

Environmental and Health Risk Management Plan (EHRMP)

Mylabs Discoverysolutions Private Limited

Proposal entitled: To scale up manufacturing of PathoDetect 2019-nCoV Detection Kit rapidly to meet the current demand in India during National Crisis

(i) Brief description of the proposed activity : We are manufacturing RT PCR Kits for Covid and other Bio molecular diagnostic Kits in the facility				
(ii) List of environment related regulatory clearances required for the activity. Pollution control Board				
Institutional Arrangement				
Area of Risk	Yes	No	Details	Proposed Plan
1. Is there a designated full-time staff for Environment Health and Safety (EHS) issues?		No		We are in process to hire the full time staff for EHS by end of FY 2021 The concerned staff will be employees as per requirement and trained on the Environment Health and Safety (EHS) and will comply with the norms and EHS requirements during the Project.
2. Does the EHS staff handle the following?				We are planning to hire the personnel who would have the skill sets of helping us with the responsibilities mentioned. We do not have any effluents disposal On consents and regulatory for product development will be done by inhouse team We will comply to Environment
Occupational Health and Safety		No	We have SOP's for accidents and procedures	
Waste Management		No		
List of consents and regulatory clearances	Yes			
Record keeping of accidents and procedures	Yes			
EHS trainings for staff		No		
Environment Management Framework compliance for Innovate in India Project		No		

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					Management Framework for compliance for Innovate in India Project.
3.	Is there a reporting structure in place regarding EHS issues?		No	Describe: (When we hire the personnel)	We would like the person to report to the Board if any issues found on EHS matters SOPs and formats to record any incidents and EHS issues will be structured as a part of EHS policy.
4.	Are regular EHS trainings provided to staff?		No	Frequency: (When we hire the personnel)	We are planning to have training every quarter across various departments Training calendars shall be prepared for employees. Training will be provided as and when required to all the existing as well as newly recruited staffs
5.	Institutional Bio-Safety Committee (IBSC)		No		Will be constituted as and when required for this project.
6.	Ethics Committee (EC)		No		Not required for the said project. However, all the necessary requisite approvals will be taken as per regulatory norms.
General Occupational Health and Safety					
	Area of Risk	Yes	No	Details	Proposed Plan

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7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	Yes		We have the SOP in place	SOPs and protocols will be maintained for any new activity included in the work.
8.	Are the following in place?			None of the substance use are of hazardous in nature All the basic emergency first aid tools are in office All are located at strategic locations for easy accessibility	Equipments in place will be checked, monitored, replaced and maintained well through out the project.
	Chemical spill kits		No		
	Eye wash		No		
	Shower stations		No		
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			
9.	Are proper signage and storage system in place?	Yes		As a GMP we maintain the MSDS The Emergency safety flyers with all the relevant contact number are displayed in all the working area	Facilities will be upgraded with the activities increased.
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes			
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	Yes			
	Signage across the facility (labs, storage, hazardous areas, etc.)	Yes			
	Are flammable materials appropriately stored to prevent fire hazards?	Yes		All details are printed on a sheet with visible fonts size and placed located at strategic locations for easy accessibility and readability	
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	Yes		Smoke Detector : 29 Fire Alaram: 01 Automatic Safety/shutoff	Maintenance for each item is done on monthly basis. Facilities will be

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				systems: 01	maintained and upgraded with the activities increased.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		No		We will install them as and when we require Preventive measures with all precautions will be put in place as and when required during the project.
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): Monthly once	Will ensure that this process will be regularly followed.
13.	Are staff provided with OHS training?	Yes		Describe: We do it every Quarter (internet)	Will ensure that this training is incorporated as a regular process.
Biomedical Waste (BMW) (Minal)					
	Area of Risk	Yes	No	Details	Proposed Plan
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes		list of biomedical waste produced in the facility (Glove, Mask, Consumables including micro-centrifuge tubes, micro-tips etc. Viral transport media, cotton)	BMW generated will be treated adhering to Bio-Medical Waste Management Rules, 2016.
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes		The present technical 15 team are trained for Biomedical Waste	Regular training and review will be done for the staff involved in this.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		Already uploaded during Grant application	Authorisations will be renewed from Time to time.
17.	Is the biomedical waste segregated at point	Yes		Yellow Contaminat	This is an ongoing

