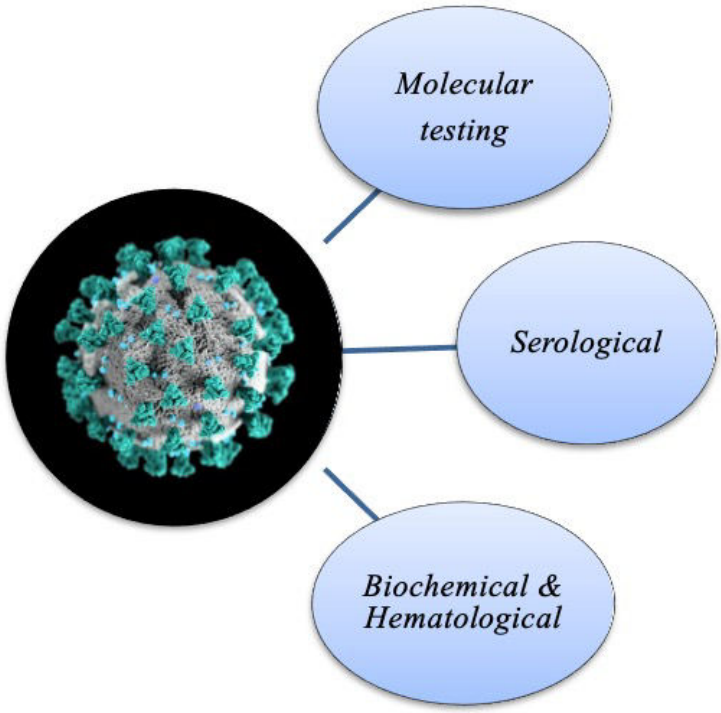
Inflammatory Biomarkers

Routine biochemical and hematological laboratory testing is essential for assessing disease severity, selecting therapeutic options, and monitoring treatment response. Several inflammatory biomarkers have been implicated insevere COVID-19, causing the“cytokine storm”.[19] A series of immune mediated events occur as a response to SARS CoV2 virus resulting in the release of proinflammatory cytokines that correlate directly with clinical severity.[22]

BIOCHEMICAL PARAMETERS	HEMATOLOGICAL PARAMETERS
Total bilirubin	WBC
AST (Aspartate aminotransferase)	Lymphocyte count
ALT (Alanin aminotransferase)	Neutrophil count
LDH (Lactate dehydrogenase)	ESR (Erythrocyte sedimentation rate)
D-dimer	Procalcitonin
Fibrinogen	CRP (C-reactive protein)
CK-MB (Creatine Kinase)	Ferritin
Troponin	IL-6 (Interleukin-6)
Prothrombin time	
BUN (Blood Urea Nitrogen)	

Higher levels of procalcitoninin COVID-19, suggest onset of bacterial infection in critically ill patients. Elevation in the D-dimer coagulation parameter has been associated with worsening disease and a higher risk of developing thromboembolic complications in COVID-19 patients. Overall, it has been studied that severe cases of COVID-19 are characterized by a massive proinflammatory response or cytokine storm that is estimated to progress to multiple organ damage and failure in severe cases. Biochemical monitoring of COVID-19 patients will thus involve assessing the inflammatory profile, as well as early recognition of cardiac, renal, and hepatic injury through routine laboratory testing.

The clinical spectrum of COVID-19 is varies from asymptomatic to, mild upper and lower respiratory tract infection, to severe clinical conditions characterized by respiratory failure requiring mechanical ventilation and support in an intensive care unit (ICU), to multiorgan and systemic manifestations in terms of sepsis, septic shock, and multiple organ dysfunction syndromes (MODS).[23]A study conducted in China showed that RT-PCR yielded a sensitivity of 79% and specificity of 100%. The RT-PCR testing accuracy may be affected by a number of factors such as the viral load in the respiratory tract, specimens source, sampling technique , quality control of the test, and inherent performance of the testing kits. Chest CT has proved to play an important role in early detection, evaluation, and treatment response monitoring of COVID-19 infection. However, chest CT manifestation of COVID-19 pneumonia overlaps with other types of viral pneumonia, questioning its specificity.[8] However correlating clinical symptoms of the patient along with radiological features, RTPCR, biochemical and haematological parameters will benefit the patient management as a whole.



