

**CLINICAL TRIALS AVAILABLE FOR TESTING CORONAVIRUS (COVID-19)**

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**ABSTRACT**

The corona virus (COVID19) is know spreading rapidly across the whole India. It's emergence highly pathogenic. Since last month India is stricken the pandemic corona virus and our researchers are working hard to find a cure for it. Many of scientists successfully developed various types of testing methods. Having this number of diagnostic tests available to detect a single virus in such a short time frame is never having before. However, the adoption of business kits for testing ought to be supported validations conducted by the ICMR, National Institute of Virology (NIV) of Pune and by the Food and drug administration (FAD), Central Drugs Standard Control Organization (CDSCO), etc. In this review, we compared variety of tests methods which are certified and are used to detect corona virus along with their costing, advantages and drawbacks. Doing these review is a hope to help the citizens of nation to recognize testing techniques, costing and which gives faster result and providing a reference for future studies.

**KEYWORDS:** Covid19, Clinical trials, Diagnostic tests.

**INTRODUCTION**

Since the novel corona virus tour through China in Gregorian calendar month, then researchers and doctors quickly launched dozens of clinical trials to check existing medications against COVID 19, the unwell ness caused by the novel corona virus. At this point, there aren't any specific vaccines or treatments for Covid19. However, there are several current clinical trials had been launched. These clinical shows complex early detection of infected cases, particularly against a background of current respiratory disease, and circulation of alternative metabolism viruses.

**Entry, replication and antiviral drugs**

Closed contact of humans is a likely route for spreading Covid 19 infection. Infection of host cells by Covid19 is expressed by the interaction of the viral spike (S) protein with receptors on the cell surface; this is an often a necessary step for genome replication. Spike (S) protein of corona virus (CoV) is accountable for entry events.<sup>[1][2]</sup> The entry pathway of Covid19 might influence the severity of the sickness. Corona virus made up of a positive-sense, single-stranded RNA genome. Viral RNA synthesis follows the translation and assembly of the viral replicase complexes. RNA's translation happens within the endoplasmic reticulum. There is No

specific antiviral treatment suggested for COVID 19. Protozoal infection medicine anti-inflammatory drug and antimalarial, Hydroxychloroquine and chloroquine are beneath investigation in clinical trials for pre-exposure or post-exposure prophylaxis of Covid19 infection, and treatment of patients with gentle, moderate, and severe COVID-19.

**Diagnostic tests**

**1) Fast diagnostic assay (qRT PCR test)**

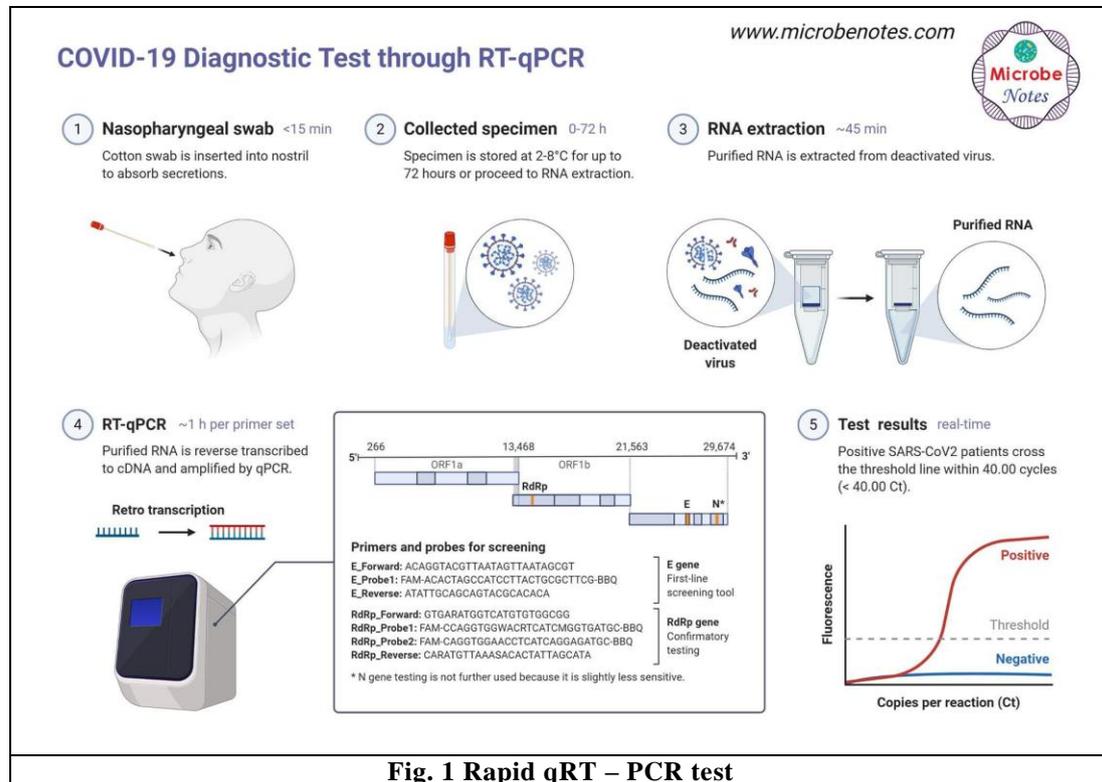
The quantitative reverse transcription enzyme chain reaction (qRT PCR) test for Covid19 is presently done on viral genetic material form nose and throat swabs from a suspect. COVID-19 RT-PCR test is meant to be used by trained clinical laboratory personnel specifically instructed and trained within the techniques of RT PCR and in vitro diagnostic procedures.<sup>[9]</sup> Many biotechnology companies like Roche Diagnostics, LabCorp and Thermo Fisher Scientific are among the top suppliers of commercial corona virus RT-PCR kits. Thermo Fisher Scientific TaqPath COVID-19 Multiplex Diagnostic Solution that got FDA approved for EUA on March 13 and received authorization for use in Europe on March 21. The kit enables testing at clinical and public health laboratories. The first Indian kit for Covid19 developed by a "Mylab discovery solutions Pvt Ltd." Pune and it has received business approval

