

Environmental Health Risk Management Plan (EHRMP)

Denovo Biolabs Private Limited

Proposal entitled: Development and validation of LFA POCT kits for SARS COV-2 Antigen detection

(i) Brief description of the proposed activity				
We are developing LFA based Point-Of-care diagnostic test to detect SARS-COV2 Antigen using Monoclonal and polyclonal antibodies developed in-house.				
(ii) List of environment related regulatory clearances required for the activity.				
Karnataka State Pollution Control Board has authorized the facility				
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		Environmental Health and Safety issues are taken care by QA of management	Environmental Health and Safety issues have been taken care according to the internal SOP by the QA department regularly.
2. Does the EHS staff handle the following?			All these are checked and recorded by QA department	QA department will update all the records and sent to the management for review. We will Environment Management Framework compliance for Innovate in India Project
Occupational Health and Safety	Yes			
Waste Management	Yes			
List of consents and regulatory clearances	Yes			
Record keeping of accidents and procedures	Yes			
EHS trainings for staff	Yes			
Environment Management Framework compliance for Innovate in India Project		No		
3. Is there a reporting structure in place regarding EHS issues?	Yes		EHS issues are reported properly as per rules	QA department will take care of EHS issues and report to the management
4. Are regular EHS trainings provided to staff?	Yes		Frequency:6 months	Training is provided according to the internal SOP
5. Institutional Bio-Safety Committee (IBSC)	Yes		Every 6 month IBSC meeting will be conducted and reports are reviewed	All the reports are discussed in the IBSC meeting where the committee members will review all the data's provided. Necessary actions are taken in suggestion by the members of committee.

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6.	Ethics Committee (EC)		No	Ethics committee is not there in the institution since we are not handling anything related to ethical issues.	In case of handling such project, necessary actions will be taken as soon as possible.
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, fire hazards, radioactive hazards etc.)?	Yes		All the actions are taken as per the internal SOP. In case of any accidents, it will be taken care according to its type. All the necessary precautions have been taken.	Standard operating procedures have been followed in the institution. It is being reviewed yearly and necessary changes are done accordingly.
8.	Are the following in place?				
	Chemical spill kits	Yes		Eye wash is kept in main lab along with shower stations.	Eye wash will spray water where eyes can be properly washed in case of any accident to eyes.
	Eye wash	Yes			
	Shower stations	Yes			
	First Aid Kit	Yes		First Aid Kit is kept in the corridor.	Showers also releases water just by pulling the nozzle which can be used in case of accident related to any body part.
	Fire Extinguishers	Yes		Fire Extinguishers are kept at all necessary places, mainly in labs and electrical room.	First Aid kit have all necessary first aid items like dettol, bandage etc.
	Register of accidents and injuries	Yes		Sand trays are kept outside the lab.	Fire extinguishers of both dry powder and carbon dioxide type present at appropriate sites. Sand trays are used when there is any liquid chemical spillage.
9.	Are proper signage and storage system in place?	Yes		Facility is working with all the precautions taken.	SOPs are updated yearly where all the details will be reviewed. In need of
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes			

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	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	Yes		MSDS file have been kept incase of need. Emergency numbers and details are given in the Waste management SOP.	any action to be taken, it is passed without delay.
	Signage across the facility (labs, storage, hazardous areas, etc.)	Yes		All the labs are labeled including the position of each instrument. Flammable substances are stored at separate area to prevent fire hazards	
	Are flammable materials appropriately stored to prevent fire hazards?	Yes			
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	Yes		There are 18 smoke detectors and 2 fire alarms in the facility.	Smoke detectors and fire alarm have been installed at all necessary areas in the facility. They are being checked quarterly.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		No	No such activities are done in the facility	If in future needed, necessary actions will be taken.
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Yearly conducted	During training period of every employee, mock drills for emergency preparedness and safety is done.
13.	Are staff provided with OHS training?	Yes		During probation period of the staff, OHS training is provided.	Occupational health and safety of the staffs of the facility is made sure. Every necessary actions are taken accordingly.
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?	Yes		Microbial culture, tissue culture, chemical waste	Bacteriological and tissue culture wastes are generated in the facility. Primary treatment is done in the facility before carried on for further treatment. Waste products are discarded in appropriate waste bins

