

Environmental and Health Risk Management Plan (EHRMP)

Huwel Lifesciences Private Limited

Proposal entitled: Complete solution for molecular diagnosis of covid19 multiplex assay along with screening for other related respiratory diseases

i) Brief description of the proposed activity:

Complete solution for molecular diagnosis of COVID 19 multiplex assay along with screening for other related respiratory diseases

ii) List of environments related regulatory clearances required for the activity:

TSPCB (Telangana State Pollution Control Board)

		Yes	No	Details	Proposed Plan
Institutional Arrangement					
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Y		Manager QA is designated with additional responsibilities for Environment Health and Safety (EHS) issue	The training to the staff will be given in every 3 months. EHS will be managed by well-established department already in place.
2.	Does the EHS staff handle the following?				These facilities will be reviewed in EHS review meetings held quarterly. Dedicated full-time staff will be there to ensure the compliance of EHS policies.
	Occupational Health and Safety	Y		Facility is designed and built considering occupational health and safety of each and every employee and complies to requirements of local state government regulations	
	Waste Management	Y		Contract with govt approved Biohazard waste collection and disposal agency	
	List of consents and regulatory clearances	Y		Manufacturing license issued by CDSCO, Govt of India , New Delhi and by DCA, Hyderabad, Telangana	

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				Pollution clearance by local govt. Pollution control board	
	Record keeping of accidents and procedures	Y		Maintained	
	EHS trainings for staff	Y		Maintained	
	Environment Management Framework compliance for Innovate in India Project	Y			
3.	Is there a reporting structure in place regarding EHS issues?	Y		Any incident has to be reported by email or by written communication to Directors of Huwel	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?	Y		Training schedule Frequency: Half yearly	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)		N		
6.	Ethics Committee (EC)		N		
General Occupational Health and Safety					
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	Y		Procedure for Destruction of Contaminated or non Contaminated or Potentially Contaminated Materials or Products or waste Procedure for General Safety	SOPs and formats to record any accidents, hazards, and other emergencies will be structured as a part of Procedure for Destruction of Contaminated or non Contaminated or Potentially Contaminated Materials or Products or waste and Procedure for General Safety.
8.	Are the following in place?			All are located at strategic locations for easy accessibility	Register will be maintained for ensuring provisions of such requisites.
	Chemical spill kits	Y			
	Eye wash	Y			
	Shower stations		N		
	First Aid Kit	Y			

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	Fire Extinguishers	Y			
	Register of accidents and injuries	Y			
9.	Are proper signage and storage system in place?			All details are printed on a sheet with visible font size and placed located at strategic locations for easy accessibility and readability	Facilities will be upgraded with the activities increased.
	Display of Material Safety Data Sheet (MSDS) where relevant	Y			
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	Y			
	Signage across the facility (labs, storage, hazardous areas, etc.)	Y			
	Are flammable materials appropriately stored to prevent fire hazards?	Y			
10.	Are smoke detectors, fire alarms, automatic safety/shutoff systems, overflow preventors, etc. in place and regularly maintained?	Y		The facility has smoke detectors and fire alarms	Facilities will be maintained and upgraded with the activities increased.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		N	The operation does not have any air emissions, do not generate high temperatures. We do not handle any live pathogens/vectors in the facility	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?	Y		Frequency: Quarterly	Mock drills are conducted on quarterly basis and will be documented.
13.	Are staff provided with OHS training?	Y		Training records available	All the staff will be provided with trainings including newly joined staff.
Biomedical Waste (BMW)					
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Y		All waste generated is considered as Potential Biomedical waste and is discarded by handing over to Telangana Pollution Control Board Biohazard waste collection agency for further treatment and decontamination	Biomedical waste will be sent to PCB authorized third party.SOP:D057

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				A) Expired In-Vitro Kits B) Plastic Tips	
15.	Is there trained staff to handle biomedical waste in the grantee?	Y		Biomedical waste handling trained staff available	Research Unit staff will be trained on biomedical waste policies.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Y		Authorizations obtained	Necessary Authorizations will be taken if required with timely renewals.
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Y		The wastes are segregated based into Yellow, Green and Red waste bags as per regulations of Telangana Pollution control Board	We proposed to follow the same policy and departmental SOP for waste management.
18.	Is the bar code system for the segregated waste in place?		N		Will incorporate this system as and when required during the Project.
19.	Is the biomedical waste being sent to an authorized common BMW facility?	Y		G.J Multiclave Pvt. Ltd. Name and address of CBMWF: Regency Towers, 7-1-47, Dharam Karan Rd, Ameerpet, Hyderabad, Telangana 500016 Distance from facility: 20KM Frequency: Mode of transport: By Road Who transports: GJ Multiclave Staff	Biomedical waste will be sent to PCB authorized facility.
20.	Does the grantee have an in-house BMW treatment facility?	N		All the BMW are sent to authorized BMW treatment facility G.J Multiclave Pvt. Ltd.	Biomedical waste will be sent to PCB authorized facility
	Is the treatment facility own (individual)?	N			

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	Is the treatment facility a shared facility in an industrial park?	N			
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		All lab waste, liquid waste and microbiological waste are decontaminated using Sodium Hypo Chlorite before being handed over to Biohazard waste disposal agency	Compliance calendar shall be maintained.
22.	Is the liquid waste checked for active cells before sending to treatment plant?		N	Since Liquid wastes are decontaminated using Sodium Hypo Chlorite before being handed over to Biohazard waste disposal agency	Will monitor this during the Project and if needed will propose a plan of treating the same as per BWM Regulations.
23.	Are necessary waste pre-treatment equipment in place?		N	No process waste effluents are generated in our process of manufacturing IVD kits	Regular monitoring shall be done adhering to the norms of SPCB
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?		N		
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Y		Yes	
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Y		Frequency: Quarterly Trainer: Quality Manager	Training will be provided to the staff handling biomedical waste as per the existing frequency mentioned.
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	Y		We have annual health check up for all employees and all employees are vaccinated with Hepatitis B Vaccine Frequency of medical examination: Yearly	This practice will be checked periodically and compliance will be ensured.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Y		We maintain both soft and hard copy of the accident reporting.	This practice will be followed and updated with constant review.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		N	Since our facility is categorized as "White" zone where in as per Telangana PCB, we do not generate any potential	Will ensure that this compliance is done regularly within the timelines.

