Environmental Health Risk Management Plan (EHRMP)

SHC Shine Biotech Private Limited

Proposal entitled: Development of highly sensitive & specific, rapid, point-of-care, low-resource requiring, colorimetric and cost-effective test for COVID-19 detection

(i) Brief description of the proposed activity

COVID-19, an infectious disease caused by SARS-CoV-2, has been declared as pandemic by World Health Organization (WHO). As of now, it has caused ~9500000 confirmed infections and ~120000 deaths in India alone. Besides tragic human consequences, it is going to cause a huge social and economic loss worldwide. Since treatment is unknown yet, diagnosis/identification of the infected subject and their isolation from the community has been one of the effective approaches to prevent COVID-19 progression and its control. Hence, accurate, rapid, POC, field-deployable self-testing and low-cost diagnostics for COVID-19 is an urgent clinical need.

Currently, RT-PCR is most commonly used technique for COVID-19 diagnostics, however since SARS-CoV2 is an RNA virus, first the RNA has to be isolated from clinical sample and then reverse translated into cDNA for getting it amplified using PCR. This whole process is high resource requiring and has long turn-around-time and costly and hence can not be applied for nation-wide testing.

Therefore, in this proposal, we aim to first develop a membrane-based cartridge for rapid capture and isolation of viral RNA from nasal swab (≤10 minutes) and then single-step amplification of membrane-bound viral RNA using RT-LAMP and its simultaneous detection with pH-based colorimetric dyes for COVID-19 diagnosis (30-45 minutes). LAMP is ~100 times more sensitive than PCR. We would optimize the process using ORF1 and N fragment as the target for COVID-19 detection. The target and the process giving optimal sensitivity, specificity and signal would be utilized for development of the diagnostic kit for the purpose.

(ii) List of environment related regulatory clearances required for the activity.

Our incubator managed by a Government of India Institution, RCB in Faridabad. The Incubator &Institution takes care of all the requisite approvals from PCB covering its incubatees.

Environmental Health Risk Management Plan (EHRMP)

SHC Shine Biotech Private Limited

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?	√		Yes there is a committee that looks after EHS related work and issues	Committee has been recently formed as per the guideline by the government.
2.	Does the EHS staff handle the following?			Any other: EHS cell has been established and EHS policy is being developed along with other required guidelines.	The EHS Cell will monitor research and development activities at RCB and its incubator.
	Occupational Health and Safety	✓			
	Waste Management	✓			
	List of consents and regulatory clearances	✓			
	Record keeping of accidents and procedures	✓			
	EHS trainings for staff	✓			
	Environment Management Framework compliance for Innovate in India Project	✓			
3.	Is there a reporting structure in place regarding EHS issues?	✓			Recently formed EHS committee will address all the issues, if any.
4.	Are regular EHS trainings provided to staff?	✓		Frequency: every 4 to 6 months	All the existing and newly recruited staff members will be trained to follow all the suggested guidelines.
5.	Institutional Bio-Safety Committee (IBSC)	✓		Yes, IBSC committee ensure that all the work is performed as per the rules suggested by government bodies	All proposals are evaluated and approved by IBSC before initiation of any work.
6.	Ethics Committee (EC)	✓		Yes, Institute has its registered Ethics Committee.	Ethics committee meetings will be continued in the future to monitor the ethics parameters involved in the project.
General Occupational Health and Safety					
	Area of Risk	**Yes**	**No**	**Details**	**Proposed Plan**
7.	Are there Standard Operating Procedures for accidents hazards, and other emergencies (chemical spills, heat hazards,	✓		Proper SOP and guidelines were provided to the users	All the new joining and existing staff will be trained time to time for

	fire hazards, radioactive hazards etc.)?			in case of any kind of emergency.	handling any such situation.
8.	Are the following in place?			All the kits were monitored timely and updated if required.	For eye wash station, incubator is planning to develop in upcoming 6 months.
	Chemical spill kits	✓			
	Eye wash		✓		
	Shower stations		✓		
	First Aid Kit	✓			
	Fire Extinguishers	✓			
	Register of accidents and injuries		✓		
9.	Are proper signage and storage system in place?	✓		Signs for toxic chemicals, and emergency contact numbers are in-place in laboratories.	In case of any emergency person or lab-in-charge will immediately inform the Incubator authorized person to take immediate action.
	Display of Material Safety Data Sheet (MSDS) where relevant	✓			
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical Places	✓			
	Signage across the facility (labs, storage, hazardous areas, etc.)	✓			
	Are flammable materials appropriately stored to prevent fire hazards?	✓			
10.	Are smoke detectors, fire alarms, automatic safety/shutoff systems, overflow preventers, etc. in place and regularly maintained?	✓		List: 1. Detectors, MCB, control panel, Hooters etc test on weekly basis. 2. Automatic fire sprinkler system 3. Automatic fire hydrant system cover all internal and external areas 4. Firefighting equipment's such as fire extinguisher cylinders. 5. weekly testing of complete fire alarm and fighting system regularly	Staff is and will be trained for the process. These are periodically monitored.