COVID-19 shows a wide range of clinical manifestations, from mild flu-like symptoms to life-threatening conditions, therefore it is important to have efficient testing during the early stages of infection to identify COVID-19 patients from thosewith other illnesses to avoid unnecessary quarantine of negative individuals and the spread of infection by positive individuals. Early diagnosis will help guide physicians to provide prompt intervention for patients who are at higher risk for developing more serious complications from COVID-19 illness. Availability of a commercial vaccine may take time and so, it is important to identify

Impact of COVID

individuals who have been infected with SARS-CoV-2, with or without accompanying symptoms, and who have developed antiviral immunity.[24]

Quality Control for PCR

Commercial QCs are usually preferred but in the absence of commercial controls, laboratories can use

- Negative control: Water/universal transport media/viral transport media
- Positive control: A known positive patient sample with a Ct value between 25-30. [25]

Newly-received lot of test kits should be tested using a panel of known positive and negative samples to confirm its performance along with the lot in use. Key performance indicators (KPIs) refer to collection and analysis of data at each step of testing to serve as an indicator for the performance of the whole testing cascade. KPIs should be analysed and reported at least once a month and should include the number of specimens tested, specimen type ,number (%) of positive, negative and invalid test results, specimen rejection rate , percentage of failed IQC results ,External Quality Assurance (EQA) or Proficiency Testing (PT) performance and Turnaround time (TAT) [25]During the time of this COVID 19 health crisis, College of American Pathologists (CAP) has recommended the following,

- For Emergency Use Authorisation (EUA) tests in a patient care setting, it is sufficient if QC is performed as per manufacturer's instructions. The US Food and Drug Administration (FDA) deems these tests to be CLIA(Clinical Laboratory Improvement Amendments) waived testsas they do not require stringent conditions and the risk of an erroneous result is insignificant.[26]

The Tamil Nadu government has announced a quality assurance programme for Government and private labs across the state whereby labs have to send 5 negative and 5 positive samples with the Ct value for the E gene between 25-35, fortnightly to The King Institute of Preventive Medicine, Guindy.[27]

CONCLUSION

No test gives a 100% accurate result; tests need to be evaluated to determine their sensitivity and specificity, ideally by comparison with a “gold standard.” The lack of such a clear-cut“gold-standard” for covid-19 testing makes evaluation of test accuracy challenging. Therefore repeat testing in negative cases especially in those with a strong clinical suspicion, detailed history and clinical examination, correlation of clinical findings with radiological features and laboratory parameters will guide us in the management of the patient. As there are currently no vaccines and proved antiviral agents for definitive treatment, it is necessary to strengthen the laboratory network for early diagnosis of COVID-19 not only for management of cases but also for isolation of asymptomatic and mildly symptomatic cases and quarantine of close contacts.

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Authors

Arthi Krishna Rao
MD Microbiology, Clinical Microbiologist, Department of Laboratory Medicine, MIOT International,4/112, Mount Poonamallee High Rd, Sathya Nagar, Manapakkam, Chennai, Tamil Nadu 600089.

Chakravarthy Narasimhachar Srinivas
MD Pathology, Director of Laboratory Medicine,MIOT International, 4/112, Mount Poonamallee High Rd, Sathya Nagar, Manapakkam, Chennai, Tamil Nadu 600089.

Preethii Narayanan
MD Microbiology ,Clinical Microbiologist, Department of Laboratory Medicine, MIOT International, 4/112, Mount Poonamallee High Rd, Sathya Nagar, Manapakkam, Chennai, Tamil Nadu 600089

COVID 19 – Testing Times

Dr. Vaidehi Jobanputra, FACMG,
Founder and Chairperson, Advanced Genomics Institute and Laboratory Medicine (LABASSURE),New Delhi,India
Email : sukrut@labassure.com
web: www.labassure.com

Abstract:

There a variety of testing methods for COVID-19 testing being advocated by different governments and healthcare institutions. This article provides an overview of the various techniques available and their respective advantages and applications.

Introduction:

COVID 19 seems to be the most popular and visible word for the year 2020. An epidemic of global scale which has brought almost all the countries and mankind to a standstill. The enigma about the novel corona virus strain, its rapid spread across continents coupled with a wide scale analysis of all aspects on pandemic has led to a plethora of questions and confusions about state of affairs, possible trajectories/scenarios, response options and potential solutions. The jury is still out and will likely to remain busy for months to come before they can conclude what went right and wrong. Meanwhile, governments, policy makers as well as private organizations and individuals continue to make decisions with limited knowledge and adjust continuously along with new found information and evidence.

