



## Background and need of more COVID19 testing 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 know that they are affected, it's too late.

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 for the 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 ORF, 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, if live virus isolation is not required, where only RNA extraction followed by Real Time PCR needs to be done. Although rapid kits are in the market, it needs to be confirmed by Real Time PCR in designated labs, NABL accredited and ICMR certified.

## IDEAL LAB SPACE

Main component of BSL2 lab for viral diagnostics is, workflow should be unidirectional. Devoted lab space should be available: Total area may require around 1500 to 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 should not be handled here. In resource poor countries too, biosafety standards should be followed as per WHO and CDC norms.

1. Sample Processing, storage and cataloging lab (100 sq. ft.)
2. DNA / RNA isolation lab (200 sq. ft.)
3. Washing room lab (150 sq. ft)
4. Master mix preparation lab (100 sq. ft.)

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5. RNA template and Master mix lab (150 sq. ft.)
6. Instrumentation lab 1 Real Time PCR instrument (150 sq. ft.)
7. Instrumentation lab 2 PCR and Gel electrophoresis (100 sq. ft.) (Not required for COVID19 testing)
8. Reporting lab (100 sq. ft.) (for staff)
9. Meeting room / small conference hall (500 sq. ft.) (Optional)
10. Pantry (200 sq. ft.) (Optional, should be away from any of the COVID19 lab)
11. Wash rooms, separate for male and female (200 sq. ft) (for staff)

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. **Number of sample testing capacity can be increased with additional staff in the future and more space for few key instruments i.e. automated Nucleic acid extraction systems and Real Time PCR machines. So, RNA extraction lab and Instrumentation lab i.e. RTPCR lab space should be designed with the vision of increasing sample load in future.**

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:**

**(For COVID19 only Real Time PCR is recommended. Other facilities are mentioned only for general BSL2 lab, if same lab will be used for training medical students once pandemic is over)**

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 (Not required for COVID19, but for future use post COVID19)
10. Submarine Gel electrophoresis system
11. Compatible PC with antivirus office 2016 and internet x 5

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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 (Not required for COVID19, but for Post COVID19 for R&D lab it may require)
21. Kits and reagents
22. HVAC (at least in the sample processing lab and RNA extraction lab, if possible)
23. UPS 5 KVA hours back up for automated RNA extraction systems and 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 (medical college / self-sponsored NGOs) 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.

### ***Completed work: Before and during COVID19 Pandemic***

1. GMC Baramati Dist. Pune INDIA BSL2 900 sq. ft. (started in April 2020 and completed in May 2020)
2. SSLS Pune INDIA BSL2+ 4000 sq. ft. lab design, business model, till recruitment (2019)
3. Advisor to ANABIO Bengaluru INDIA for BSL2 lab for model Coronavirus 229E cultivation (July 2020)
4. Onsite visit and online guidance by skype/ Microsoft team/ Zoom. (work from home/only online)

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Our Other services on COVID19

Clinical Trials as CRO and C-Lab

Antiviral studies BSL2: 229E or Beta Coronavirus (Model viruses)

Antiviral studies BSL3: COVID19 (Actual SARS 2 Coronavirus)

Documentation services for Diagnostic Kits

School screening for COVID19 before reopening of schools

SOP and guidance for Schools on special request

Import Export on COVID19 drugs and diagnostic kits

Smart Biotechnologies for COVID19

Technical and Virology Consultant

Free guidance on: [How to stay fit during pandemic?](#)