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	of generation in the facility and stored in suitable containers?			ed Consumables including micro-centrifuge tubes, micro-tips etc. Viral transport media and cotton	process which will be followed throughout the Project.
			Red	Gloves, mask, plastic ware	
			White	Waste sharp if any	
			Blue	NA	
18.	Is the bar code system for the segregated waste in place?	Yes		PASCO has given us the barcodes	Will follow the bar code system
19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes		Name and address of CBMWF: PMC site office: Kailash Crematorium compound, Next to Naidu Hospital, Pune 411001 Distance from facility: Around 13 km Frequency and Mode of transport: Weekly once; by road	Will continue this process and agreement with authorized facility will be renewed from time to time.

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				Who transports? Person from BMW facility visits Mylab laboratory for waste collection	
20.	Does the grantee have an in-house BMW treatment facility?		No	biomedical waste being sent to an authorized BMW facility	
	Is the treatment facility own (individual)?		No		
	Is the treatment facility a shared facility in an industrial park?		No		
21.	Are lab waste, microbiological waste and chemical liquid waste pre-treated before storing and sending to treatment facilities according to guidelines prescribed in BWM, 2016 regulations?	Yes		Types of treatment: 1% Sodium hypochlorite treatment and autoclaving	Will be done as per BWM 2016.
22.	Is the liquid waste checked for active cells before sending to treatment plant?		No		Routine checks will be done.
23.	Are necessary waste pre-treatment equipment in place?	Yes		List of equipment (autoclaves, shredders, incinerators, etc.): Only Autoclave Details of waste pre-treatment:	Regular monitoring shall be done.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes			
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes			chlorinated plastic gloves and bags will not be utilized
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Frequency: Yes every quarter Trainer: Minali Dakhave	This will be a regular process during the project.

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26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?		No	Frequency of medical examination:ann ually	We are planning to get examined from December onwards
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		We have register for the same	Will continue this activity
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		No		Timely submission will be done as per PCB norms.
Hazardous Waste (HW)					
	Area of Risk	Yes	No	Details	Proposed Plan
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?		No		If any hazardous waste is generated as per rules it will be handled and disposed.
30.	Is there trained staff in the facility to identify and handle hazardous waste?		No	In our activity we do not generate the Hazardous waste	As and when required a separate staff will be recruited and trained to treat and handle the hazardous wastes.
31.	Does the grantee have authorization from SPCB for hazardous waste?		No	In our activity we do not generate the Hazardous waste	Necessary Authorizations will be taken if required.
32.	Is there a secure location for storage of HW with proper signage?		No	In our activity we do not generate the Hazardous waste	We will arrange proper storage facilities when required
	Are hazardous waste stored for more than 90 days in the grantee's premises?		No		
33.	Is the hazardous being send to an authorized disposal facility or user?		No	In our activity we do not generate the Hazardous waste	
	Is the disposal facility in house?		No		
	Is the disposal facility external/outsourced?		No		
34.	Is a register maintained on production and treatment, and a manifest system followed for transport of hazardous waste from the grantee to treatment		No	In our activity we do not generate the Hazardous waste	We will maintain the register when required

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	facility?				
E-Waste and Batteries					
	Area of Risk	Yes	No	Details	Proposed Plan
35.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?		No	In our activity we do not generate the E-Waste and Batteries	Essential measures will be taken as and when the need arises during the project.
36.	Has the grantee obtained SPCB authorization on e-waste?		No	In our activity we do not generate the E-Waste and Batteries	Necessary Authorizations will be taken if required.
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?		No	In our activity we do not generate the E-Waste and Batteries	As and when the need arises proper system will be put in place during the project.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	In our activity we do not generate the E-Waste and Batteries	Will Ensure that a proper ERP system is put in place as and when required.
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No	In our activity we do not generate the E-Waste and Batteries	We do not use hazardous substances and are not involved in manufacturing of electrical and electronic equipment or its part.
40.	Does the grantee provide detailed information on the constituents of the equipment and their components/spares and declaration of conformation to Reduction in Hazardous Substances in the product user documentation?		No	In our activity we do not generate the E-Waste and Batteries	We do not use hazardous substances and are not involved in manufacturing of electrical and electronic equipment or its part
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		No	In our activity we do not generate the E-Waste and Batteries	We do not deal with the manufacturing, sale or collection of electronic or electrical items and do not foresee any e-waste in