In such times, testing for Corona virus infection has emerged as a very critical and controversial topic as testing forms the basis of confirming the infection and learning about its characteristics and spread. Since testing is very crucial, it was evoked a lot of interest, investments, interventions from policy makers and resultant dialogues and debates.

Testing Options

The testing tools and techniques have been continuously evolving along the way. The primary testing tools include:

A. **NAAT or Nucleic Acid Amplification** Tests are considered the gold standard for viral detections as these deals directly with the DNA/RNA of pathogens present in the patient sample. The quantification of the viral load or copy numbers further help in monitoring the progression of the disease and response to therapy. are considered the gold standard for viral detections as these deals directly with the DNA/RNA of pathogens present in the patient sample. The quantification of the viral load or copy numbers further help in monitoring the progression of the disease and response to therapy. NAAT tests are performed using a variety of approaches such as Real Time – PCR (RT-PCR), Isothermal Amplification (LAMP), Micro NMR (μNMR), Next Generation Sequencing (NGS) etc.

The primers for NAAT testing can be designed to cover one or more specific loci of the gene and thereby can used for very targeted detection and differentiation of COVID-19 or SAR2-CoV-2 with other types of Corona viruses. The NAAT test promise very high sensitivity for detection even in instances of very low copy numbers (typically > 50 copies).

The main challenges with NAAT include the higher cost of setup and per sample run, technical complexities of performing the tests and turnaround time (TAT).

Despites its higher sensitivity, there have been issues of false positive or negatives due to sample specific issues, pre-analytical errors or cross contaminations. Even then, NAAT remains the most potent tool in the fight against COVID-19.

B. **Serology or Antigen/Antibody testing** is a technique to rapidly evaluate the infection by testing for proteins produced by the body in response to the infection. These antibodies are typically made within 1 to 3 weeks after infection.

Antibodies are Y-shaped proteins that can recognize Antigens or foreign particles whereby Antibodies target and eliminate them. A specific antibody recognizes and binds to its corresponding antigen. Antigens, also known as immunoglobulins can be a protein,

polysaccharides or lipids. Similarly there are different classes of antibodies (IgG, IgM, IgA) each having a unique role in immunity. It takes 1-2 weeks post symptom onset for patients to seroconvert to SARS-CoV-2.

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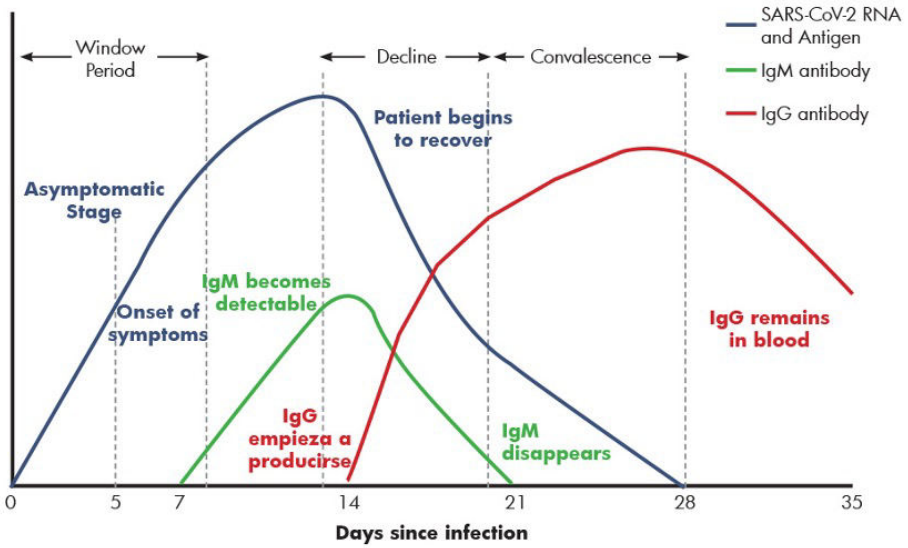

Source: https://www.hcmarbella.com/en/techniques-for-an-accurate-and-early-diagnosis-of-covid-19/

By detecting the presence of antibodies to SARS-CoV-2 in the patient, one can judge the immune response irrespective of symptomatic or asymptomatic state of the patient. And the nature of immune response can help distinguish a recent vs. an older infection. Hence, serology tests play an important role in management and surveillance of the disease and have several applications in patient care as well as epidemiology.