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					according to waste management rules.								
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes		Every staff is trained for handling biomedical waste. Wastes are pretreated accordingly if necessary before being discarded. Wastes are sorted according to the type it belongs.	Wastes are sorted on the basis of waste management SOP. Staffs are trained to sort it. And for convenience the list is pasted on the walls near to where the waste bins are placed.								
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		Karnataka State Pollution Control Board has authorized the facility	Pollution Control Board has approved the working of the facility and its waste management. The final disposal of the wastes is also done by industries approved by KSPCB.								
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		<table border="1"> <tr> <td>Yellow</td> <td>Regular microbiology and biotechnology waste</td> </tr> <tr> <td>Red</td> <td>Recyclable waste contaminated with potentially hazardous material</td> </tr> <tr> <td>White</td> <td>Sharp items</td> </tr> <tr> <td>Blue</td> <td>Glass Items</td> </tr> </table>	Yellow	Regular microbiology and biotechnology waste	Red	Recyclable waste contaminated with potentially hazardous material	White	Sharp items	Blue	Glass Items	Different colored bags have been kept for each type of wastes. Segregation is and will be done at the initial stage only and then taken for waste management.
Yellow	Regular microbiology and biotechnology waste												
Red	Recyclable waste contaminated with potentially hazardous material												
White	Sharp items												
Blue	Glass Items												
18.	Is the bar code system for the segregated waste in place?	Yes											
19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes		M/s MARDI ECO INDUSTRIES PVT. LTD for solid wastes. And ECO GREEN INDUSTRIES PVT.	Solid and liquid waste will be treated separately at different places. The authorized BMW facility will be taking								

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				<p>LTD via IBAB for care of the waste bio-hazardous liquid treatment appropriately. wastes.</p> <p>M/s MARDI ECO INDUSTRIES PVT. LTD is located 18km away and IBAB is located 1.2km away from the facility.</p> <p>Solid waste is collected twice in a week and transported via road. Liquid waste is collected whenever it is required.</p> <p>The BMW facility collects the waste from the lab.</p>
20.	Does the grantee have an in-house BMW treatment facility?		No	<p>The facility doesn't own in-house BMW facility</p> <p>In future if the facility launches, necessary actions will be taken.</p>
	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		<p>Types of treatment: Sodium Hypochlorite treatment, charcoal filtration, autoclaving</p> <p>Microbial and tissue wastes have been treated by Sodium Hypochlorite for certain time before taking for further treatment.</p> <p>Contaminated plates and cultures are decontaminated in the autoclave.</p> <p>Chemical and hazardous wastes are passed through charcoal and filtered as a primary treatment method.</p>
22.	Is the liquid waste checked for active cells before sending to treatment	Yes		<p>The liquid waste is</p> <p>Confirmation of no live</p>

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	plant?			checked for active cells by plating method. pH of the liquid is also checked before sending.	cells in the liquid waste is done before sending for further treatment. All the necessary actions will be taken from the facility before dispatching for final treatment.
23.	Are necessary waste pre-treatment equipment in place?	Yes		List of equipment : Autoclave	Contaminated media and cultures are decontaminated in autoclave at 121°C for 20 minutes which will kill the entire living organism in the media.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes		Details of waste pre-treatment: Autoclaving of cultures and cells in moist heat for 20 minutes.	
	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes		Chlorinated plastic gloves and bags are no more using in the facility	Blue Nitrile powder free gloves will be used in the facility for every activity.
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Frequency: 6 months Trainer: QA according to internal SOP	Biomedical waste handling training is provided by QA department.
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	Yes		Frequency of medical examination: Yearly	Health test reports will be maintained for every staff before they enter to employment.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		An accident reporting register is maintained	In case of any accidents occur in lab, it will be recorded in the register with date and cause.
28.	Are annual reports on BMW submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes		Annual report on BMW is provided to state pollution control board as per requirement.	The reports are and will be submitted in provided format by internal team.
Hazardous Waste (HW)					
	Area of Risk	Yes	No	Details	Proposed Plan

