






BIOGENIX

PERSONAL PROTECTIVE EQUIPMENT

	NAME	DESIGNATION	SIGNATURE	DATE
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VERSION: 1.0

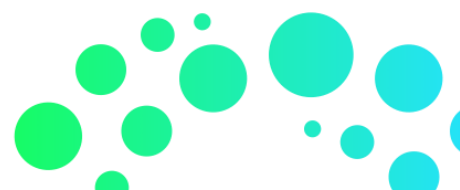
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2 REVISION HISTORY

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1	1.0				





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4 POLICY STATEMENT:

- 4.1 Personal Protective Equipment (PPE) and clothing may act as a barrier to minimize the risk of exposure to aerosols, splashes and accidental inoculation.
- 4.2 PPE is considered the last line of defense for protection and when possible should not be only form of exposure control. PPE should be used in combination with engineering controls, such as biological safety cabinets, and work practice controls, such as minimizing aerosol generation and using good microbiological practices.
- 4.3 Personal Protective Equipment (PPE) also protects the experiment from contamination.
- 4.4 Selection of PPE is dependent on the nature of the work performed.
- 4.5 Protective clothing should be worn when working in the laboratory. Before leaving the laboratory, protective clothing should be removed, and hands should be washed.
- 4.6 The extent and kind of PPE to be selected for any particular activity depends upon the laboratory operation and levels of risk associated with the procedure followed in Biogenix laboratory.

5 PURPOSE

- 5.1 This policy aims to provide guidelines for usage of the required PPE while working inside the Biogenix laboratory, as per the degree of risks which each specific tasks performed in each room could pose to laboratory personnel.
- 5.2 The reason for this policy is to prevent occupational diseases, injuries, and fatalities that may be avoided through the use of appropriate protective equipment, and to comply with Occupational Safety and Health Administration (OSHA) regulations (29 CFR 1910 Subpart I)
- 5.3 To educate the laboratory personnel on how to protect themselves and their colleagues from being infected while working, as well as avoiding accidentally spreading out the microorganisms when leaving the laboratory.





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6 SCOPE

- 6.1 The scope of this policy extends to proper use Personal Protective Equipment to all the staff in Biogenix Laboratory.
- 6.2 Explaining the process of putting on (Donning) the PPEs before entering the laboratory and the process of taking them off (Doffing).

7 DEFINITIONS

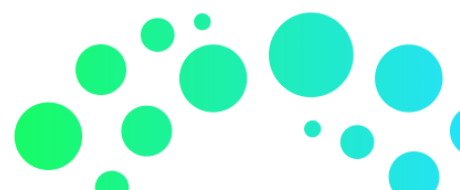
- 7.1 Personal Protective Equipment Definition: “specialized clothing or equipment worn by an employee for protection against infectious materials” (OSHA)

8 ACRONYMS

- 8.1 PPE – Personal Protective Equipment

9 RESPONSIBILITIES

- 9.1 Laboratory Director is responsible for compliance with health and safety requirements and implementation of this policy in all the rooms of the Biogenix Laboratory
- 9.2 Biogenix laboratory personnel are responsible for following laboratory safety requirements and for wearing personal protective equipment as defined in this policy and in corresponding laboratory specific training.
- 9.3 Infection Control Staff must:
 - 9.3.1 Provide education for laboratory staff and management on this policy.
 - 9.3.2 Act as a resource for guidance and support when advice on PPE is required.
 - 9.3.3 Provide advice on individual risk assessments for PPE decisions.
 - 9.3.4 Providing illustration posters in the changing rooms.





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9.3.5 Follow up on any reported PPE / ill health-related incidents

9.3.6 Report on any hazards, associated with any particular PPE, coming to light during use.

10PROCEDURE

10.1 Principle of PPE:

10.1.1 Laboratory Staff must follow the basic principles below to ensure that no infectious material reaches unprotected skin or mucous membranes while working in the laboratory.

10.1.2 Donning:

10.1.2.1 PPE must be donned correctly in proper order before entry into the work area;

10.1.2.2 PPE should not be later modified while in the work area.

10.1.3 During work:

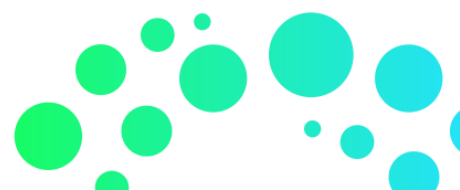
10.1.3.1 PPE must remain in place and be worn correctly for the duration of work in potentially contaminated areas.

10.1.3.2 PPE should not be adjusted during the procedure. In the event of a significant splash, the healthcare worker should immediately move to the doffing area to remove PPE.