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Serology assay are relatively less complex, easier to perform, cheaper and faster as compared to NAAT. Hence these can be widely used. However the main challenge with serology testing is lower sensitivity & specificity leading to higher false negative and false positive reports.

Hence Serology is not recommended for primary detection of the infection. Although it has an important role in post infection monitoring and surveillance

C. **Other diagnostic tools:** While NAAT and Serological testing are the appropriate testing mechanisms for presence or absence of virus or the antibodies, there are several criteria defined for case selection for testing. Additional challenges of affordability and accessibility means that the entire population cannot be subjected to COVID testing in a short time. Hence the use of various other diagnostic tools for identification and monitoring of suspected cases. These include blood gas analyzers, CT and X-rays amongst others.

Radiology techniques are useful in early identification and monitoring the disease progression, given that COVID is a respiratory disorder and many patients end up with lung or related discomforts. There have been some claims related with improved speed and sensitivity of radio diagnosis techniques in diagnosis of corona cases. Yet these techniques are most useful in hospital settings while managing patients under treatment and those with acute infections and respiratory complications.

D. **Testing for Co-morbidities:** Analysis of corona related fatality rates across geographies have highlighted the role of co-morbidities in adverse outcomes. Fatality rates are typically higher in older populations, immune compromised patients (e.g. cancer or transplant cases) or those with other disorders. Patients with hypertension, diabetes or cardiovascular disorders were found to be developing more severe symptoms leading to higher hospitalization and fatality rates. Hence the routine surveillance of such patients is useful in early identification of high risk cases and better management of infected patients.

From testing perspectives, although testing for co-morbidities has been part of routine healthcare, it has more significance in the present COVID times given the impact on patient outcomes and generally stretched healthcare infrastructure.

Testing Challenges

From testing perspectives, although testing for co-morbidities has been part of routine healthcare, it has more significance in the present COVID times given the impact on patient outcomes and generally stretched healthcare infrastructure.

Accuracy: As described in the previous section, there are known differences in the sensitivity/specificity of various techniques. And yet each approach has its advantages, applications and use cases. Most countries have adopted NAAT as the primary testing option supported by Serology based surveillance.

The test sensitivity varies as per the duration of illness as the actual viral load varies over time and antibodies are generated only after certain period from the date of infection. Further the actual mutation and the assay design can also have a bearing on the sensitivity in practice. Sensitivity is also affected by pre-analytical factors like type, site and quality of specimen collected. Hence there have been reports of false positive/negative cases even in NAAT testing though it is a very sensitive assay.

Capacity: The key challenge for most countries has been the testing capacity. The rapid advent and spread of the disease across geographies and all strata of population has led to an exponetiatial rise in the testing needs. Most countries adopted preventive measures such a social distancing and lockdowns to ‘flatten the curve’ of the spread of the disease with varying success. The primary aim of the preventive measures was the match somewhat the rise in peak with the availability of hospital beds/ventilators/ICUs etc. However, testing has remained the primary mechanism for identification or ruling out of the infection and the subsequent classification of a recovered patient.

Developing such a vast testing infrastructure is a challenge. Especially for RT-PCR setups which have elaborate infrastructure, equipment and manpower requirements. There has been a shortage of RT-PCR machines and other lab equipments. On top of this, the consumables and testing kits have also been in short supply. The lockdown leading top roduction and logistics disruptions further exacerbated the problem.

Changing Regulations: Regulators worldwide have had to step-up to managing the sudden influx of new technologies and providers across all the technologies. Most of the regulators managed to create provisions for 'emergency use authorizations and fast track approvals but not without complains and criticisms from various stakeholders. Validating new technologies, methods and kits is a time consuming process and doing so in a rushed fashion in bound to have mistakes and loose ends.

Different countries and regulatory bodies have been recommending various criteria for referring of patients for NAAT testing. This is true especially in India where the government has defined and further refined or changed the testing criteria several times. The main reason was to prevent a panic or chaos and to avoid over burdening of the limited testing infrastructure. The guidelines which aimed at limiting the testing raised a lot more questions than it answered leading to more confusion. For e.g. whether to test asymptomatic patients or not? Should one test relatives of a patient? Do healthcare workers or police or media qualify as exposed population and should they be screened? Many of these guidelines are varying from one state to another.

This has further accentuated the testing availability and caused lot of stress and challenged to analready stretched healthcare system.

