Environmental Health Risk Management Plan (EHRMP)

Medsource Ozone Biomedicals Private Limited

Proposal entitled,"**Development and evaluation of antigens to capture antibodies on Lateral flow Immunoassay device for the screening of Covid19 infection**

(i) Brief description of the proposed activity

– Development and Evaluation of Lateral Flow device

- Optimization of components and reagents and development of the lateral flow Immunoassay for detection of antibodies IgA, IgM and IgG
- Evaluation of Specificity and Sensitivity of the newly established rapid card test for detecting of IgA, IgM and IgG
- Evaluation of Stability of antigens and prepared test
- Report on LFIA development and Validation

(ii) List of environment related regulatory clearances required for the activity.
Consents and authorizations from State pollution control board is available

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?		√	QA team members work on EHS issues.	Well defined procedures will be followed for Biohazard waste. Bi-monthly records will be maintained for follow up.
2.	Does the EHS staff handle the following?			Any other: Pollution NOC, Regular records were maintained for disposal of Biohazard waste.	The records will be continuously maintained.
	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?		√		We will make a plan for EHS issues

4.	Are regular EHS trainings provided to staff?		√	Frequency: Yearly training done.	The trainings, which are given will be continued in the future.
5.	Institutional Bio-Safety Committee (IBSC)		√		We will ensure that the committee is in place and meets regularly to discuss key issues.
6.	Ethics Committee (EC)		√		If, required it will be proposed in the future.
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		SOP for handling corrosive chemicals, chemical spill. SOP for fire extinguisher.	SOPs and protocols will be maintained for any new activity included in the work
8.	Are the following in place?				We wear lab aprons, No hazardous chemicals will be used in laboratory with PPE.
	Chemical spill kits		√		
	Eye wash		√		
	Shower stations		√		
	First Aid Kit	√			
	Fire Extinguishers	√			We will implement the register.
	Register of accidents and injuries		√		
9.	Are proper signage and storage system in place?	√		MSDS are available with core team members handling chemicals.	Periodic monitoring will be continued imparted on material safety data sheets and on chemical handling to the concerned personnel
	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 (labs, facilitystorage, hazardous areas, etc.)	√			We will display

	Are flammable materials appropriately stored to prevent fire hazards?	√			emergency numbers. Dedicated storage area for explosive chemicals.
10.	Are smoke detectors, fire alarms, automatic safety/shutoff systems, overflow preventors, etc. in place and regularly maintained?	√		List: Smoke detector Fire alarm	The company will maintain appropriate emergency and safety trainings throughout the Project.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	√		List: Only temperature controlling instruments are in place like Cold chain, Deep freezer, Air conditioners.	Daily tempera ture monitoring records will be maintained.
12.	Are regular mock drills conducted foremergency preparedness and safety?	√		Frequency (type wise): Fire training once in a quarter.	Fire extingui sher handling and usage training will be provided quarterly.
13.	Are staff provided with OHS training?	√		Describe: Employee training at the time of joining for handling instruments, health and hygiene.	On job training will begiven to workers to handle instruments. Training will be given to new joiners for safety, health, hygiene and material handling.

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Medsource Ozone Biomedicals Private Limited

	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 Syringe, lancets, Droppers, Sample applicators, vacutainers, Microcentrifuge tubes, tips, gloves and mask.	The biomedical waste will be disposed as per the procedure of handling biohazardous waste. Training will be given to quality chemist for use of disposal of blood stained tips, gloves, vacutainers etc.
15.	Is there trained staff to handle biomedical waste in the grantee?	√		Training provided to biomedical waste handling personnel.	It will be a regular process throughout the project.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?		√		The Company will ensure that proper approvals and disposals of any waste generated is treated as per existing applicable laws.
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	√		Yellow Yes Red Yes White Yes Blue Yes	This will be done as per Bio-Medical Waste Management (Amendment) Rules, 2018
18.	Is the bar code system for the segregated waste in place?		√		Waste is not a part of inventory. If required Bar coding will be put in place and regularly updated as per policy guidelines.

19.	Is the biomedical waste being sent to an **authorized** common BMW facility?		√	Name and address of CBMWF: In house Biomedicals waste Management by autoclaving before handlingthe waste toMCF Waste. Distance from facility: Inhouse autoclaving Frequency and Mode oftransport: Weekly	. Continue the standard practice of BMW management as per Procedure.
20.	Does the grantee have an in-house BMWtreatment facility?		√	Reason: In house autoclaving. Authorization:QA Personnel	Continue the standard practice of BMW management as per SOP.
	Is the treatment facility own (individual)?		√		
	Is the treatment facility a shared facility inan industrial park?		√		
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?	√			ETP Treatment plant installed in our facility will be maintained and utilized for this Project.

