



## **CONSULTANCY SERVICES FOR CORONAVIRUS LAB SET UP: DIAGNOSTICS ONLY**

### **Background and need of the lab**

Since December 2019, after outbreak in Wuhan China, transmission of the virus started in various countries and most of the countries are now affected by Coronavirus 2.0. World health organization (WHO) suggested for more and more testing so that infected person can be diagnosed and isolated, suspected contacts can be quarantined and all affected cases of COVID19 can be admitted in designated hospitals for better treatment and management. As the asymptomatic cases carrying viruses transmits the viruses before they themselves comes to known that they are affected, it's too late. As on April 17, 2020 total affected population of the World is more than 22 lakhs, with more than 1.5 lakhs deaths. Out of the declared status of outcome of around 7.14 lakhs population, 21% died and 79% recovered.

As on today i.e. April 17, 2020, status of COVID19: Total confirmed cases in India 14229 (exactly doubled in 5 days) and 479 deaths (nearly doubled in 5 days). Most of the death cases are in the state of Maharashtra. Due to huge population size and population density, after European countries and USA, India may get badly affected and current hot spot status in few places may severely transformed into stage 3 i.e. community spread. To avoid this, India needs to ramp up testing from 16000 per day to at least 100000 per day or more. At present, more than 250 labs are doing tests in India and majority of them are Government medical colleges, regional viral diagnostics and research labs including ICMR designated lab in Pune and few private labs throughout India. It's a social responsibility of all competent authorities, civil societies including private science and medical colleges who have the facilities or at least infrastructure or lab space, should propose their contribution for increasing the testing capability of the Indians for larger public interest.

### **BSL2 lab and viral diagnostics**

Virus genome is around 29 Kb and four important genes were proposed and advised by WHO. These are RdRp, N gene, E gene and S gene. Real time PCR using any two genes are considered as gold standard for confirmatory diagnosis of Coronavirus 2.0 i.e. COVID19. Reagents and kits are readily available and it requires BSL2 lab for viral RNA isolation. But if the samples are inactivated at the source of collections, its risk of infections is minimized to zero in the lab if only denatured virus samples are brought to diagnostics lab, where only RNA extraction followed by Real Time PCR needs to be done. Even though in next few weeks or next month rapid tests come in the market for IgG and IgM testing, it needs to be confirmed by Real Time PCR in designated labs.

Main component of BSL2 lab for viral diagnostics is, workflow should be unidirectional. Devoted lab space should be available: Total area may require around 2000 sq. ft. open built up space on second or third floor. All water and electricity connections should be separate from common facilities, with separate electric back up for HVAC unit. Effluent treatment plant should be below the level of actual lab space i.e.



if lab is on 3<sup>rd</sup> floor, ETP should be on 2<sup>nd</sup> floor and HVAC on 4<sup>th</sup> floor. (Extra precaution for ETP should be consider while designing BSL2 diagnostic lab for novel Coronavirus, although standard practices are same like any other BSL2 lab for any BSL2 level diagnostic labs). Following space requirement is advised: However, all these can be on single floor, as the live virus will not handled here.

1. Sample storage and cataloging lab (100 sq. ft.)
2. DNA / RNA isolation lab (150 sq. ft.)
3. Washing room lab (150 sq. ft)
4. Master mix preparation lab (100 sq. ft.)
5. RNA template and Master mix mixing lab (150 sq. ft.)
6. Instrumentation lab 1 Real Time PCR instrument (100 sq. ft.)
7. Instrumentation lab 2 PCR and Gel electrophoresis (100 sq. ft.)
8. Reporting lab (100 sq. ft.)
9. Meeting room / small conference hall (500 sq. ft.)
10. Pantry (200 sq. ft)
11. Wash rooms, separate for male and female (200 sq. ft)

Following lab staff should be available to start BSL2 Real Time PCR lab for viral diagnostics. However, to speed up work for per day screening staff and machineries can be expanded to double in the same space. Real time PCR and automated DNA RNA extraction systems are among the first to double. To start with minimum set up, following minimum staff is highly advised.

1. BSL2 in charge (PhD Post Doc with Molecular Virology experience 5 to 10 years)
2. DNA RNA extraction R.A. x 2 (M.Sc. Biotech/Virology 2 years' experience)
3. Master mix preparation and PCR R.A. x 2 (M.Sc. Biotech/Virology 2 years' experience)
4. Results analysis and reporting R.A. x 1 (M.Sc. Biotech/Virology 2 years' experience)
5. Lab attendant / delivery boy (12<sup>th</sup> pass)
6. Office assistant / computer operator (Graduate with MS office and good typing speed) x 1
7. For more output i.e. number of testing per day, few equipments and more staff is required.

#### **Instrumentation required**

1. Real Time PCR Thermal Cycler
2. Automated DNA RNA extraction system
3. Refrigerated Centrifuge machine 4 °C
4. Deep freezer -80 °C x 2
5. Deep freeze r -20 °C x 2
6. Normal Refrigerator 2 to 8 °C x 2
7. Spectrophotometer /Nanodrop / Fluorometer kit for RNA DNA estimation
8. MiliQ water and / or Double Distillation plant
9. Thermal Cycler Gradient PCR machine
10. Submarine Gel electrophoresis system



11. Compatible PC with antivirus office 2016 and internet x 5
12. Dry bath 0.2 ml / 1.5 ml and Dry bath 1.5 ml / 15 ml / 50 ml
13. Hot air Oven
14. Autoclaves
15. All lab furniture, all general furniture e.g. chairs in reception hall should be in 304 grade SS only
16. Other lab accessories and minor instruments including Plasticwares and Glassware's
17. Bacterial incubator
18. Biosafety cabinets A2 x 4
19. Laminar air flow x 1
20. Gel documentation system with PCR and software
21. Kits and reagents
22. HVAC
23. UPS 2 KVA x 2 for 2 hours back up for Real Time PCR
24. Sensor based water tap
25. ETP separate for BSL2 labs
26. Separate DG for HVAC and all necessary equipment which required UPS or minimum UPS backup for all necessary equipment including deep freezers and computers

Along with infrastructure, instruments, consumables, and human resource including office and skilled lab staff, establishing institute should keep readiness with Lab biosafety committee, Scientific Advisory committee, Biowaste handling SOP, Sample barcoding, and SOP for all steps from sample receipt to results reporting. While considering HVAC for BSL2 level diagnostic labs, recirculated air is required, system / areas segregation is recommended, interlocked supply, return, and exhaust system to ensure negative airflow is recommended, negative room pressure is recommended, alarmed positive room pressure is recommended.

Estimated budget Govt. of India should give in the form of grant under COVID19 funding for establishing BSL2 level lab. Other charges can be contributed by host institute for internal construction work, lab space, interior, electricity and water. Salary of lab staff and running cost including maintenance and kits and reagents can be availed from central govt funding.

We provide all types of consultancy and turn key project for lab set up in virology and genetics. Contribution in developing virology facilities for diagnostics i.e. BSL2 and for drug testing BSL3 is required. With expertise in molecular diagnostics and genomics and equally supported by expert scientific advisors, we provide not only initial setup but also helps in skill development, scale up of number of sample testing, protocol troubleshooting and suggestions for first year of initial lab set up, as a turn key basis project completion. All staff of molecular diagnostic requires workshop and further knowledge enhancing. With our virology and molecular diagnostics expertise, we are committed to serve our client, so that by providing our domain knowledge in virology and molecular diagnostics, society at large gets benefitted.

Best wishes.

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