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Many technologies are still not available or accessible in India due to lack of regulatory clarity. Example - there is no clarity if serological testing can be used in general population for screening or in remote locations where no other testing is available. Till date, it has been allowed only for Zero-survelliance only by the state governments.

Way ahead

The Pandemic has indeed stressed and challenged the healthcare systems worldwide. And despite slowdown in new cases in various countries, the ordeal is far from over. The infection is unlikely vanish or become insignificant in a short time. It will continue to require more investments in testing capabilities, quarantine facilities, treatment centers, drug & vaccine development and hygiene practices in general. Although the pace and nature of investments will keep changing.

A reduction in public focus, media attention and political interference over time will enable an environment for more scientific debates and improved regulatory response. The new found focus in healthcare should attract more private investment leading to greater capacities and innovations. This would be perhaps one of the few positive impacts of this pandemic in these testing times.

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The AUTHOR:

Dr. Vaidehi Jobanputra hold Ph.D degree from All India Institute of Medical Sciences (AIIMS), New Delhi India and Post Doc from Columbia University Medical Centre (CUMC), New York,USA
She is

* Director, Molecular Diagnostics, New York Genome Center
* Co-Director, Clinical Cytogenetics Diagnostic Laboratory , New York Presbyterian Hospital
* Co- Director of Laboratory of Personalized Genomic Medicine at Columbia University Medical Center.
* Founder & President – Advanced Genomics Institute and Laboratory Medicine,New Delhi,India
* Certified in Clinical Cytogenetics and Molecular Genetics by American Board of Medical Genetics
* Has vast clinical experience across genetic and molecular diagnostics technologies, especially microarray and next-generation sequencing
* Pioneer in launch of newer molecular technologies in clinical diagnostics
* Has extensive list of publications and research projects.

CORONA AND ITS EFFECT ON PATIENTS WHO GO IN ISOLATION

Kushal Sachan
Email : legendkushal@gmail.com

Abstract:

Corona pandemic has disturbed daily life every one. Adverse effects on human caused by loneliness /isolation have been noticed. The paper is devoted to psychological/behavioural aspects emerged due to corona virus endemic.

Introduction:

Corona virus is a newly discovered virus and known to cause infectious disease “Corona virus disease” also called (COVID-19).

Mild to moderate respiratory illness with a dry cough is the main characteristic of COVID-19. In most cases, people recover from such a state without taking any treatment.

People suffering from different medical conditions such as diabetes, cancer, respiratory disease, and cardiovascular diseases are at high risk to develop corona virus disease.

Various studies have been performed on the psychological effects of isolation during COVID-19. Most of them reported that COVID-19 and self-isolation negatively affect your mental health. different psychological effects have been reported including anger, depression, panic attacks, confusion, boredom, frustration, and anxiety.

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Quarantine vs Isolation

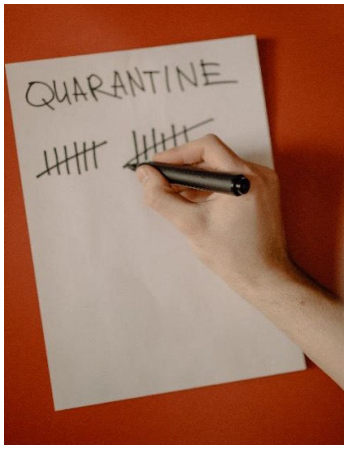
In communication with the public, these terms have been used interchangeably. Quarantine is the segregation and limitation of movement of people who have potentially been exposed to contagious diseases in order to determine whether or not they become ill, thus lowering the impact of infecting others. Isolation is the separation between those who have been afflicted with infectious illness and those who are not sick.Social isolation can be described as "limiting or discontinuing social interaction, contacts, relationships with friends and family, and with society on a broader level.

What is the Incubation period for COVID-19?

The time frame between infection and the initiation of symptoms is called the incubation period. The incubation period of coronavirus is about 14 days. In infected people, the symptoms of coronavirus can appear within five to six days. Moreover, some infected patients can also be asymptomatic.

The influence of COVID-19 on psychological behavior

Typical adverse psychological outcomes of COVID-19 outbreaks including fear and distress, sadness, frustration, confusion and insecurity, and financial tension, with an average 25 to 33% of the population reporting elevated rates of fear and anxiety during related pandemics.



