

Environmental Health Risk Management Plan (EHRMP)

Achira Labs Private Limited

Proposal entitled: “Development of an ELISA kit for COVID 19”

(i)	Brief description of the proposed activity The project involves optimization of an ELISA kit for the detection of antibodies generated against proteins of SARS-CoV-2 virus in the serum samples of the people infected with the virus.
(ii)	List of environment related regulatory clearances required for the activity. 1. We have a KSPCB (Karnataka State Pollution Control Board) permit for waste disposal, sanction number is AW-306172

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		The Management Representative, is designated for dealing with EHS issues	We are currently ISO 13485 compliant. We plan to make a committee for EHS issues in the next 6 months.
2.	Does the EHS staff handle the following?			SOP no. SOP_003 (Work Environment & Waste Management) and SOP_058 (Accident Prevention Guidelines). Form no: F101 Record of Accidents and Mitigation.	Waste Management will be monitored by Quality. Health & Safety by HR
	Occupational Health and Safety	Yes			We have a KSPCB (Karnataka State Pollution Control Board) permit for waste disposal, sanction number is : AW-306172
	Waste Management	Yes			
	List of consents and regulatory clearances	Yes			
	Record keeping of accidents and procedures	Yes			
	EHS trainings for staff	Yes		The last EHS (first aid training) was done on 15/06/2020	Environment Management Framework compliance for Innovate in India Project will be followed
	Environment Management Framework compliance for Innovate in India Project	Yes			

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3.	Is there a reporting structure in place regarding EHS issues?	Yes		The reporting structure is outlined in SOP_058 (Accident Prevention Guidelines)	Individual staff report their concerns to the respective manager. Managers report the concerns to the EHS head. This process will be followed throughout.
4.	Are regular EHS training provided to staff?	Yes		Frequency: <ul style="list-style-type: none"> EHS training is provided to all new employees. EHS training is provided once in six months to staff. The date of last training was 15/06/2020 	The next training session for EHS is planned for January 2021. Attendance record and minutes of the meeting will be maintained.
5.	Institutional Bio-Safety Committee (IBSC)		NO	We do not have any IBSC committee at present	We will institute an IBSC as and when required.
6.	Ethics Committee (EC)	Yes		We do not have a formal EC, but captured in SOP_003 (Work Environment & Waste Management)	We will periodically review (once in 6 months) the need for an EC and institute the same based on the assessment.

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_041- Procedure for Waste Disposal SOP_058 for Chemical Spills and Hazards and other emergencies.	Currently we are not using any hazardous chemicals as of now, and as per the SOP, any hazardous waste materials if at all generated, are to be handed over to our current vendors, Maridi Bio Industries and Pai and Pai Chemicals.
8.	Are the following in place?			We have 'First Aid' Trained Employees to take care in case	We are not using any hazardous chemicals as of now and if we use such
	Chemical spill kits		No		
	Eye wash	Yes			

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	Shower stations		No	of First Aid and we have a register for keeping record of lab based accidents and injuries. We have 2 eye wash stations. We have 17 handheld fire extinguishers of Type ABC. They can be used for fire on common combustible material, flammable liquid and electric fires. This covers all the anticipated types of fire incidences in the company.	chemicals we will keep appropriate anti-dotes Sufficient quantity of eye wash bottles, first aid kit, fire extinguisher will be in place. - Will maintain the register for accident and injuries.
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			

9.	Are proper signage and storage system in place?			F82 Risk Register and F100 Risk Mitigation, SOP_023 Risk Management. All the Material Safety Data Sheet (MSDS) have been kept accessible Emergency numbers have been displayed along with the Floor plan at multiple places. Exit signage is clearly marked at all areas. Fire extinguishers are provided with appropriate signage.	We will evaluate and modify the Risk Register on a periodic basis based on changes to existing processes.
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes			
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	Yes			
	Signage across the facility (labs, storage, hazardous areas, etc.)	Yes			
	Are flammable materials appropriately stored to prevent fire hazards?	Yes			

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				<p>Location of all fire extinguishers is included in the Floor plan as well. Floor Plans have been provided at the end of this Annexure</p> <p>These fire extinguishers are of Type ABC.</p> <p>They can be used for fire on common combustible material, flammable liquid and electric fires.</p>	
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?		No	<p>We don't have smoke detectors, but we have fire extinguishers. We have mechanisms in place to prevent the overflow.</p>	<p>We currently have sufficient fire extinguishers and exit points at the premises. We will ensure fire extinguishers are maintained on a periodic basis</p>
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		No	<p>We are not a smoke stack industry or dealing with live pathogens</p>	<p>In case of any new projects that require the use of live pathogens, then we will evaluate and install control measures and notify appropriate authorities.</p>
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		<p>Fire drills are conducted on a yearly basis.</p>	<p>Next drill is planned for the last week of December 2020. This would be performed as per schedule.</p>
13.	Are staff provided with OHS training?	Yes		<p>Every new joinee is provided with this training for OHS.</p>	<p>We plan to give OHS training to all new and old staff once every six months. The next training sessions are planned for December 2020 and June 2021. We will prepare planner</p>