10.1.3.3 The one exception is that visibly contaminated outer gloves can be changed while in the work area and work can continue.

10.1.3.4 Lab Staff should perform frequent disinfection of gloved hands using an approved hand sanitizer, particularly after contact with hazardous material.

10.1.3.5 If during work any breach in PPE occurs (e.g., a tear develops in an outer glove, a glove separates from the sleeve, accidental slip of N95 mask), the healthcare worker must move immediately to the doffing area to assess the exposure. The facility exposure management plan should





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be implemented; including correct supervised doffing and appropriate occupational health follow-up, if indicated by assessment. In the event of a potential exposure, infectious pathogen exposure procedures must be followed in accordance with the occupational exposure policy of Biogenix Laboratory.

10.1.4 Doffing:

10.1.4.1 Removing used PPE is a high-risk process that requires a structured procedure, a doffing assistant in some situations, and a designated area for removal to ensure protection.

10.1.4.2 PPE must be removed slowly and deliberately in the correct sequence to reduce the possibility of self-contamination or other exposure to infectious agent.

10.1.4.3 A stepwise process should be developed and used during training and working.

10.1.5 Training on Correct Use of PPE;

10.1.5.1 Training ensures that healthcare workers are knowledgeable and proficient in donning and doffing PPE before carry the work in Biogenix Laboratory.

10.1.5.2 Comfort and proficiency when donning and doffing are only achieved by repeatedly practicing correct use of PPE.

10.1.5.3 Lab staffs should be required to demonstrate competency in using PPE, including donning and doffing while being observed by a trained observer, before working in Laboratory.

10.1.5.4 Training should be tailored to the intended audience and effectively transmit the required information.

10.1.5.5 In addition, during practice, Lab Staff and their trainers should assess proficiency and comfort with performing required duties while wearing PPE.

10.1.5.6 The following elements are essential for PPE training:





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- 10.1.5.6.1 How to safely don, adjust, use, and doff the specific PPE that the lab Staff will use;
 - 10.1.5.6.2 How to safely perform procedure;
 - 10.1.5.6.3 Limitations of the PPE (e.g., duration of use, degree of protection);
 - 10.1.5.6.4 What to do in the case of breach in PPE;
 - 10.1.5.6.5 How to maintain PPE and appropriately dispose of it after use; and
 - 10.1.5.6.6 The possible physiologic strain associated with using PPE, and how to recognize and report early signs and symptoms, such as fatigue.
- 10.1.6 Designating Areas for PPE Donning and Doffing:
- 10.1.6.1 Ensure that areas for donning and doffing are designated as separate from the work area.
 - 10.1.6.2 Confirm that the doffing area is large enough to allow freedom of movement for safe doffing as well as space for a waste receptacle, a new glove & mask supply, and hand rub used during the doffing process. Also equipped with hand wash.

10.2 Selection of PPE

10.2.1 The use of Personal Protective Equipment (PPE) is essential for health and safety. Selection of PPE must be based on an assessment of the risk of contamination of the laboratory personnel's clothing and skin/mucous membranes by aerosols produced while handling the samples or performing the experiments.

10.2.2 Molecular Laboratory:

- 10.2.2.1 Laboratory area such as sample inactivation & extraction area where staff handling direct samples with possible contact with sample and aerosol generation cover all PPE is used along with N95 & face Shield/Goggle.





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10.2.2.2 Reagent Preparation room and qPCR room is clean area and no aerosol-generation procedure is done, which requires minimal PPE such as Gown, Mask, Gloves and shoe cover.

10.2.3 Core Laboratory:

10.2.3.1 Gown/ Lab coat, Mask and gloves are recommended to use for routine procedures.

10.2.3.2 Where possible aerosol generation such as centrifugation face shield or goggles should be use.

10.2.4 Systematically consider protecting each body area, i.e eyes, face, head, hands, feet, ears/ hearing, respiratory system, and whole body.

10.2.5 The specific PPE requirements for the Sample Collection, Reagent Preparation, and Nucleic acid Extraction Rooms, are as follows

10.2.5.1 Disposable hat: cover your ears and make sure your hair doesn't leak out.

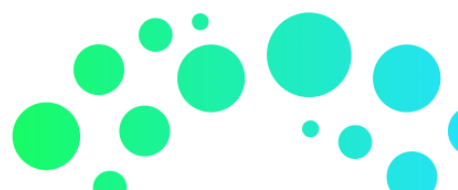
10.2.5.2 N95 Mask: when you put on the mask, the metallic strip should be uppermost, the upper elastic bands should be put on your neck, the lower put on your head, mask should fit snugly over the face, extend it to cover fully the mouth, nose and chin, make the metallic strip cling over nose bridge. If the mask wearing is qualified, the front of the mask will rise and fall when breathe hard.

