

Environmental Health Risk Management Plan (EHRMP)

Scigenom Labs Private Limited

Proposal entitled: Development of a rapid cost-effective point-of-care SARS-CoV2 (COVID-19) detection test

(i) Brief description of the proposed activity: Development of a point-of-care lateral flow assay rapid test device for SARS-CoV2 IgG/IgM detection (ii) List of environment related regulatory clearances required for the activity: SPCB clearance required for handling and disposing BMW through IMAGE. Same is applied with SPCB in consultation with SEZ.					
Institutional Arrangement					
Area of Risk		Yes	No	Detail s	Proposed Plan
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?		N	Since we are a small R&D lab, we do not have a designated full-time staff for EHS issues. All the EHS responsibilities have been assigned to a senior scientist in the lab. He/She is responsible for ensuring all the staff are abiding the EHS policy laid down by the company and reports any accidents and any non-conformities to the EHS committee.	SciGenom Labs has applied for clearance from SPCB as advised from SEZ. The official procedure will take around 3-4 weeks. Supporting documents of authorization will be presented immediately once received.
2.	Does the EHS staff handle the following?			Any other:	The EHS lab in-charge
	Occupational Health and Safety	Y		The EHS lab in-charge ensures proper conduct of training, waste management, proper record maintenance	conducts regular training for lab staff and housekeeping staff to ensure proper maintenance of a system for safety
	Waste Management	Y			
	List of consents and regulatory clearances	Y			
	Record keeping of accidents and procedures	Y			
	EHS trainings for staff	Y			
	Environment Management Framework compliance for Innovate in India Project	Y		Company has an EHS policy in place	The company management committee along with the senior scientists in the company will be responsible for laying down the policy

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					and ensure proper adherence to safeguard staff and environment safety
3.	Is there a reporting structure in place regarding EHS issues?	Y		Describe: The company has an EHS policy. Any accidents and non-conformities in the lab/company are reported to the Director of the company in writing. The Director is responsible for taking necessary action to solve the issue immediately. The Director is the Chairperson of the EHS committee.	The Institutional EHS committee comprise the CEO, Director and Senior Scientists of the company. An EHS policy has been laid down to ensure proper safety to company staff and to the environment. The policy will be reviewed once a year and amended from time to time. The Chairperson (Director) of the committee is authorized to make urgent decisions in case of emergency situations.
4.	Are regular EHS trainings provided to staff?	Y		Frequency: Once in 6 months. A training calendar is maintained	Attendance record and minutes of the meeting will be maintained.
5.	Institutional Bio-Safety Committee (IBSC)	Y		IBSC in place	IBSC meetings conducted twice a year/on project-to-project basis. Safety features of the project are discussed and the committee with recommend the project only if found safe for personnel and environment
6.	Ethics Committee (EC)	Y		IEC in place	IEC meetings will be conducted on project-to-project basis and committee will review the safety and ethical aspects of the project
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.)?	Y		SG.SOP.PRO.101 We do not have any radioactive hazards. We have SOPs related to BMW management, managing chemical spillage, Fire hazards.	Detailed SOPs in place will be followed for managing BMW, chemical waste and any fire hazards. SOPs for heat hazard and chemical spillages in place will be followed throughout the Project.
8.	Are the following in place?			Detailed SOP on how to use Eyewash, Chemical spillage kit, First aid kit, Fire extinguishers are in place. Register for recording accidents and injuries in place.	Detailed SOPs in place The EHS lab in-charge describes the procedure for correct usage of all these emergency services during the periodic EHS classes. Registers for recording accidents and injuries will be maintained by the lab team
	Chemical spill kits	Y			
	Eye wash	Y			
	Shower stations	Y			
	First Aid Kit	Y			
	Fire Extinguishers	Y			
	Register of accidents and injuries	Y			
9.	Are proper signage and storage system in place?	Y		Yes, in place	There are specific areas like cell culture lab where only authorized person can enter. 'Entry restricted' signage in place
	Display of Material Safety Data Sheet (MSDS) where relevant	Y		Wherever relevant	Emergency numbers are and will be displayed in common areas for easy visual access.
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	Y		Yes	Specific signage are displayed in all restricted areas in the facility so the entry precaution will be taken during entry
	Signage across the facility (labs, storage, hazardous areas, etc.)	Y		Decontamination area is having signage of biomedical hazard	Fume hood is present for handling hazards chemicals, all these aspects have been covered during the periodic training sessions.
	Are flammable materials appropriately stored to prevent fire hazards?	Y		Flammable materials have lockable cupboards near the fume hoods. With proper signage	Proper signage are placed on storage areas delineated for Bio-