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					and will impart the training 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		Heat inactivated serum samples are used by us in a BSL-2 hood. They are non-infectious but discarded as biomedical waste.	We will collect all the solid and liquid waste that will come in contact with serum or antibodies as biomedical waste. Solid and liquid waste are collected separately. Both solid and liquid waste will be treated with bleach, 0.4 %, before the disposal. The liquid waste post treatment is disposed of in a designated chemical sink. Before disposal, liquid waste will be separated from solid waste via procedure elaborated in the SOP 041. It is wrapped into a plastic bag and left at a designated place with the date and name of the operator.				
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes		The staff is trained to handle the waste as per "SOP 041-Procedure for Waste Disposal"	The summary of SOP is provided on the previous row.				
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		The PCB Sanction number is : AW-306172	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?	Yes		<table border="1"> <tr> <td>Yellow</td> <td>Infectious waste</td> </tr> <tr> <td>Red</td> <td>Non sharp and glass biomedical waste including plastic and</td> </tr> </table>	Yellow	Infectious waste	Red	Non sharp and glass biomedical waste including plastic and	SOP_003 and SOP_041, detail the procedures for Biomedical Waste generated will be followed throughout the Project.
Yellow	Infectious waste								
Red	Non sharp and glass biomedical waste including plastic and								

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				paper	
				White needles, sharps	
				Blue Glass bottle, broken glass	
18.	Is the bar code system for the segregated waste in place?		No	We do manual segregation of the waste at the time it is being generated by putting in different colored bins Bar code system will be implemented after discussion with the vendor.	We will plan with our vendors Maridi Bio Industries Pvt. Ltd. and Pai Pai Chemicals private limited so we can switch to a coded system when it becomes available.

19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes		Name and address of CBMWF: Maridi Eco Industries Pvt Ltd Off. No.5, 2nd Floor, C.M.Plaza #71, 8th Cross, 1st Main S.R.Nagar, Bangalore - 560027 Distance from facility: 13 Kms Frequency and Mode of transport : Once a week: Who transports? : Vendor picks up the BMW	SOP 041-Procedure for Waste Disposal The BMW is carried away by an authorized company and we keep a record of the dated collection slips.
20.	Does the grantee have an in-house BMW treatment facility?		No	We do not currently have in house BMW	The BMW will be carried away by

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	Is the treatment facility own (individual)?		No	treatment facilities.	authorized people and
	Is the treatment facility a shared facility in an industrial park?		No	<p>We do following two types of pretreatments to the biomedical waste that we generate depending on the type of the waste.</p> <ol style="list-style-type: none"> 1. Autoclaving 2. Bleach 3. pH neutralization <p>Authorization: Our vendors Maridi Bio Industries Pvt. Ltd. and Pai Pai Chemicals private limited are authorized for collecting and disposal of the BMW.</p> <p>Distance of nearest CBWM from facility: 20 km</p> <p>Types of treatment: Our vendors Maridi Bio Industries Pvt. Ltd. and Pai Pai Chemicals private limited treat the waste as per the PCB norms.</p>	<p>we will keep a record of the dates and the collection slips.</p>
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:</p> <ol style="list-style-type: none"> 1. Autoclaving 2. Bleach treatment (0.4 %) 3. pH neutralization 	<p>SOP 041-Procedure for Waste Disposal will be followed. Briefly, The non-hazardous solid and liquid chemical waste will be</p>

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				<p>collected and disposed of separately. Any plastic or paper that comes in contact with laboratory chemicals will be collected separately and care will be taken that there is not liquid in it.</p> <p>The liquid chemicals those have pH in range 5-10 will be disposed off in the chemical sink as it is.</p> <p>The non hazardous liquid chemicals those do not have pH in range 5-10 will be neutralized before discarding.</p> <p>Hazardous, non-convertible or explosive chemicals will never be discarded into the sink. A bottle/container to collect these waste is kept, and then it is handed over to a vendor Pai and Pai or Maridi Bio Industries. Example of such waste: Chlorinated solvents (dichloromethane)</p>
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes		<p>SOP 041-Procedure for Waste Disposal. We are neutralizing all biomedical waste with bleach</p> <p>Liquid waste that are likely to have active cells will be autoclaved before it is sent for treatment.</p>