10.2.5.3 Protective cover all: choose the right type and wear it from bottom to top. The feet should pass through the pant leg. Check and adjust the protective clothing cap so that the hair doesn't leak out. Finally, close the zipper, make sure the cloth is completely sealed. Use sellotape to seal exposed areas

10.2.5.4 Shoe cover: wear 2 layers.

10.2.5.5 Sleeve: it is mainly used to protect the joint of protective clothing and gloves, prevent it from slipping off.

10.2.5.6 Gloves: Two layers of nitrile gloves are required. Ensure that your gloves extend over the sleeves of the coveralls





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10.2.5.7 Goggles: cover the eyes completely and leave no gaps. Care with bio hazard waste (specific garbage can, bag and label). Note: Goggles should be only worn in the Sample Collection Room

10.2.5.8 Face Shield: The face shield should be worn on top of the hat and mask. Note: The face shield is only applicable to be worn in the Reagent Preparation and Nucleic Acid Extraction Rooms

10.2.5.9 The specific PPEs for the reagent room and qPCR room are different as it is considered a clean area of active virus. The list of PPEs are disposable hat, lab coat, shoe cover, gloves, and mask.

10.3 General Precautions:

10.3.1 Wear a clean set of PPE each time you enter the laboratory room.

10.3.2 Wear double gloves for performing work within the biological safety cabinet (BSC). Remove the outer pair before exiting the BSC and don a new pair each time you re-enter the BSC. Also outer gloves should be replaced with new one between each sample batch and whenever it is soiled.

10.3.3 All laboratory staff must receive training in the principles of and correct use of PPE.

10.3.4 PPE should be located close to the point of use.

10.3.5 PPE should be appropriate, fit for purpose and suitable for the person using/wearing it, with the donning and removing of items carried out appropriately each time.

10.3.6 PPE should not be a source of further contamination, e.g. by being taken off and left on environmental surfaces, or by being removed inappropriately and contaminating hands or clothing.

10.3.7 Do not take your personal belongings inside the laboratory, store them in the locker.

10.3.8 The use of gloves does not negate the need for hand hygiene.





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- 10.3.9 Stocks of PPE should be stored off the floor, e.g. on appropriate shelving, in designated clean and dry storage areas to ensure that they are not contaminated prior to use.
- 10.3.10 Torn, punctured or otherwise damaged PPE should not be used and should be removed immediately (safety permitting) if this occurs during a procedure.
- 10.3.11 It is important to know that you cannot move between the laboratory's rooms using the same set of PPEs. If there is a need to go to another room, you should follow the below steps of doffing and then don another set of PPEs specific for the room you want to enter.
- 10.3.12 Remove the PPEs before leaving the anteroom of the laboratory. Do not perform the Doffing in the changing room as this will be a source of contamination.
- 10.3.13 Used PPE should never be placed on environmental surfaces, but disposed of safely and immediately following use into yellow biohazard bag in the anteroom.
- 10.3.14 Hand hygiene should be carried out before donning gloves and immediately after removal and disposal of gloves.
- 10.3.15 Reusable items (e.g. non-disposable goggles) should have a decontamination schedule with responsibility for this assigned. Items should be dealt with immediately following use.
- 10.3.16 Perform the donning and doffing under the supervision and guidance of an experienced infection control officer or a colleague.