				maintained.	
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	✓		List: 1. Regularly maintained temperature 24±2 degree centigrade within lab by controlling AHU's 2. Regularly executing preventive maintenance of all DG sets available in cluster. 3. Execute air emission test once in a year through CPCB authorized agency. 4. All laboratories and colliders are regularly sanitized.	Assigned person will look after the maintenance of all the facility annually.
12.	Are regular mock drills conducted for emergency preparedness and safety?	✓		Frequency (type wise): Two times a year	Staff will be periodically trained for emergency situations.
13.	Are staff provided with OHS training?	✓		Facility conducts training programs on regular basis.	The staff will be trained regularly to ensure that they are given complete training to handle any accidents/incidents.
	Biomedical Waste (BMW)				
	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?	✓		list of biomedical waste produced in the facility 1. Chemical waste 2. Microbiology waste	For the management of laboratory chemical liquid waste there is Pit for collection which is tested before discard once filled by authorized partner

					Bharat oil. For the biomedical waste there will be a separate biohazard chamber for autoclaving the waste before given to the authorized partner for disposal.
15.	Is there trained staff to handle biomedical waste in the grantee?	✓		Proper trained staff was assigned to handle the BMW.	Training will be conducted for the handling staff periodically.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	✓		We are incubated in BIRAC-funded incubator managed by a Government of India Institution, RCB in Faridabad. The Incubator &Institution takes care of all the requisite approvals from PCB covering its incubatees.	Will ensure that timely approvals and renewals will be done by the Incubator for our Organization.
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	✓		Yellow ✓ Red ✓ White ✓ Blue ✓	The collected waste will be disposed of as per the regulatory guidelines.
18.	Is the bar code system for the segregated waste in place?	✓		Waste is separated and regularly updated to SPCB	Committee performs regular monitoring to ensure that proper procedures have been followed.

19.	Is the biomedical waste being sent to an **authorized** common BMW facility?	✓		Name and address of CBMWF: M/s Golden Eagle Waste Management Company, Village Jasana, Tigaon road, Faridabad Distance from facility: 15 kms Frequency and Mode of transport: 48 hrs, & Transport provided by M/s Golden Eagle Waste Management Company Who transports? M/s Golden Eagle Waste Management Company	The BWM that we generate is sent to SPCB authorized facility and sending the waste will be continued. This will help in mitigating environment and health risk.
20	Does the grantee have an in-house BMW treatment facility?		✓		As we are part of a cluster, we will send the BMW to GoI approved facility, as detailed above, for disposal after taking all the safety measure.
	Is the treatment facility own (individual)?		✓		
	Is the treatment facility a shared facility in an industrial park?		✓		
21.	Are lab waste, microbiological waste and chemical liquid waste pre-treated before storing and sending totreatment facilities according to guidelines prescribed in BWM, 2016 regulations?	✓		Types of treatment: - Autoclave in double bag - Adding bleach Acid base neutralization	- Compliance calendar shall be maintained.
22.	Is the liquid waste checked for active cells before sending to treatment plant?		✓		Will plan to do in next 6 months which include, check for growth on media after autoclave before discarding the waste.
23.	Are necessary waste pre-treatment equipment in place?	✓		List of equipment (autoclaves, shredders,	Pre-Treatment will be done by

	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	✓		incinerators, etc.): Details of waste pre-treatment: Autoclaves are available for disinfecting all biological waste before sending to the waste disposal agency. STP is used to treat liquid effluent.	decontamination by our staff regularly. Existing systems will be maintained.
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	✓		Non-chlorinated gloves and bags were used for the purpose.	Proper stock will be maintained.
25.	Are grantee's personnel involved in handling BMW provided with regular training?		✓	Frequency: Quarterly Trainer: As appointed by the facility in charge	Proper training will be provided as per the regulatory guideline by the trained assigned person.
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	✓		This is ensured by the outsourced BMW agency for their employees as mandated by law.	The outsource service provider will be recommended to frequency of medical checkups will be increased and vaccination will be continued for all the personnel getting involved in BMW handling.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	✓		Bio medical waste record is maintained	The maintenance of bio medical waste register will be continued.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	✓		Due to bar coding on waste, it is updated to the SPCB regularly.	The annual report submission will be continued to ensure effective handling of BMW as per the rules and for the prevention of adverse events.