22.	Is the liquid waste checked for active cells before sending to treatment plant?		√	All the liquid waste discardedwith Sodium hypochlorite treatment.	Treatment of liquid waste with sodium hypochlorite solution will be followed.
23.	Are necessary waste pre-treatment equipment inplace?			List of equipment (autoclaves, shredders, incinerators, etc.): ETP Machine, autoclave Details of waste pre-treatment: Sodium hypochlorite solution.	
	Do the equipment adhere to prescribed normsby State Pollution Control Board (SPCB)?				
24.	Are chlorinated plastic gloves and bagsphased out in the grantee?		√		Decomposed in regular waste after sodium hypochlorite treatment.
25.	Are grantee's personnel involved inhandling BMW provided with regular training?		√	Frequency: Weekly routine followedfor decomposing BMW. Trainer: QA Personnel	
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?		√	Frequency of medical examination: Yearly	Records will be maintained on yearly basis.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	√		Records kept in the company.	Register will be maintained to record accident reporting.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		√		
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?		√	.	If any hazardous waste is generated as per rules it will be handled and disposed. Monthly review will be conducted to ensure the handling of hazardous waste.
30.	Is there trained staff in the facility to identify and handle hazardous waste?	√		QA personnel handles hazardous waste.	As and when required astaff will be trained to treat and handle thehazardous wastes.
31.	Does the grantee have authorization from SPCB for hazardous waste?		√		Necessary Authorizations will be taken if required.
32.	Is there a secure location for storage of HW with proper signage?		√		We will arrange proper storage facilities when required.
	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?		√		
	Is the disposal facility in house?		√		
	Is the disposal facility external/outsourced?		√		
34.	Is a register maintained on productionand treatment, and a manifest system followed for transport of hazardous waste from the grantee to treatment facility?		√		We will maintain the register when required
E-Waste and Batteries					
	Area of Risk	**Yes**	**No**	**Details**	**Proposed Plan**
35.	Does the grantee generate e-waste, produce or manufacture electricaland electronic equipment?		√	No substantial electrical waste is generated in the factory	Procedures will be followed as per the given guidelines.
36.	Has the grantee obtained SPCB authorization on e-waste?		√	No substantial electrical waste is generated in the factory	Necessary Authorizationswill be taken if required.

37.	Does the grantee channelize the e-waste to **authorized** recycling or disposal facility?		√	No substantial electrical waste is generated in the factory	Necessary Authorizationswill be taken if required
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		√	No substantial electrical waste is generated in the factory	
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		√	No substantial electrical waste is generated in the factory.	
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 substantial electrical waste is generated in the factory	
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		√	No substantial electrical waste is generated in the factory	
42.	Does the grantee submit annual reports on e-waste to SPCB?		√	No substantial electrical waste is generated in the factory	
43.	Is there accident reporting and records in place?		√	No substantial electrical waste is generated in the factory	
44.	Are PPEs available to staff?		√	No substantial electrical waste is generated in the factory	The stock status of PPEwillbe regularly monitored an dprocurement will be done in time to avoid any situation of stock out.
45.	Is the grantee involved in manufacture of batteries?		√	No substantial electrical waste is generated in the factory	
46.	Does the grantee generate battery waste?		√	No substantial electrical waste is generated in the factory	
47.	Does the grantee deposit the battery waste to **registered** recycler/dealer/manufacturer/reconditioner/collection center?		√	No substantial electrical waste is generated in the factory	

48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		√	No substantial electrical waste is generated in the factory	
Community Health and Safety and risk mitigation					

		Yes	**No**	**Details**	**Proposed Plan**
49.	Safety Transportation Management System (for transport Of hazardous material)	√		Only autoclaved material is disposed off.	Will follow the safety transport manageme ntsystem if required
50.	Emergency preparedness and participation of local authorities and potentially affected communities		√		Will develop theemergency 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)?		√		We don't use and don't intendto use radioactive materials in the future.
	Does the grantee have appropriate radioactive materialand waste storage and disposal system in place?		√	Describe:	We don't use and don't intend to use radioactive materials inthe future.
	Are radioactive warning signs in place?		√		We don't use and don't intendto use radioactive materials in the future.
52.	Is the lab/room air regularly checked for microbial contamination?		√	No microbial work is done in lab	Will be implemented if required
53	Are there any odor control measures in place?		√		Periodic checks will be donepreventive measures will be taken if required
54.	Are fume hoods and exhausts regularly checked and maintained?	√		Exhaust installed and checked in dedicated area,	The fume hoods or exhaustswill be maintained and checked regularly.

55.	Does the grantee use DG set > 15 KVA?		√		DG sets emissions will be regularly monitored as per CPCB norms
	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?	√			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.)	√		Types of wastewater: Treatment of wastewater: Chemical waste is treated by ETP Plant. Chemical management in wastewater treatment plants: By ETP Plant	Records will be maintained fordisposal of Chemical waste.
	Are there sludge management and cut off drains in place for wastewater?		√	No, Regular waste is disposed in sewer drainage and chemical waste in ETP Plant	
58.	Are necessary provisions for Noise cancellation in place?	√		Describe: No noise is generated.	If necessary ear buds and ear muffs will be given.
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		√		
60.	Are there any buffers, fire vehicle routes in the grantee's premises?		√		
COVID Precautions & Guidelines Implementation					
61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal ofCOVID Waste Generated iswhether being followed?	√		Training provided on Covid to all the staff.	Masks and are use glovesinside d the company.

62	SOP on preventive measures to containspread of COVID-19 issued by ICMR/GoIfrom time to time is whether being followed?	√		All the necessary procedures are followed	Regular sanitization in thepremises, Thermal screening.

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.