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				Pollutants and hence no necessity to submit annual reports)	
Hazardous Waste (HW)					
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?		N	No hazardous waste is generated by facility All wastes are treated as “potential” biohazard wastes only as precautionary reasons	If generated in future disposal shall be done as per BMWM rules.
30.	Is there trained staff in the facility to identify and handle hazardous waste?	Y		Though no hazardous waste is generated by facility, the staff are trained on safety and handling of potential bio hazardous wastes	This will be a continuous practice to ensure safety at the Project site.
31.	Does the grantee have authorization from SPCB for hazardous waste?		N	Our facility has been categorized as non pollutant facility (WHITE ZONE) by Telangana PCB	Timely proper and relevant renewals will be taken.
32.	Is there a secure location for storage of HW with proper signage?	Y		Potential Biohazard waste bags are stored in secured place before they are picked up by the local govt PCB approved biohazard waste disposal agency	Appropriate labeling and demarcation of these items will be done to ensure proper precautions when handling these items.
	Are hazardous waste stored for more than 90 days in the grantee’s premises?	Y			
33.	Is the hazardous being send to an authorized disposal facility or user?				This process will be continued with the authorized facility
	Is the disposal facility in house?		N		
	Is the disposal facility external/outsourced?	Y			
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?	Y			Will continue to maintain the register with frequent reviews to be done by assigned staff and department.
E-Waste and Batteries					
35.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?		N	E waste is not generated in our activity	The list of authorized centres will be obtained from Govt. and

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					disposal of the e-waste will be done as per E-waste Management Rules.
36.	Has the grantee obtained SPCB authorization on e-waste?		N	E waste is not generated in our activity	Company will obtain the authorization from SPCB as and when the need arises.
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?		N	E waste is not generated in our activity	Will select an authorized vendor authorized and listed by the Government to channelize any e-waste generated in future.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		N	E waste is not generated in our activity	Appropriate authorization will be obtained before moving to mass production stage.
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		N	E waste is not generated in our activity	
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	E waste is not generated in our activity	
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		N	E waste is not generated in our activity	
42.	Does the grantee submit annual reports on e-waste to SPCB?		N	E waste is not generated in our activity	
43.	Is there accident reporting and records in place?		N	E waste is not generated in our activity	
44.	Are PPEs available to staff?		N	E waste is not generated in our activity	The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out as and when needed.

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45.	Is the grantee involved in manufacture of batteries?		N	E waste is not generated in our activity	
46.	Does the grantee generate battery waste?		N	E waste is not generated in our activity	
47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/collection center?		N	E waste is not generated in our activity	The list of authorized centres will be obtained from Govt. and disposal of the e-waste will be done as per E-waste Management Rules.
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		N	E waste is not generated in our activity	
Community Health and Safety and risk mitigation					
		Yes	No	Details	Proposed Plan
49.	Safety Transportation Management System (for transport of hazardous material)	Y			Will follow the guidelines of PCB
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Y			Emergency preparedness plan will be developed
Others					
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc.)?		N	Radioactive materials not involved in our activity	Not in a scope of radioactive materials
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		N	Radioactive materials not involved in our activity	Not in a scope of radioactive materials
	Are radioactive warning signs in place?		N	Radioactive materials not involved in our activity	Not in a scope of radioactive materials
52.	Is the lab/room air regularly checked for microbial contamination?	Y		Environmental Monitoring of facility is performed periodically at defined schedules for checking microbial contamination	Periodic checks will be done
53.	Are there any odor control measures in place?	N	N	Since No Odours are generated	Periodic cleaning will be done
54.	Are fume hoods and exhausts regularly checked and maintained?	Y			Periodic checks will be done and fume extractors will be maintained.
55.	Does the grantee use DG set > 15 KVA?	Y		These DG sets are	

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	Does the grantee have consent for DG > 15 KVA?	Y		common for other offices/commercial units in the building and activities are managed by the committee in the complex building	
	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		Discarding the reagent into disposable zip lock covers containing 1% Hypochlorite, Discarding the vials in the disposable red plastic bag and submit to biohazard waste disposal team. All plastic tips are ejected after use into a discard bottle containing 1% Sodium hypochlorite. The discarded tips are filtered and sodium hypochlorite is removed by passing through a sieve. The filtered tips are dropped into the disposable red plastic bag.	It will be ensured that segregation rules are followed. This will be maintained and monitored by an authorized Committee
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)		N	No waste water is generated in process by the unit	Will provision such a facility if required for the project.
	Are there sludge management and cut off drains in place for wastewater?	Y			These will be periodically checked and maintained to ensure their proper functioning.
58.	Are necessary provisions for noise cancellation in place?		N	No noise is generated by the unit since all equipment being installed do not generate noise above 10 db	Will keep a check on the noise generated and cap them with proper cancellation provisions.
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's		N		

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	premises?				
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Y			Will ensure cleared for fire safety including vehicle routes throughout the project.
COVID Precautions & Guidelines Implementation					
61.	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	Y		Guidelines are being followed	Guidelines will be followed
62.	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	Y		Preventive measures are being taken	Preventive measures will be followed

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.