from the Indian FDA/ central medication commonplace management organization (CDSCO).<sup>[7]</sup> The RT-PCR technology may be a fairly costly method.<sup>[8]</sup>

### How can it work ?

The above test works by amplifying a selected genetic sequence within the virus. Short complementary

sequence called primers facilitate to urge the repetition started. If it shares an equivalent genetic sequence as SARS-CoV-2 virus, then it's deemed positive. RT-PCR tests detected it properly 71% of the time.<sup>[5]</sup> And results given for bushed in under two hours Or 2 1/2 hours.



**Fig. 1 Rapid qRT – PCR test**

## 2) Antibody test

Another approach relies on identifying antibodies to the corona virus in a patient's bloodstream to determine whether that person previously had COVID-19. An antibody test, also known as a 'serology test' or 'rapid antibody blood test' for COVID19. The first test for corona virus that measures antibodies in the blood, developed by Cellex, has been authorized by the U.S. Food and Drug Administration (FDA).<sup>[12]</sup> The serological test—which uses a finger prick of blood and a small strip, similar to a combination of a blood glucose test and a home pregnancy test kit—detects two different types of antibodies produced by the body to fight off the infection.

### How the tests detect corona virus?

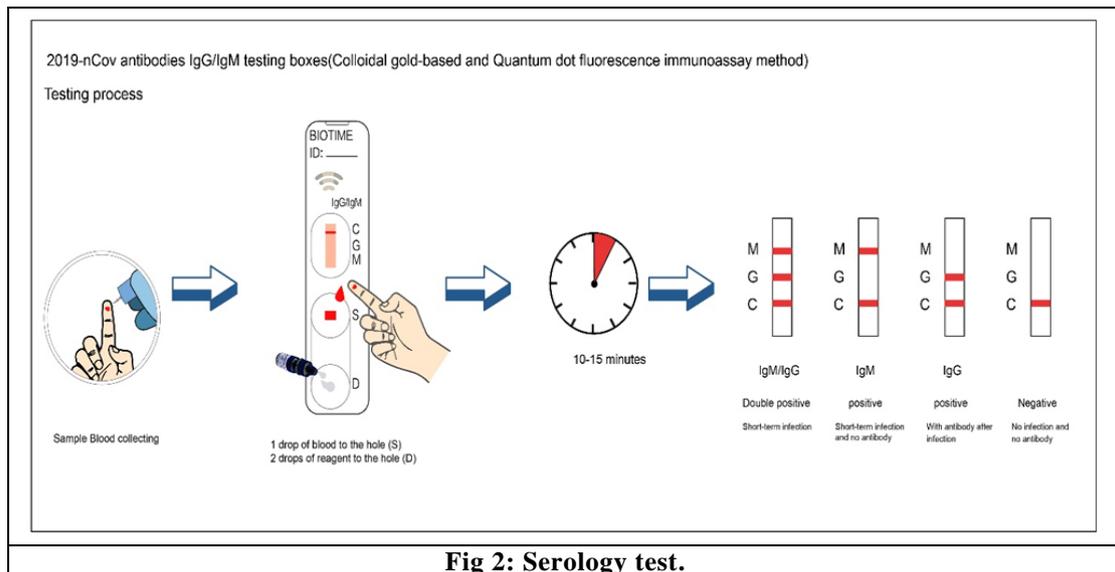
There are two antibodies in the blood which the test looks for, the antibody IgG and IgM. The body has memory cells, so that the body will be able to attack if the same pathogen is exposed again is through antibodies.