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23.	Are necessary waste pre-treatment equipment in place?	Yes		<p>List of equipment Autoclaves: 2 Shredders: 1 Incinerators: None</p> <p>Details of waste pre-treatment: Depending on the waste we use following type of pretreatments 1. Autoclaving 2. Bleach treatment (0.4%) 3. pH neutralization</p>	Sterilization and disinfection is done (detail) Most of the biomedical waste is sterilized using bleach (0.4%). The waste that has biomolecules and micro-organisms is autoclaved for sterilization. Examples of such waste include the agar plate used for estimation of microbial contamination, any reagents in which microbial contamination/growth is detected or suspected. This process will be followed throughout the Project.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?		No		
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes		We use nitrile gloves. Bags are non-chlorinated, if any.	We plan to not use chlorinated plastic gloves and bags.
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Two personnel have been trained on BMW handling. The last training was held on July 10 2020	The plan is to have training once every six months. The next training session is planned on January 2021
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		Hepatitis B immunization has been done regularly for all employees. Last immunization date was in 20 December 2019	We are conducting Health Check for all the employees in November 2020. Next immunisation is scheduled for the last week of November 2020

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27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		The BMW is carried away by authorized people and we keep a record of the dates of the collection slips. We do have a record keeping for accidents whenever they occur.	A daily log for BMW generated in the lab is and will be recorded throughout the Project. 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)?	Yes		SPCB, yes we do submit these annual reports	Annual submissions will be done.

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?		No	<p>None of our processes have hazardous chemicals usage and if any, we will be collected separately and will be handed over to the vendor for disposal.</p> <p>Please find a list of all waste produced in the facility below.</p> <p>The list of common waste generated at Achira,</p> <p>Aqueous solutions or buffers in the pH range of 5-10 (containing phosphate PBS, tris, bicarbonate, acetate, glycine, sucrose, mannitol, dextran, trehalose, (all mono, di and poly-saccharides), PEG, Tween, Triton-x, NaCl, KCl,</p>	<p>Before using any new chemical or assay in the the company the possibility of generating hazardous waste is and will be analysed.</p> <p>If there is any hazardous waste being generated it is included in the list of waste in SOP 041.</p> <p>Employees will be informed and trained to handle it properly.</p> <p>We plan to conduct a Hazardous Waste training session in January 2021</p>

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				acrylation-washes, conjugation-washes), IPA (isopropyl alcohol), ethanol, dilute acids (HCl < 1% or 0.3M), dilute bases (NaOH < 0.1 M), DMSO, IPA, Acetone	
30.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes		Quality Control personnel has been trained on hazardous wastes	Quality Control personnel will conduct training sessions for all employees.
31.	Does the grantee have authorization from SPCB for hazardous waste?	No		We do not require authorization for Hazardous Waste	We will apply for authorization if required
32.	Is there a secure location for storage of HW with proper signage?	No		We do not use hazardous material and hence we do not require any special storage.	
	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?	No		We do not generate hazardous waste and waste generated is sent to the following disposal facilities 1. Pai and Pai Chemical Pvt Ltd. 438/1, 20 the block, 1st block, Rajajinagar, Bengaluru-560010, India 2. Maridi Bio Industries Pvt. Ltd. Building # 8, Sunaga Arcade, 1st main, 8th cross, S.R. Nagar,	The contract renewal will be done as and when required.
	Is the disposal facility in house?				
	Is the disposal facility external/outsourced?				

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				Bengaluru-560027, India	
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?	No	We do not generate hazardous waste	In case any hazardous waste would be generated by future projects, we will put appropriate plans in place and notify relevant authorities	
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	Our activities do not create E-Waste and Batteries	We will periodically review if waste management plans should include e-waste. Battery waste if produced in future will be sent to authorized Recycler.
36.	Has the grantee obtained SPCB authorization on e-waste?		No	SPCB authorization is not required as we do not generate e-waste and batteries	Will obtain necessary permission or authorization as and when required.
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?		No	We do not currently have any authorized vendors for e-waste and till now we have not generated e-waste. Soon considering vendors contract for e-waste collection and disposal.	We plan to appoint an e-waste recycler when the need arises

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38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	We do not require this	
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No	We do not generate 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?		No	We do not generate e-waste	
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		No	We do not generate e-waste	
42.	Does the grantee submit annual reports on e-waste to SPCB?		No	We do not generate e-waste	
43.	Is there accident reporting and records in place?	Yes		Yes - As per Factories Act	Will ensure a register is being maintained recording any such incidents in future.
44.	Are PPEs available to staff?	Yes		Yes - As per GLP and Factories Act	Use of PPE's for staff will be made mandatory. Ensure regular and sufficient provision under the project.
45.	Is the grantee involved in manufacture of batteries?		No	We do not manufacture batteries	
46.	Does the grantee generate battery waste?		No	We do not generate battery waste	Battery waste if generated in future will be sent to authorized Recycler.
47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/collection center?		No	We do not generate any battery waste and do not have any registered recyclers for the same	Battery waste if generated in future will be sent to authorized Recycler.
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure		No		We are not manufacturing any batteries