Individuals with previously existing anxiety disorders, existing health anxieties (those who are overly concerned about having or contracting illnesses) and other mental health disorders (e.g. depression and post-traumatic stress) are at risk of suffering higher levels of anxiety during the outbreak of COVID-19 and may require more support or access to mental health treatment during this time.

The COVID-19 is associated with a psychological and epidemiological crisis. The mental health and well-being are seriously affected by many individuals while living in isolation. Job loss, changes in daily life, and hardships or distance from loved ones negatively affect a person's mind.

The following are the signs of different psychological disorders suffered by many individuals during COVID-19.

Anxiety during COVID-19

- Persistent anxiety or feeling overcome by emotion.
- Persistent worry and negative thoughts about different things such as financial and health problems.
- Restlessness and short temperament.
- Insomnia and lack of concentration.

The Panic attack during COVID-19

- Choking, excessive sweating, congestion, trembling and shortness of breath.
- Sudden terrifying behavior, rapid heart rate, and palpitations.
- Those who have panic disorders are sometimes apprehensive about the next event, which can lead them to alter or limit their usual activities.

Signs of depression during COVID-19

- No pleasure and lack of interest in daily activities.
- Change in eating habits leads to weight gain or loss.
- Sleep disturbance, excessive sleeping, or lack of sleep.
- Low energy and lack of concentration.
- Guilt feeling.
- Suicidal thoughts.

What can be done to alleviate the concerns of quarantine?

Isolation and quarantine are compulsory preventive measures in infectious disease outbreaks like COVID-19. In the quarantine time, the adverse psychological impact seems unsurprising, but there is proof that the psychological effect of quarantine may also be observed months or years afterward. Effective measures must be taken as a part of the isolation and quarantine planning process.

Increase communication level to decrease the boredom

Isolation and quarantine are compulsory preventive measures in infectious disease outbreaks like COVID-19. In the quarantine time, the adverse psychological impact seems unsurprising, but there is proof that the psychological effect of quarantine may also be observed months or years afterward. Effective measures must be taken as a part of the isolation and quarantine planning process.

Distress during isolation is caused by isolation and boredom. Different stress management techniques are used to stave off the boredom of people during the quarantined. In the current situation, it is a common perception that the use of a mobile phone is essential during quarantine.Your anxiety and long term distress can be treated by activating your social network as many psychological complications happen due to social-isolation. Providing social support, mobile phone, WiFi, cords, internet access, telephone to isolated or quarantined patients prove to be effective.

It is essential for patients to communicate with family and friends. Isolated patients can inform their loved ones about their health conditions. In this way, the stress, anxiety, and panic state of many patients have been reduced.

Provide clear information

It has been seen that the fear of infecting others is obvious in isolated or quarantined patients. It is a common experience reported by patients of infectious diseases. The public health officials didn't provide accurate and correct information to them that increases fear in them and increases the risk of psychological illness.

Providing correct information to the patients about isolation and their disease understanding on a priority basis to minimize the risk of psychological issues.

Serious psychological outcomes are obvious with a longer duration of isolation. Longer the duration higher would be the chances of psychological problems. The longer triggers increase the chances of anxiety and stress. By adopting proper precautions, the length of the isolation and quarantine can be restricted and it also helps to reduce the chances of psychological effects. The frustration of isolated patients can be minimized by reducing the length of isolation with the help of health authorities. The detrimental effects of psychological problems are reduced by reducing the incubation period.

About the author

Kushal Sachan is the author behind “corona and its effect on patients who go into isolation “. He besides spending time researching on topics of his interest is a Consultant Psychologist at Khetarpal Hospital, an elected associate of American Psychologist Association, certified diabetes educator from Indo Vietnam Medical Board and International Diabetes Federation (Europe), an Adjudicator for India book of records. Apart from this , he is also a co-founder and director of RWH Holistic Wellness and Research Foundation. His interest lies across multiple disciplines broadly addressing narratives of human experience which led him to delve into being a Senior Qualified Hypnotherapy Practitioner (SQHP) from General Hypnotherapy Register London and he is an alternative medicine practitioner in drug less therapies.

Kushal is a Registered Medical Practitioner in Natural Healthcare in India from British Government’s Complementary and Natural Healthcare Council (CNHC) London. He with his team is working towards the establishment of Complementary and Natural Healthcare Council in India with support of Ministry of Health and Family Welfare with a mission to establish a Universal Natural Healthcare Council Cum Training, Rehabilitation and Wellness Center that would provide all natural healthcare modalities (Asian, European, Americans, London etc.) under one roof.