IgM appears within several days of the infection, and they are the first line of defence.<sup>[10]</sup>

Because the body starts to clear the infection later, the IgG antibodies seems. During this case, through a technique like ELISA (enzyme-linked immunosorbent assay), clinicians explore for antibodies that were created in response to the large protein that sticks out of the corona virus's surface.

A Covid19 fragment is placed on a plate. If there's an antibody within the patient sample, it'll attach to this "spike" protein. After they bind, the new antibody can activate an enzyme that changes the color of the solution, indicating that the patient has the antibodies we're searching for, and thus been exposed to the corona virus.

Usually, it takes around 15-30 minutes to allow the result.<sup>[11]</sup>



### 3) Abbott's test

The Food and drug Administration has approved a test by Abbott Labs that use isothermal nucleic acid amplification technology rather than PCR. The test runs on Abbott's ID NOW device, that is regarding the dimensions of the toaster. Abbott test—like the gold commonplace COVID-19 test developed by the U.S. government. Throughout this device, uses chemicals to shatter the virus' outer shell, so, it spills out its genetic material, in the form of RNA (ribonucleic acid). Chemical reactions then amplify that genetic material therefore, special molecular probes in the test solution will acquire even tiny amounts of virus. That's where the fast test differs from the others in use right now; With the normal technology that amplification method requires repeatedly cycling the temperature of the chemical reactions from low to medium to high and back down

again. The ID NOW device can perform the genetic expansion at a constant temperature, which suggests it will spit out results a lot of quickly.

#### How the technology works?

1. A nasal or throat swab is mixed with a chemical solution, breaking open the virus and release its genetic material
2. The mixture is inserted into Abbott's ID Now system, which weighs three.18 kg
3. The technology identifies and amplifies choose sequences of the COVID19 genome and ignores contamination from alternative viruses
4. A positive test result takes as very little as 5 minutes, whereas a negative result to definitively rule out associate degree infection will take up to thirteen minutes.<sup>[18, 19]</sup>