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					medical waste, chemical waste etc.
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	Y		List: Smoke detectors inside the company. Centralized fire alarms in place.	As per SEZ rules it is mandatory for all companies in the campus to have smoke detectors and floor-wise fire alarms. These are periodically monitored by the SEZ authorities.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		N	No solvents are used	
12.	Are regular mock drills conducted for emergency preparedness and safety?	Y		Frequency (type wise): Once in 6 months	As per instructions from the SEZ authorities, regular mock drills for any emergency preparedness are and will be conducted by the HR dept.
13.	Are staff provided with OHS training?	Y		Describe: as per SOP	The HR dept. along with the EHS lab in-charge will ensure proper conduct of OHS training in the company
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?	Y		If Yes, provide a list of biomedical waste produced in the facility – We have only BMW like E.coli cells waste and Mammalian HEK293 cell waste	We have specific SOPs for decontaminating the microbial waste and cell culture waste (autoclaving at 121C). Liquid waste are decontaminated separately from BMW. Decontaminated BMW is taken away from the lab by IMAGE. We will maintain record of BMW generated in the lab and also record of BMW taken by IMAGE.
15.	Is there trained staff to handle biomedical waste in the grantee?	Y		Trained IMAGE staff come for collecting the	Trained IMAGE staff will come for collecting the BMW.

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				BMW. In the company lab staff and housekeeping staff are trained by the lab in-charge as per recommendations from IMAGE	Separate training as per IMAGE guidelines will be given to all lab staff and housekeeping staff for proper waste segregation and management
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Y		SciGenom has obtained approval from SPCB for the BMW quantities generated in the lab and has approval for disposal of its waste through IMAGE, recognized by the SPCB	SPCB approval for the R&D activities and related bio-medical waste generation. Waste segregation as per IMAGE rules. Waste disposed by IMAGE, authorized by the SPCB. Timely renewals and proper approvals in future will be taken.
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Y	Yellow	We do not generate human/animal anatomical or other solid wastes. Antibiotic waste, cytotoxic gel waste, ampules and vials are discarded into yellow bags. We do not have chemical waste and discarded wastes. Laboratory cultures, mammalian cell culture, dishes used for culturing are discarded in yellow bags.	Bio-medical waste segregation will be performed as per the colour-code schedule I of the 2016 BMW rule. Yes, colour-coded segregation of lab waste is and will be strictly being followed by all lab staff. Appropriate training has been given to the housekeeping staff for proper packing of these waste into bar-coded bags for transportation by the IMAGE team. IMAGE team does not carry food waste and general plastic waste.

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				Red	Used syringes (without needles), gloves, tubes are discarded into red bags.	Food waste and general plastic waste will be collected and disposed by authorized agency within SEZ. The colour coding system is and will be strictly implemented and followed at SciGenom Labs.
				White	All sharps including needles, scalpel blades are discarded into White bottles provided.	
				Blue	Broken/discarded glass and glass ampules are discarded in Blue bags.	
18.	Is the bar code system for the segregated waste in place?	Y			Barcoded covers are provided by IMAGE for waste collection	Yes, the implemented system will be followed.
19.	Is the biomedical waste being sent to an authorized common BMW facility?		N		Name and address of CBMWF: IMAGE Distance from facility: Frequency and Mode of transport: in 48hours Who transports? IMAGE authorized transporters	The bio-medical waste is not send to centralized BMW facility. It is collected and disposed appropriately as per IMAGE guidelines. Transported within 48 hours (regular course) in authorized vehicles for disposal. Food waste and plastic waste will be sent to the centralized SEZ facility for disposal
20.	Does the grantee have an in-house BMW treatment facility?		N		Reason:	As per SEZ rules
	Is the treatment facility own (individual)?		N		Authorization:	Used water and sludge

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	Is the treatment facility a shared facility in an industrial park?			Distance of nearest CBWM from facility: Types of treatment:	treatment plants are functional within the SEZ campus for centralized recycling. Hence, individual companies will not need to have individual facilities.
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?	Y		Types of treatment: Soiled cotton waste, paper towels, blood and other biological fluids, face masks are disposed into Yellow bag and are send for incineration by IMAGE team in non-chlorinated yellow bags. Used lab plastic waste including syringe, gloves and plastic pipettes are autoclaved and packed into Red bags and are send for shredding by IMAGE team. Broken glass are collected into containers for glass and needles are collected into containers for sharps.	Specific SOPs in place will be followed for colour-coded segregation of waste as per IMAGE guidelines
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Y		Yes, samples from liquid waste after autoclaving are tested before discarding. This is a random checking done after every 5 th sterilization cycle performed. Also every autoclaving	Specific SOP are in place. During random checking, done once after every 5 th sterilization, swabs from the BMW and liquid waste are inoculate on NA plates and ensured for contamination before sending for disposal.