Maintaining performance of test / calibration laboratory: Post COVID 19

Manjul Bhati
ERTL(North). STQC Directorate, New Delhi
Email : <manjula_bhati@yahoo.com

Abstract:

The corona virus endemic has shaken the entire world. The health, safety ,economy are worst affected. The laboratories and establishments have come to stand still. The paper describes how a test and calibration laboratory can continue to operate in current adverse circumstances.

Introduction:

After COVID 19 outbreak throughout the world, the operational strategy for most of the organisations is likely to be changed. The change may be for for betterment of the society.

Everyone is expected to deliver his/ her share of responsibility towards society for safe and healthy environment to live in and for building economically sound society.

This calls for change in working style for safety& health, still being productive as well as efficient . The need of the hour is to have staggered office timings and work from home as much as possible.

Paper describes, how a test / calibration laboratory , which operate in compliance to of a ISO/IEC 17025 standard, which undertake the testing / calibration of electrical equipment for customers and is open to all, may manage its functions to maintain its performance after COVID 19 outbreak lockdown.

Laboratory operations:

Being a test / calibration laboratory all it needs to operate and maintain accreditation broadly includes:

- Skilled and experienced manpower
- for acceptance of job from the customers (Job here shall include requirements for test / calibration plus the test /calibration item and service charges payment)
- for execution of jobs i. e test / calibration engineers
- Authorized signatories for review and final issue of test / calibration reports
- Quality manager to maintain accreditation and ensure that requirements ISO/IEC 17025, regulation bodies, accreditation bodies are effectively implemented.
- Reference standards, working standards, Test and measuring equipment etc. which shall be calibrated to carry out the testing / calibration of customer items.
- Adequate operating conditions (power supply, environment conditions etc.) as per the scope of working to enable test / calibration engineer to carry out the testing / calibration.

- Standard operating procedures which shall be validated and shall be elaborate enough to give the executor sufficient information for carrying out the specific test / calibration job.
- Controlled form and formats for collecting data, processing data and preparation of final test report calibration certificates.

Now one can segregate the activities that can be undertaken from home and those that need physical presence in laboratory. The major activities and their segregation are as follows :

Now one can segregate the activities that can be undertaken from home and those that need physical presence in laboratory. The major activities and their segregation are as follows :

(A) Job Related - Job acceptance, Job Execution & Issuing of test/calibration reports
Acceptance of job from the customers :

(a) Customers' Requirement for testing /calibration :
The sub activities include feasibility of undertaking job after accessing scope of laboratory, status of test and measuring equipment /reference standards, existing work load , availability of required manpower to carry out the specific testing /calibration and the service charges etc.
If provision is made that all queries for testing / calibration from the customers are to be made through email, this can be studied and with due communication with the concerned officials of laboratory, can be undertaken while working from home.

(b)Payment of testing / calibration service charges:
Provision for online payment by the customers to be made so that there is no hard cash exchange and physical presence of somebody is not required. Payment can be made by the customer from his location. Verification and confirmation of receipt of payment may be done by authorized official of the laboratory on line.

(c) Receiving Customer item for testing /calibration:
There may be separate area for keeping the received items which after due time interval while following all protocol like sanitizing the customer item, use of gloves and mask by dealing official, received items may be crossed checked for its condition, correct identification (nomenclature, make , model , serial number etc.) and working status.
For this sub activity some designated official needs to be physically present. Certainly the specific days of week and time slot for acceptance and verification of customer items may be fixed and communicated to customer at the time of acceptance of job.

Execution of job :
It is better to have as much as possible, automated test / calibration set ups. Keeping in mind the workload and skill level required, a duty roaster may be made with segregated working hours for the officials expected to carryout the received test / calibration jobs. The authorized signatory needs to supervise the activity. For this physical presence of both is required. Provision for online storage of raw data may be made, so that, when needed for cross verification and preparation of test report / calibration certificate, it is readily available,

Maintaining operating conditions (environmental and power supply etc) :
Different test / calibration call for specific operating conditions for carrying out testing / calibration. The sub activities related to award of contracts for maintenance, placing purchase of some material etc. can be undertaking while working from home, but of course recording and maintaining the required conditions in laboratory do require physical presence of concerned official.