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					near future. But if the case, will do the needful.
42.	Does the grantee submit annual reports on e-waste to SPCB?		No	In our activity we do not generate the E-Waste and Batteries	We do not foresee any e-waste in near future. But if the case, will do the needful.
43.	Is there accident reporting and records in place?		No	In our activity we do not generate the E-Waste and Batteries	The system is in place, however no incident has happened and hence recorded yet
44.	Are PPEs available to staff?		No	In our activity we do not generate the E-Waste and Batteries	The stock status of PPE will be regularly monitored and if, required procurement will be done on time.
45.	Is the grantee involved in manufacture of batteries?		No	In our activity we do not generate the E-Waste and Batteries	We do not deal with manufacturing, sale or collection of batteries.
46.	Does the grantee generate battery waste?		No	In our activity we do not generate the E-Waste and Batteries	We do not deal with manufacturing, sale or collection of batteries.
47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/ collection center?		No	In our activity we do not generate the E-Waste and Batteries	We do not foresee any battery-waste in near future. But if the case arises in future, will do the needful.
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		No	In our activity we do not generate the E-Waste and Batteries	We do not deal with manufacturing, sale or collection of batteries.
Community Health and Safety and risk mitigation					
		Yes	No	Details	Proposed Plan
49.	Safety Transportation Management System (for transport Of hazardous material)		No		Will follow the safety transport management system if required
50.	Emergency preparedness and participation of local authorities and potentially affected communities		No		Will develop the emergency

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					preparedness plan if required
Other					
	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No		we don't use radioactive material
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No		If we use, then we will arrange for proper storage and disposal
	Are radioactive warning signs in place?		No		Will be implemented if required
52.	Is the lab/room air regularly checked for microbial contamination?		No		Will be implemented if required Periodic checks will be done if required
53.	Are there any odor control measures in place?		No		Periodic checks will be done preventive measures will be taken if required
54.	Are fume hoods and exhausts regularly checked and maintained?		No		Periodic checks will be done if procured
55.	Does the grantee use DG set > 15 KVA?	Yes		We have 280KVA DG sets and we have a consent to use the same. We have a factory in Lonavala, where the electricity is not supplied for a day in a week. To keep the factory operational for all the days in month we use the DG set. We do not have	DG sets emissions will be regularly monitored as per CPCB norms
	Does the grantee have consent for DG > 15 KVA?	Yes			
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	Yes			

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				any Boilers	
56.	Does the grantee have proper disposal process for solid and plastic waste in compliance to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016?	Yes			Necessary compliance will be taken It will be ensured that segregation rules are followed. This will be maintained and monitored
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)		No		Will be implemented when needed
	Are there sludge management and cut off drains in place for wastewater?		No		Will be implemented when needed
58.	Are necessary provisions for noise cancellation in place?		No		Preventive measures will be taken for reducing noise levels if generated
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No		
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Fire vehicle routes available	
COVID Precautions & Guidelines Implementation					
61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	Yes		COVID guidelines are being followed	Will follow the guidelines issued by CPCB/SPCB/GoI for COVID waste generation in future also.

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62	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	Yes		Preventive measures are being followed.	Guidelines issued by ICMR/GoI will be followed. Preventive measures to contain the spread of COVID-19 will be followed time to time in the future also.
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Notwithstanding the above other risk (relevant to the project activities) that will be identified in the course shall be addressed as per standard mitigation monitoring parameters and manner of records keeping shall be in accordance to the recommendations of the project monitoring committee on subject experts engaged by BIRAC.