Environmental Health Risk Management Plan (EHRMP)

SHC Shine Biotech Private Limited

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?		✓		We are not generating any hazardous waste, however disposal of hazardous waste will be done as and when required according to Bio-medical waste rules 2016.
30.	Is there trained staff in the facility to identify and handle hazardous waste?	✓		Yes, trained person was assigned for the completion of this task.	
31.	Does the grantee have authorization from SPCB for hazardous waste?		✓		Since, we are incubated in an incubator, the incubator and managing institution (RCB) takes care of it.
32.	Is there a secure location for storage of HW with proper signage?	✓		Describe how each item is stored – platforms, distances from critical installations/movement areas, spill collectors, gas escape facility, etc.	Biomedical waste will not be stored more than 48 hours, and other kind of waste will not be stored more than 60 days.
	Are hazardous waste stored for more than 90 days in the grantee's premises?		✓		
33.	Is the hazardous being send to an **authorized** disposal facility or user?		✓		We do not generate any hazardous material yet. But if generated in the future, it will be sent to GoI-authorized disposal facility
	Is the disposal facility in house?		✓		
	Is the disposal facility external/outsourced?	✓			
34.	Is a register maintained on production and treatment, and a manifest system followed for transport ofhazardous waste from the grantee to treatment facility?		✓		We do not generate any hazardous material yet. But if generated in the future, it will be appropriately recorded

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?		✓		We do not produce any e-waste as we are working in the domain of in-vitro diagnostics.
36.	Has the grantee obtained SPCB authorization on e-waste?		✓		We do not produce any e-waste as we are working in the domain of in-vitro diagnostics.
37.	Does the grantee channelize the e-waste to **authorized**recycling or disposal facility?		✓	:	In near future, we are not going to generate any kind of E waste and Battery waste therefore there is no risk to the person working in the lab. (Since no use of battery thus no risk of leakage that can harm start up and incubator) We will do the needful, as and when required in the future.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		✓		We do not plan to enter into manufacturing in near future. But if the case, will ensure the EPR system in place.
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		✓		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?		✓		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?		✓		We do not deal with the manufacturing, sale or collection of electronic or electrical items and do not foresee any e-waste in near future. But if the case, will do the needful.
42.	Does the grantee submit annual reports on e-waste to SPCB?		✓		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?		✓		The system is in place, however no incident has happened and hence recorded yet
44.	Are PPEs available to staff?	✓		PPE is monitored and maintained regularly.	The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out.
45.	Is the grantee involved in manufacture of batteries?		✓		We do not deal with manufacturing, sale or collection of batteries
46.	Does the grantee generate battery waste?		✓		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?		✓		We do not foresee any battery-waste in near future. But if the case, will do the needful.
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old 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)	✓		All the hazardous waste was inactivated and then autoclave before given to the authorized facility f sal	The reagents are sealed in the bag, double bagged and then packed in the appropriate container, sealed and then double boxed again and sealed for transportation. There is minimal and no chances of causing issue during transport.
50.	Emergency preparedness and participation of local authorities and potentially affected communities		✓		Since we are incubated in an incubator, the incubator and managing institution (RCB) takes care of it and has appropriate preparedness. They have proper SOP for handling in such situation.
Other					
	Area of Risk	**Yes**	**No**	**Details**	**Proposed Plan**
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc.)?		✓		We do not use radioactive material. But if the case, will do the needful.
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		✓		We do not use radioactive material. But if the case, will do the needful.
	Are radioactive warning signs in place?		✓		We do not use radioactive material. But if the case, will do

					the needful.
52.	Is the lab/room air regularly checked for microbial contamination?	✓		Lab benches are kept clean. Routine fogging is also in place to further ensure the minimal risk of microbial contamination in the lab.	
53	Are there any odor control measures in place?	✓			We do not use such reagents.
54.	Are fume hoods and exhausts regularly checked and maintained?	✓			Cleansing before and after work will be done.
55.	Does the grantee use DG set > 15 KVA?	✓			Facility doesn't have boiler but DG set is regularly maintained and monitored.
	Does the grantee have consent for DG > 15 KVA?	✓			
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	✓			
56.	Does the grantee have proper disposal process for solid and plastic waste in compliance to Solid WasteManagement Rules, 2016 and Plastic Waste Management Rules, 2016?	✓			Non- hazardous solid and plastic waste is disposed to Municipal corporation.
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	✓		Types of waste water: sewage water is treated through STP and treated water is being utilized for horticulture and chiller plant. Chemical management in wastewater treatment plants: Chemical waste is disposed off through third party approved by UPPCB. Laboratory medium and cultures: These are treated with bleach and is disposed off as bio-medical waste.	
	Are there sludge management and cut off drains in place for wastewater?	✓			These are and will be periodically maintained

					and checked.
58.	Are necessary provisions for noise cancellation in place?	✓		We are having closed cabin to reduce the noises as much as possible. Silent DG generator is used in the facility according to the test report their noise level is within permissible limit.	
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		✓		Not in the vicinity of the facility.
60.	Are there any buffers, fire vehicle routes in the grantee's premises?		✓		We are geographically located at well-isolated place
COVID Precautions & Guidelines Implementation					
61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	✓		We are working with inactive virus or artificial synthesized RNA thus no threat for infection.	Autoclave at 121 deg C for 1 hour in double bags as suggested by CPCB for covid-19 waste
62	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	✓		Since, we are incubated in an incubator, the incubator and managing institution (RCB) takes care of it and implements all the relevant policies.	Preventive measures to contain the spread of COVID-19 will be followed time to time in the future also by the Incubator as well as in SHC Shine Biotech. SHC Shine Biotech will ensure that all the necessary guidelines issued for COVID-19 by the GoI will be followed regularly.

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.