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				is having autoclaving indicator tape affixed so the colour change denotes complete autoclaving cycle.	
23.	Are necessary waste pre-treatment equipment in place?	Y		List of equipment (autoclaves, shredders, incinerators, etc.): Yes, autoclaves assigned for decontamination are in place and SOP in place We do not have incinerators and shredders, wastes that needs treatment by this method is given to IMAGE for disposal	Specifically assigned autoclaves are available for decontamination. Specific area is allocated for decontamination and washing of the glassware. Detailed SOPs in place for decontamination and safety. Periodic training given to ensure safety.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Y		Details of waste pre-treatment: Bacterial cells autoclaved before disposal	Swabs are taken from BMW and liquid waste after decontamination by autoclaving. The swabs are checked for contamination by spreading them on NA plates and incubating overnight at 37C. Only if there is no contamination observed, the waste are disposed by IMAGE team
24.	Are chlorinated plastic gloves and bags phased out in the grantee?		N	We do not use chlorinated gloves or plastic bags	No we do not use chlorinated gloves or bags
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Y		Frequency: Once in 6 months Trainer: IMAGE trainer	This will be a regular process during the project.
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like	Y		Frequency of medical examination: Once in a year	There is a clinic situated within the SEZ campus with a full-time doctor. Hence, apart from the

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	Hepatitis B and Tetanus?			or as needed. Immunization (HBV - 3 booster dosed) have been taken by all staff working with blood/human samples.	facility of periodic checkup available/as needed. A doctor on call is always available to attend any unforeseen accidents
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Y		Registers are maintained	A daily log for BMW generated in the lab is and will be recorded throughout the Project. BMW taken by IMAGE will also be recorded. Separate register will be maintained for reporting accidents in the lab
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Y		Annual reports are send to SPCB/SEZ with approximate quantities of colour-coded bag wise BMW generated	SPCB/SEZ is informed of the BMW quantities generated and submitted to IMAGE for disposal.

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?		N	No, we do not used hazardous solvents. We use very little quantities (~100ml in total once in 2 months) of solvents like alcohol, methanol and acetic acid to be used as ingredients in	Solvents are handled only with the fume hood after wearing personal protective clothing and goggles. Solvents are stored in containers having activated charcoal and once dry taken by IMAGE team

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				reagent used in the.	
30.	Is there trained staff in the facility to identify and handle hazardous waste?		N	we are not handling any hazardous waste	
31.	Does the grantee have authorization from SPCB for hazardous waste?		N	we are not handling any hazardous waste	
32.	Is there a secure location for storage of HW with proper signage?		N	we are not handling any hazardous waste	
	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?		N	we are not handling any hazardous waste	
	Is the disposal facility in house?		N		
	Is the disposal facility external/outsourced?		N		
34.	Is a register maintained on production and treatment, and a manifest system followed for transport of hazardous waste from the grantee to treatment facility?		N	we are not handling any hazardous waste	

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?	Y		We do not generate any E-waste. Any E-waste like end-of-life UPS batteries, waste like end-of-life UPS batteries, laptops/desk tops will be given to authorized recycling agents or will be taken back by the vendors.	Any E-waste like end-of-life UPS batteries, laptops/desk tops will be given to authorized recycling agents or will be taken back by the vendors.
36.	Has the grantee obtained SPCB authorization on e- waste?		N	We do not generate any E-waste	

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37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	Y		Name and address of disposal facility/recycler: Inhouse or outsourced Facility:	E-Waste whenever generated as specified in Point 35 is and will be handed over to authorized recycler/vendor.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		N	We do not generate any E-waste	
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		N	We do not generate any E-waste	
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?		N	We do not generate any E-waste	
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		N	We do not generate any E-waste	
42.	Does the grantee submit annual reports on e-waste to SPCB?		N	We do not generate any E-waste	
43.	Is there accident reporting and records in place?		N	We do not generate any E-waste	
44.	Are PPEs available to staff?		N	We do not generate any E-waste	
45.	Is the grantee involved in manufacture of batteries?		N	We do not generate any Battery waste	
46.	Does the grantee generate battery waste?		N	We do not generate any Battery waste	
47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/collection center?		N	We do not generate any Battery waste	
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		N	We do not generate any Battery waste	