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29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	Yes		Ethidium Bromide agarose gel, Silver Nitrate solution, Acrylamide-bis acrylamide gel, TEMED	Ethidium Bromide which is neurotoxic is used in agarose gels. Silver nitrate which is also toxic used in silver staining. SDS gel containing acrylamide-bisacrylamide which is both carcinogenic and neurotoxic used. Agarose gel and SDS gel is discarded in Yellow bag which is for hazardous waste. The solutions are passed through charcoal filter before further proceedings.
30.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes		All staffs are trained for handling the hazardous wastes	Training sections are there for every staff according to the internal SOP, where all the important classes are taken including the handling of hazardous wastes.
31.	Does the grantee have authorization from SPCB for hazardous waste?	Yes		The facility has taken permission from KSPCB for hazardous waste management.	All the rules are followed in the facility according to the KSPCB guidelines.
32.	Is there a secure location for storage of HW with proper signage?	Yes		Hazardous wastes produced in the facility are Ethidium Bromide agarose gel, Silver Nitrate solution, Acrylamide-bis acrylamide gel, TEMED etc. Solid wastes are disposed in the yellow waste bag. Liquid wastes are passed through charcoal and then send for further treatment.	Hazardous waste is sorted in the initial stage. Staffs are trained for handling such wastes. Waste management will be done according to the waste management SOP.
	Are hazardous wastes stored for more than 90 days in the grantee's premises?		No		

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33.	Is the hazardous being sending to an authorized disposal facility or user?	Yes		Name and address of facility:	Since facility does not have an in-house disposal system for wastes, it will be given for treatment at authorized waste management authorities. They will collect the waste regularly.
	Is the disposal facility in house?		No	For solid wastes	
	Is the disposal facility external/outsourced?	Yes		M/S Mardi Eco Industries Pvt. Ltd., Building No. 8, Sunaga Arcade, 4 th floor, 8 th cross, 1 st main road, Sampangiram Nagar, Bengaluru, Karnataka-560027 For bio-hazardous liquid wastes ECO GREEN INDUSTRIES PVT. LTD via IBAB Institute of Bioinformatics and Applied Biotechnology, Biotech Park, Electronic City Phase1, Electronic City, Bengaluru, Karnataka-560100	
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?	Yes		The register is followed up every time after the collection of wastes by the authorized people.	Details will be entered in the register for the transport of the wastes from the 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	No e-wastes generated in the facility	Facility is not related to electrical manufacture sector.
36.	Has the grantee obtained SPCB authorization on e-waste?		No	No authorization from SPCB	Since there is no e-waste generation, SPCB authorization is not

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					taken. Will ensure proper and timely approvals as and when required.
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?		No	No e-wastes generated in the facility	Since there is no e-waste generation, no disposal facility needed. Will ensure proper disposal facility is established as and when needed.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	No e-wastes generated in the facility	There is no e-waste generation
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No	No e-wastes generated in the facility	There is no e-waste generation
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	No e-wastes generated in the facility	There is no e-waste generation
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		No	No e-wastes generated in the facility	There is no e-waste generation and hence no record
42.	Does the grantee submit annual reports on e-waste to SPCB?		No	No e-wastes generated in the facility	There is no e-waste generation and no annual reports
43.	Is there accident reporting and records in place?		No	No e-wastes generated in the facility	Since there is no e-waste generation, records are not maintained.
44.	Are PPEs available to staff?		No	No e-wastes generated in the facility	There is no e-waste generation
45.	Is the grantee involved in manufacture of batteries?		No	No manufacturing of batteries	No e-waste production
46.	Does the grantee generate battery waste?		No	No battery waste production	No e-waste production
47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/collection center?		No	No e-wastes generated in the facility	No e-waste production
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and		No	No e-wastes generated in the facility	No e-waste production