**Fig. 3: Abbott's ID now device.**

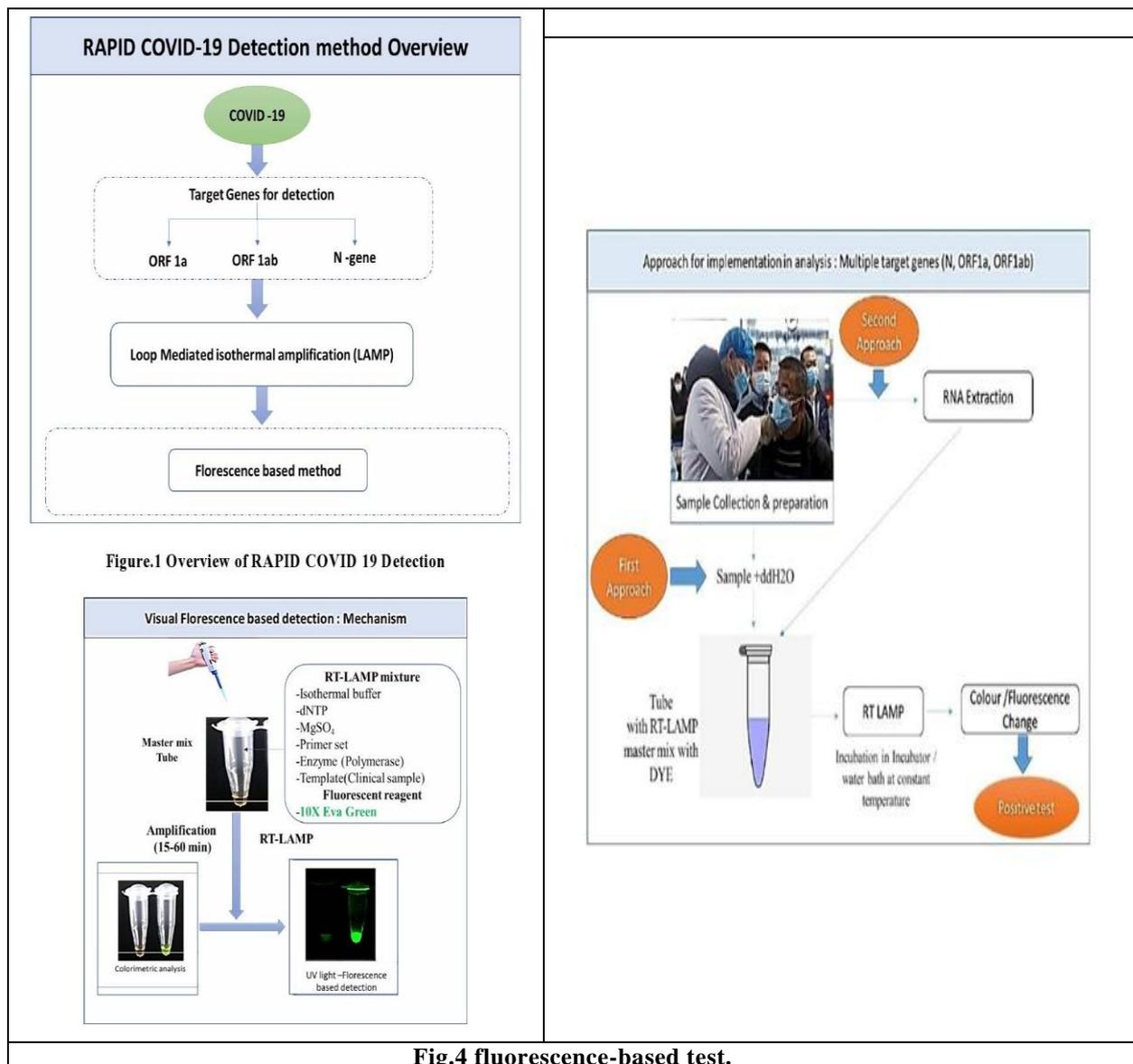
#### 4) Fluorescence based test

Rapid onsite detection kit for Covid19 with a fast, modest, straightforward to use and climbable technique supported color modification for corona virus detection. Developed by ICT Mumbai Ph.D. student Jayesh Mevada. The strategy relies on “Loop Mediate Isothermal Amplification” (LAMP) and quantitative chemical analysis detection employing a hydrogen ion concentration (pH) indicating dye. Hence, the kit would offer an identification in a small compact kit will be used for First level purpose of care detection. It's the capability to relinquish leads to an awfully short time (estimated time within 1h), compared to this technique getting used. Now they are hoping for ICMR validation and certification.<sup>[13]</sup>

#### How does it work?

Firstly, gene selection is carried out for diagnosis of Covid19 are N- gene and Orf1a and Orf1ab based on LAMP method.

Visual color detection or fluorescence-based detection system used. Fluorescence is used when amplification is not enough due to the other protein present in the sample. For which needs an extracted RNA, so they also developed paper-based chromatography which can easily couple above system. No required expensive lab facility, quick implementation and extensible possible.



#### 5) paper-strip test

At Delhi, CSIR-IGIB lab —Scientists Dr. Souvik Maiti and Dr. Debjyoti Chakraborty have successfully developed a cheap (among a merely Rs.500) and

named, ‘Feluda’ — FNCAS9 Editor Linked Uniform Detection Assay (Feluda), simply called as paper-strip test to detect COVID-19 within an hour. And India’s urgent want for rapid-testing can be met with

this kit. A combination of the paper strip chemistry and Crispr-Cas9 technique — a cutting-edge gene-editing tool- to test COVID-19 in the samples of suspected of us. Paper-strip test, targets, and determined the genomic sequences of the

COVID-19. It does not want any varied specific skills or skills to hold out the testing and is fairly less-sophisticated. However, they're hoping to hunt validation from the restrictive body of the ICMR.<sup>[14]</sup>



**Fig 5: Paper strip test.**

#### How much will it cost?

An antibody test for corona virus antibodies be much less expensive than a rapid PCR test that search for corona virus genetic material. California-based Biomerica, as an example, sells a serological test for fewer than \$10. A PCR test for covid-19 will price up to \$51 beneath Medicare.<sup>[11]</sup>

In India, Under the existing PCR test, in private labs, the government has already placed a cap of Rs 4,500 for Covid-19 test. This includes Rs 1,500 for a screening test for suspect cases, and a further Rs 3,000 as confirmation charges. Rapid onsite detection kit is obtainability at a fraction of price estimated is a smaller amount than 300INR per test. And Blood testing kits are coast between Rs 2,000-3,000 depending on their accessibility and supply.<sup>[17]</sup>

#### CONCLUSION

The COVID-19 virus outbreak has challenged the medical and public health infrastructure of entire countries. While the epidemic is growing exponentially, the health-care system will face severe burdens. In this dangerous situation our researchers, scientists, doctors, and every one the people from the medical trade nonetheless work hard to find more solutions. Currently, it's easier to check the corona virus on above techniques. There has been a rapid rush in research in response to the pandemic event of COVID-19. Therefore, development of new research ways and standards to learn from and improve upon the global response.

But Clinical trials, and evaluations of affordable and implementable interventions of all types behavioural,

organizational, medical, and supportive—are our priority.

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