Preparation and transmission of test report / calibration certificate :
To facilitate preparation and transmission of final test reports /calibration certificates, the on line stored raw data collected while execution of job, controlled test report formats/ calibration certificate formats to be used may also be on line so that while working from home this activity can be undertaken.

Preparation and transmission of test report / calibration certificate :
To facilitate preparation and transmission of final test reports /calibration certificates, the on line stored raw data collected while execution of job, controlled test report formats/ calibration certificate formats to be used may also be on line so that while working from home this activity can be undertaken.

(B)Calibration of reference standards/ Test and measuring laboratory equipment from some other laboratory having better CMC
This is the foremost requirement that the laboratory reference standards, test and measuring equipment of laboratory must be calibrated. Again all the correspondence with the calibration laboratory from whom the laboratory wants to get its reference standards/ test and measuring equipment, calibrated including payment of calibration service charges may be done from home by the designated official. For sending the own reference standards / test & measuring equipment,due packaging by own official or courier agency to be ensured.
Of course for handing over and receiving back laboratory own reference standards/ test and measuring equipment, presence of some designated official is required. He may or may not be the same official who has been given the responsibility of accepting customer items.
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(C) Maintaining accreditation
The major sub activities for maintaining accreditation include :
External and Internal audits:
Not all the aspects of audit, whether internal or external, can be addressed through remote auditing. For certain aspects specially related to testing / calibration execution, do require physical presence of audits and auditors. Further not all but some follow up actions for ensuring effective closure of Non conformances, depending upon the non conformance, physical presence of all concerned officials, may be required.

Management Review Meetings :
Management Review Meeting which may be conducted through video conferencing. Follow up of action points, if any, may or may not require physical presence in laboratory, depending on action point.

Feedback Analysis :
Customer and laboratory personnel feedback analysis and follow up for action points, if any. With the provision of on line submission or acceptance of feedback, the analysis may be done while working from home. The follow up action for some cases may invite for physical presence of certain officials.
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Customer Complaints Analysis:
With provision of on line (through emails etc.) submission of any complaint, analysis process can be taken while working from home. Certain situations may call for physical presence of concerned officials in laboratory, for verification.

Submission of applications to accreditations bodies:
This activity includes compilation and collating information. With proper on line communication, this can be undertaken from home by the designated official.

Internal Surveillances :
As a good practice, quality manager may conduct regular internal surveillance to ensure proper implementation of requirements of IEC 17025, accreditation body, regulatory bodies and that of customer. Some such internal surveillance may call for physical presence of the designated officials.

Ensuring availability of Controlled documents:
Provision may be made so that the Standard operating procedures, all forms and formats, the quality Manual, the Executive Procedures etc. i.e all controlled documents are available on line for access by the concerned officials at any point of time for reference or use to carry out their assigned duties, whether they are in office or are working from home. Access rights may be defined for all documents.

Thus for maintaining accreditation and quality manager role, not all, but many sub activities under this activity can be undertaken from home.

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(D) Administrative work
Besides these technical activities there are many administrative activities which are required to run any organization. Here too activities can be categorized which can be taken up while working from home like preparing , processing and making payments for employees salaries and other bills, suppliers' bills, utilities services bills, filing GST etc.

Conclusion : By and large it can be interpreted that a test / calibration laboratory can work with better efficiency while allowing some activities from home while cutting down on their running cost. What is required, is to go online for your activities, both technical as well as administrative to the extend possible, so that all required data for undertaking any assigned responsibility is available to the concerned official at any stage of time, because many sub activities specially related to compiling and collating information which can be undertaken from home, may be done by the concerned official at any time of the day or night.

But at the same time , it is very important to have secure on line platform for exchange of information within laboratory officials as well as for data transmission to and from customers /suppliers etc.

The outbreak of COVID 19has taught the society to remain connected while staying at home and working efficiently for a healthy and safe society which is economically sound too.

Author

Manjula Bhati

Manjula Bhati, Scientist 'F', Group Head of Quality Assurance Division and Customer Service Cell of the Electronics Regional Test Laboratory (North), STQC Directorate, New Delhi. which is a test and calibration laboratory under the Ministry of Electronics and IT. Bhati also worked as the laboratory's technical assessor for IECEE-CB and qualified lead assessor for ISO 9001. She has 35 years of experience in component testing, electromagnetic compatibility testing, customer relations management, and quality assurance. Bhati is the author of many articles published in national and international magazines. She is a graduate engineer in electronics and communication engineering