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	ensure collection of old batteries?				
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Community Health and Safety and risk mitigation

		Yes	No	Details	Proposed Plan
49.	Safety Transportation Management System (for transport Of hazardous material)	Yes		Authorized committee is taking the wastes by road in their own transportation system	Safety Transportation Management system are followed for carrying the hazardous waste for final disposal.
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		All precautions are taken before sending the wastes	Waste management SOP will be followed regularly.

Other

	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No	Facility is not using any radioactive materials	No radioactive wastes are generated in the facility and so no harm to environment and staff health.
	Does the grantee have appropriate radioactive material land waste storage and disposal system in place?		No	Facility is not using any radioactive materials	No radioactive wastes are generated in the facility and so no harm to environment and staff health.
	Are radioactive warning signs in place?		No	Facility is not using any radioactive materials	No radioactive wastes are generated in the facility and so no harm to environment and staff health.
52.	Is the lab/room air regularly checked for microbial contamination?	Yes		The lab is checked for microbial contamination regularly. LB Agar plates are kept open for a day in the lab to check the bacterial contamination. Fungicidal	Lab is maintained in a sterile and dust free environment. It is been regularly checked and notified if actions have to be taken. Proper cleaning and maintenance is followed as per internal SOP.

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				disinfectants are sprayed in necessity.	
53.	Are there any odor control measures in place?	Yes		Air purifier is placed in the cabin for odor control measure	All rooms are air conditioned and proper ventilation will be maintained
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes		Fume hoods and exhausts are checked regularly and maintained appropriately	In case of any problem related to fume hoods and exhausts, actions are taken soon with all precautions.
55.	Does the grantee use DG set > 15 KVA?	Yes		62.5 KVA DG is installed after due permission and inspection electricity board	DG inspection and service reports are and will be maintained annually.
	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?		No		
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		All wastes are sorted according to the waste management SOP. Plastic and paper wastes will be thrown in black waste bin.	Solid and Plastic Waste Management rules are followed in the facility. Disposal of each type of waste is according to the Waste Management SOP as mentioned earlier.
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		Liquid Chemical waste and media cultures Culture and media wastes are added with sodium hypochlorite and kept for sometime before discarding for further treatment. Chemical wastes are passed through charcoal filter before final treatment.	Living organisms will be dead by adding sodium hypochlorite in cultures. Charcoal will absorb all the chemicals when it is passed through.
	Are there sludge management and cut off drains in place for wastewater?		No	Final treatment is done by corresponding authorities and there it will be taken care.	Sludge management is done by third party and hence it is not applicable.
58.	Are necessary provisions for noise cancellation in place?		No	Final treatment is done by corresponding authorities and there it	Sludge management is done by third party and hence it is not applicable.

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				will be taken care.	
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	There are no water bodies, cultivated land or any other eco-sensitive areas near the premises	
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		The experts in the field of safety reside about 700 Mts. away. Emergency exits are properly labelled. Premises around the facility are open so that the fire vehicles can easily enter. The facility is situating at the second floor of the building.	Facility is located near to police station, hospital and fire station. In case of emergency, all the help lines are available.

COVID Precautions & Guidelines Implementation

61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?		No	No COVID wastes is generated in the facility	Facility is working with antigens, antibodies etc. No live virus handling is occurring in the lab and hence no COVID wastes. However, will ensure to maintain this as per GoI norms.
62	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	Yes		An internal SOP for sanitation is prepared and being followed by every member of the constitution. Sanitizer, mask, temperature check and SpO2 check is done.	Masks are necessary for every employee. Sanitizer is placed outside the office which has to be used before entering the company. Temperature and SpO2 check is done every day for everyone prior entering the company.

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.