10.4 Sequence of Donning and Doffing (see illustrations in Appendix 1)

10.4.1 Sample Collection, Reagent Preparation, and Extraction Rooms of Molecular Laboratory

10.4.1.1 Follow the below sequence to put on (Donning) PPE: -

10.4.1.1.1 Remove watches and jewellerys

10.4.1.1.2 Perform hand hygiene using water and soap





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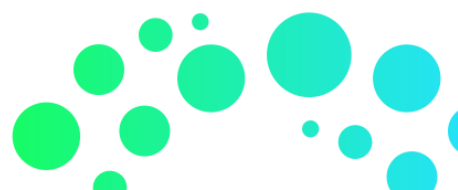
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- 10.4.1.1.3 Put on the disposable hat
- 10.4.1.1.4 Put on the first disposable shoe cover
- 10.4.1.1.5 Put on the first pair of nitrile gloves
- 10.4.1.1.6 Put on coverall
- 10.4.1.1.7 Put on the second shoe cover and tie it on top of the coverall
- 10.4.1.1.8 Put on the N95 mask
- 10.4.1.1.9 Put on the head cover and seal opened areas using Cellotape to avoid being aerosol contamination
- 10.4.1.1.10 Wear the face shield or the goggles as explained in points 2.7.1.3.7 and 2.7.1.3.8.
- 10.4.1.1.11 Put on the second pair of gloves.
- 10.4.1.1.12 Enter the ante room and then to the dedicated laboratory room.
Note: Do not leave with your PPE in wash room or Lab/office corridor.
- 10.4.1.2 Follow the below sequence to take of (Doffing) the PPE:-
 - 10.4.1.2.1 Ensure that there is a biohazard waste bin is available in the anteroom. There should be a bag for the usable goggles.
 - 10.4.1.2.2 Perform hand hygiene using 75% Ethanol on the gloved hands.
 - 10.4.1.2.3 Remove outer pair of gloves in the outward direction without contaminating the inner pair
 - 10.4.1.2.4 Perform hand hygiene on gloved hands
 - 10.4.1.2.5 Remove face shield or reusable goggles by pulling the string from behind the head and dispose of it safely.





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- 10.4.1.2.6 Remove the head cover and the coverall by removing the cellotape and untying the knot or zipper, then pulling from back to front rolling it from inside to outside (while avoiding touching your scrub suit or domestic clothes) and dispose it safely.
- 10.4.1.2.7 Remove the mask from behind the head by first untying the bottom string above the head and leaving it hanging in front and then the top string next from behind head and dispose of it safely.
- 10.4.1.2.8 Perform hand hygiene on gloved hands
- 10.4.1.2.9 Remove gloves carefully and dispose of them safely in the biohazard bag
- 10.4.1.2.10 Do not re-enter the room. Leave the ante room to the changing room.
- 10.4.1.2.11 Wash your hands using soap and water.

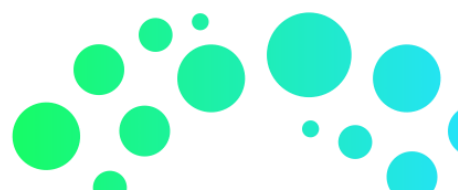
10.4.2 qPCR Room

10.4.2.1 Sequence for Donning PPE: -

- 10.4.2.1.1 Disposable hat
- 10.4.2.1.2 Shoe disposable cover
- 10.4.2.1.3 Lab coat or gown
- 10.4.2.1.4 Mask
- 10.4.2.1.5 Goggles or face shield
- 10.4.2.1.6 Gloves

10.4.2.2 Sequence for Doffing PPE: -

- 10.4.2.2.1 Shoe cover
- 10.4.2.2.2 Gloves





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10.4.2.2.3 Lab coat or Gown

10.4.2.2.4 Mask

10.4.2.2.5 Disposable hat

10.4.2.2.6 Perform hand hygiene using water and soap

10.4.3 Core Laboratory

10.4.3.1 Sequence for Donning PPE: -

10.4.3.1.1 Gown/ Lab Coat

10.4.3.1.2 Mask

10.4.3.1.3 Googles/Face Shield

10.4.3.1.4 Gloves

10.4.3.2 Sequence for Doffing PPE: -

10.4.3.2.1 Gloves

10.4.3.2.2 Googles/face Shield

10.4.3.2.3 Gown/Lab Coat

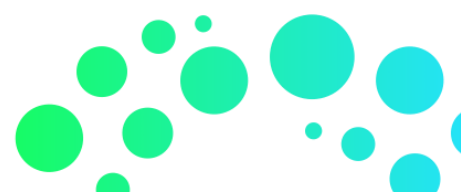
10.4.3.2.4 Mask

10.5 Disinfecting Reusable Safety Goggles:

10.5.1 Refer SOP G42/COVID-19 Lab/SOP/007 titled Goggle Cleaning Policy & Procedure.

11 CROSS REFERENCE:

11.1 World Health Organization, How to put on and how to remove personal protective equipment – posters, <https://www.who.int/csr/resources/publications/ebola/ppe-steps/en/>





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11.2 <https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html>

12 RELEVANT DOCUMENTS & RECORDS:

12.1 BG-POS-INF-004 – Donning of PPE Illustration Posters – Molecular Laboratory.

12.2 BG-POS-INF-005 – Doffing of PPE Illustration Posters – Molecular Laboratory.

12.3 BG-POS-INF-006 – Donning of PPE Illustration Posters – Core Laboratory.

12.4 BG-POS-INF-007 – Doffing of PPE Illustration Posters – Core Laboratory.

