

2. Process Risks

Risk	Control measure	Explanation	Evidence of Compliance
Biological material entering site	Approved specimen receipt process	All items being received must be double bagged and collected by qualified personnel.	Records of collection and procedures for collection,
Biological material in freezer or storage	Approved specimen storage process	All items inside the freezer must be entered in an inventory, all items in the collection are preserved and registered.	An inventory of items located in the freezer, including what, when collected, who owns the item and where it came from, and risks present.
	Identify biological risk within freezer	Ensure only specimens are stored in the freezer, post clinical risk image on outside surface of freezer and refrigeration units.	
Airbourne material contaminated with zoonotic organisms	Restrict laboratory access	All personnel entering the laboratory must show a business need to be there and proof of immunity or wear a P2 protective mask.	Register of training for employees and visitor instruction.
	Prohibit drilling or mechanical cutting	Avoid any activities that would aerosol biological material.	Prohibit drilling or mechanical cutting.
	Mechanical Ventilation producing negative pressure	The input of air through mechanical ventilation or air conditioning must result in a negative air pressure with less air input than output.	Desing specifications show air exchange rate for input and extraction. Regular maintenance.
	Local exhaust ventilation	Movable ventilation systems that can be positioned over the working surface.	Inspection and testing by qualified provider every 6 months.
	Fume Cupboard	Enclosed space that provides fume extraction and splash protection.	
	Fume hood	Air extraction hood often located above specific machinery or sinks.	
Biological contamination of equipment inside the laboratory	Restrict personal equipment from high-risk areas	Provide enclosed cabinets for workers and visitors to the laboratory to store personal items.	Laboratory Access and Egress SOP.
	Decontaminate all equipment being removed from high-risk area	Procure decontamination chemicals, develop process for decontamination and implement with development of SOP with training.	Record of decontamination of large items. Decontamination SOP.

Risk	Control measure	Explanation	Evidence of Compliance
Biological contamination of surfaces within the laboratory	Implement regular cleaning of laboratory surfaces	Use appropriate chemicals to decontaminate floors, doors, walls, benches, and fixed equipment within the laboratory.	Records of cleaning and decontamination.
	Impervious floors and walls	The floors and walls of the laboratory are designed for regular exposure to water and decontamination chemicals.	Design specifications of floors and walls. Inspection of floors and walls.
	High-quality stainless-steel benches	All benches are fabricated with 316 grade stainless steel to withstand regular use of VirkonS.	Design specifications of benches.
	Stainless-steel or metal storage cabinets and equipment	Benches, shelving, storage cupboards and equipment is designed for regular decontamination.	Design specifications of cabinets and equipment.
Entrapment in restricted space such as freezer	Area designed for easy escape and alarm	Functional door release mechanism and bell to alert nearby workers of entrapment.	Inspection records of door release mechanism and bell.
	Avoid work alone in freezer	Develop work schedule restrictions to ensure workers can call for assistance and others know of their presence in the restricted space.	Walk in Freezer SOP and training records.
Fridge and Freezer icing over	Airflow around specimens in freezer	Promote airflow within the freezer with shelving and raised surfaces to allow air to move around specimens.	Inventory records.
	Freezer inspection process	Inspect freezer for ice build-up, freezer seal integrity and storage protocols.	Inspection records.
Biological contamination of clothing and footwear	Implement laboratory coat requirements	Issue laboratory coats to workers, restrict their use and arrange laundering by appropriately qualified provider.	Laundering records, training records.
	Protect footwear	Ensure workers wear enclosed shoes, provide boot covers and shoe decontamination process.	Laboratory Access and Egress SOP.
Disposal of contaminated waste	Clinical waste disposal	Organise for all waste that is biologically contaminated to be secured and then collected for disposal by appropriate qualified provider.	Clinical waste disposal SOP and training records
	Sharps waste disposal	Organise for all sharps waste to be separated from other waste and collected in appropriate sharps containers and collected for disposal by an appropriately qualified provider.	Sharps use and disposal SOP and training records.

Risk	Control measure	Explanation	Evidence of Compliance
Exposure to biological risk during activities	High risk activities conducted by qualified personnel	All workers that conduct high risk activities have appropriate laboratory qualification and/ or experience, a business need to be in attendance, and immunity to the biological risk/s.	Induction records and access restrictions.
		Install signage on the entry door when high risk tasks are underway.	Signage, SOP for high-risk work.
Contractor and visitor access	Restrict High risk activities	Identify the different High-risk activities. Ensure that high risk activities do not occur when contractors or visitor are scheduled to visit the laboratory.	SOP for contractor entry.
	Log all access into the laboratory	Keep a register of all visitors, contractors, and other access into the laboratory. Implement a check to ensure that access is approved and for business purposes, and not public access or sight-seeing.	Induction and approval of laboratory entry. Visitor Access SOP.
Emergency Response	Access into lab by Emergency personnel	Ensure emergency service officers wear appropriate protection should they need to clear area of personnel in the event on an emergency.	Emergency Access SOP.
	Biological spill or exposure response	Ensure biological materials can be cleaned up and decontaminated following a spill.	Biological Exposure SOP.