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	collection of old batteries?				
Community Health and Safety and risk mitigation					
		Yes	No	Details	Proposed Plan
49.	Safety Transportation Management System (for transport Of hazardous material)		No	We do not generate Hazardous Waste.	In the future, if any hazardous waste is generated, these vendors would be contacted for safe transport Vendors: <ul style="list-style-type: none"> ● Pai and Pai Chemical Pvt Ltd. 438/1, 20 the block, 1st block, Rajajinagar, Bengaluru-560010, India ● Maridi Bio Industries Pvt. Ltd. Building # 8, Sunaga Arcade, 1st main, 8th cross, S.R. Nagar, Bengaluru-560027, India
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		We have displayed information for reaching appropriate local authorities on premises, to be used for emergencies	We plan to periodically review emergency plans with local fire stations, hospitals and police authorities.

Other

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	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No	We do not generate any radioactive waste.	We will incorporate plans for radioactive materials if we plan to use any radioactive material.
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	We do not generate any radioactive waste	
	Are radioactive warning signs in place?		No	We do not generate any radioactive waste	
52.	Is the lab/room air regularly checked for microbial contamination?	Yes		<p>For all areas, we are performing in-house testing for microbial contamination as per procedure given below:</p> <p>We monitor the microbial contamination by passive sampling of air using the “settle plate” method. Briefly, the nutrients agar plates are kept open for appropriate time in the area to be tested and incubated at 37 C overnight. The colonies are counted, and the Index of microbial air contamination is calculated as CFU/plate/hour.</p> <p>If CFU/plate/hour is above threshold limit, the affected areas are fumigated as per standard protocols.</p> <p>Additionally, the Clean Room validation is regularly</p>	<p>If there is some microbial growth above the threshold is detected. The concerned hoods or clean room will be fumigated as per standard protocols.</p>

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				performed with air particulate count.	
53	Are there any odor control measures in place?		No	We do not currently have any processes that generate foul odors. Lab areas in the premises are well-ventilated.	We will evaluate odor control measures as and when new processes are introduced.
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes		The fume hoods and exhausts were checked in the last week of October 2020.	Fume hoods and exhaust are checked every quarter for preventive maintenance.
55.	Does the grantee use DG set > 15 KVA?	Yes			We plan to control for noise by providing ear plugs to our employees. We get the DG set serviced regularly so it functions properly
	Does the grantee have consent for DG > 15 KVA?	Yes		Yes. We have 100 KVA Diesel Generator	
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	Yes		Yes. we do have consent for DG > 15 KVA Yes. Generally Serviced	
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		Yes. As per KSPCB Norms. SOP 041-Procedure for Waste Disposal Pre-treatment of contaminated Solid and Plastic waste is done in-house, and handed over to vendors for further disposal.	BBMP is the assigned vendor for the same.
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		Yes. As per KSPCB Norms. General Waste Water gets disposed off through BWSSB sewage line. Chemical liquid and other laboratory fluid waste is collected in a tank and	Periodic checks will be done.

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				neutralized in-house and handed over to 'Pai & Pai Chemicals" for further disposal. Appropriate signage is displayed on this chemical collection tank.	
	Are there sludge management and cut off drains in place for wastewater?		No	Our current processes do not generate sludge.	In case of new processes or projects that would generate sludge, we will evaluate and implement appropriate measures.
58.	Are necessary provisions for noise cancellation in place?		No	Ear plugs are provided to employees in case of loud noise during equipment operation	Will keep reviewing the noise generated and cap them according to the existing cancellation. provisions.
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	There are no settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises.	Since, no water bodies or cultivable land nearby, no environmental risk.
60.	Are there any buffers, fire vehicle routes in the grantee's premises?		No	Achira premises is a small single building unit with easy access for fire engines.	If required in future Fire vehicle routes and buffers will be accessed in our existing premises.
COVID Precautions & Guidelines Implementation					
61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	Yes		We are only using heat inactivated serum samples of covid 19, and following appropriate guidelines for the disposal of waste.	We will continue to comply with the latest Govt. guidelines
62	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	Yes		Yes, we have being taking preventive measures to contain the spread of COVID-19 issued by GoI and BBMP time to time, including: 1.All employees have Arogya Setu app on their mobile for contract	Employees are trained on COVID - 19 measures regularly.

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				<p>tracing.</p> <p>2.We ensured the 14 day quarantine of the employees who traveled from different states during lockdown periods.</p> <p>3.All employees wear masks and appropriate PPE is provided to staff dealing with samples.</p> <p>4.We make sure all the meetings are online, and lunch timings are dispersed to avoid crowding at the canteen.</p> <p>5.We disinfect premises regularly</p>	
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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.