Community Health and Safety and risk mitigation

	Yes	No	Details	Proposed Plan
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49.	Safety Transportation Management System (for transport Of hazardous material)	Y		We have specific SOPs and MSDS prepared for safe transport of antibody-related devices from the premise until it safely reaches the designated end user. Similarly, when we receive antibody reagents and cell lines from vendors, the vendors provide specific instructions for the transport agency and all the items are accompanied by MSDS for attending to any unforeseen causality management.	When we transport any reagents or antibody devices to other labs we always provide detailed SOP to the logistics team on how to transport the items. All items always are accompanied with MSDS. Similarly, reagents transferred from other research labs are also accompanied by MSDS and proper handling instructions. Items received from vendors are also accompanied by MSDS and are transported as per proper instructions from vendors.
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Y		BMW management and other potential wastes generated have SOPs for management in case of any emergency preparedness action required	The local community health workers and community leaders will be informed about any issues that can affect the community. The Emergency Preparedness plan will be executed as per the SOP in place.
Other					
	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		N	We do not use any radioactive materials	
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		N	Describe: Not applicable	
	Are radioactive warning signs in place?		N		
52.	Is the lab/room air regularly checked for microbial contamination?	Y		SOP in place for checking microbial	Will be maintained as per SOP.

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				contamination in the lab. NA plate method are used to monitor contamination.	
53.	Are there any odor control measures in place?		N	Not applicable	
54.	Are fume hoods and exhausts regularly checked and maintained?	Y		Manufacturer service	Periodic service
55.	Does the grantee use DG set > 15 KVA?	Y		There is only 1 DG set maintained by the company. 200KVA capacity. Records maintained by the HR/Admin team including the emission monitoring report.	Maintenance of the DG set is performed on an annual basis. Generates oil change and filter changes are performed. The filters are disposed along with BMW. The oil is taken by the authorized recyclers approved by the SPCB for disposal
	Does the grantee have consent for DG > 15 KVA?	Y			
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	Y			
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?	Y		Describe: All the BMW waste including lab-related plastic waste are collected and disposed by IMAGE. IMAGE (Indian Medical Association Goes Eco-friendly) is an IMA-Kerala state branch established common bio-medical treatment and disposal facility commissioned in 2003. It is the single authorized collection agency in Cochin to collect hospital and bio-medical wastes (https://imageima.org/about-us). IMAGE is authorized by the Kerala State	IMAGE has provided bar-coded disposal bags with specific colour codes. BMW are segregated at the point of collection itself into these colour coded disposal bags. Authorized IMAGE staff come to collect these waste twice a week (on all Wednesdays and Fridays – once in 48 hours). Weight of BMW generated and weight taken for disposal is recorder in a register maintained in the company by the HR/Admin team

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				<p>Pollution Control Board to collect bio-medical waste, liquid waste and lab-related plastic waste from hospitals and research labs in the state.</p> <p>Non-lab plastic waste, food waste, paper waste are collected by SEZ-authorized agency.</p>	<p>Food waste is collected separately, on a daily basis, by the authorized agency within SEZ.</p> <p>General plastic waste, paper and card board waste are also collected separately by the authorized agency within SEZ.</p>
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Y		<p>Types of wastewater: Toilet and pantry waste water and lab ware washing waste water</p> <p>Treatment of wastewater: SEZ has a centralized water treatment system in place</p> <p>Chemical management in wastewater treatment plants: RO waste water and domestic water waste</p>	<p>The Treatment will be done as per SEZ rules. Central SEZ facility.</p> <p>Common SEZ has a water treatment and waste water treatment plants</p>
	Are there sludge management and cut off drains in place for wastewater?	Y		Facility inside SEZ. Centralized facility.	As per SEZ rules
58.	Are necessary provisions for noise cancellation in place?	Y			Only source is the DG set. But it is accompanied with acoustics for noise controls
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		N		
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Y		Specified Fire exits in place	

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COVID Precautions & Guidelines Implementation					
61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?		N		
62	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	Y		Specific COVID prevention plan is followed in the campus	Masks are mandatory, daily temperature logs taken and submitted to SEZ office, hand sanitizers are provided, face shields provided.

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.