



STEM CELL LABORATORY (STCL)



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STCL-EQUIP-004

OPERATION OF BIOLOGICAL SAFETY CABINETS

1 PURPOSE

- 1.1 The purpose of this procedure is to provide users with basic instructions regarding the proper use and operation of biological safety cabinets (BSCs). This procedure will be used in conjunction with the Operator's Manual for Biological Safety Cabinets provided by the manufacturers

2 INTRODUCTION

- 2.1 The biological safety cabinets (BSCs) in use in the laboratory are a Class II, Type-A design. The BSCs feature vertical laminar airflow and a front access opening. They are designed to protect not only the environment and the people using the cabinet, but also the product within from airborne contaminants. A laminar flow biological safety cabinet, although not a replacement for it, is a valuable supplement to good sterile technique.
- 2.2 Every measure should be taken to minimize contamination of cellular products that will be infused directly to our patients. This includes following strict cleaning schedules and wearing the appropriate personal protective equipment needed to protect the employee and the cellular products being handled

3 SCOPE AND RESPONSIBILITIES

- 3.1 The Medical Director, Laboratory Manager, and Stem Cell Laboratory staff is responsible for ensuring that the requirements of this procedure are successfully met

4 DEFINITIONS/ACRONYMS

- 4.1 BSC biological safety cabinet
- 4.2 UV ultraviolet light
- 4.3 PPE personal protective equipment

5 MATERIALS

- 5.1 Surface Decontamination supplies can include:
- 5.1.1 Activate Bleach (*followed with deionized water rinse*)
 - 5.1.2 10% bleach solutions (*followed with deionized water rinse*)
 - 5.1.3 Sterile 70% Isopropyl Alcohol (IPA) or equivalent
 - 5.1.4 Germicidal Wipes
 - 5.1.5 Steri-Perox 6% wipes
- 5.2 Additional materials (*as needed*)
- 5.2.1 Disposable sterile sleeve covers

- 5.2.2 Disposable gowns
- 5.2.3 Paper towels or lint-free wipes
- 5.2.4 Sterile Gloves (*various sizes*)
- 5.2.5 Non-Sterile Gloves (*various sizes*)

6 EQUIPMENT

- 6.1 Biological Safety Cabinets

7 SAFETY

- 7.1 Wear appropriate personal protective equipment when handling potentially hazardous blood and body fluids to include, but not limited to, gloves, lab coat, aprons, sleeve covers, etc.
 - 7.1.1 **HPC Plating Section of the STCL** - Wear disposable gown and gloves whenever processing specimens inside the biological safety cabinet.
 - 7.1.2 **Processing Section of the STCL** - Wear disposable gown with tight-fitting cuffs, sterile sleeve covers, and gloves (*both non-sterile and sterile gloves are available*); wear PPE combinations to ensure skin is not exposed when working with cellular products infused directly to a patient. Use sterile 70% Isopropyl Alcohol (IPA) or equivalent as needed on gloves to maintain sterility throughout procedure.
- 7.2 Do **NOT** work in the BSC with arms or hands exposed. Gloves should fit over disposable gown and/or tight-fitted sleeve covers to ensure skin is not exposed
- 7.3 Handle all cellular products following universal precautions and sterile technique
- 7.4 Use EXTREME CAUTION when working with needles. When needles must be recapped, use the "**one-handed scoop technique**" in an effort to prevent needle sticks
- 7.5 NEVER leave UV light on while working in the area
- 7.6 AVOID blocking the front and rear perforated grills; it will disrupt the airflow within the cabinet
- 7.7 NEVER operate the cabinet when a warning light or alarm is sounding

8 PROCEDURE

- 8.1 START-UP PROCEDURE:

- 8.1.1 If the cabinet has not been left running continuously (*starting leaving BSCs running at all times effective 08/24/2017*), first turn the blower switch to the **ON** position. Make sure there is cabinet airflow, either by listening for the sound of the blower or by feeling the airflow. The blower should run for 10-15 minutes prior to use (*if turned OFF for some reason*). If the cabinet has a functioning magnehelic gauge (*which measures suction*), the reading should be greater than zero. If the cabinet has a functioning minihelic gauge (*measuring suction*), check

for a range on respective BSC maintenance form. The gauge reading should be consistent from day to day. Fluctuations in this reading could indicate a problem so it should be investigated and reported to senior staff as soon as possible. If there are concerns about the cabinet's functionality, service may need to be scheduled.

8.1.2 Turn ON the fluorescent light at the same time making sure that the ultraviolet light (*optional*) is turned off.

8.1.3 Run UV light for a minimum of 15 minutes at the end of the day IF the BSC was used that day.

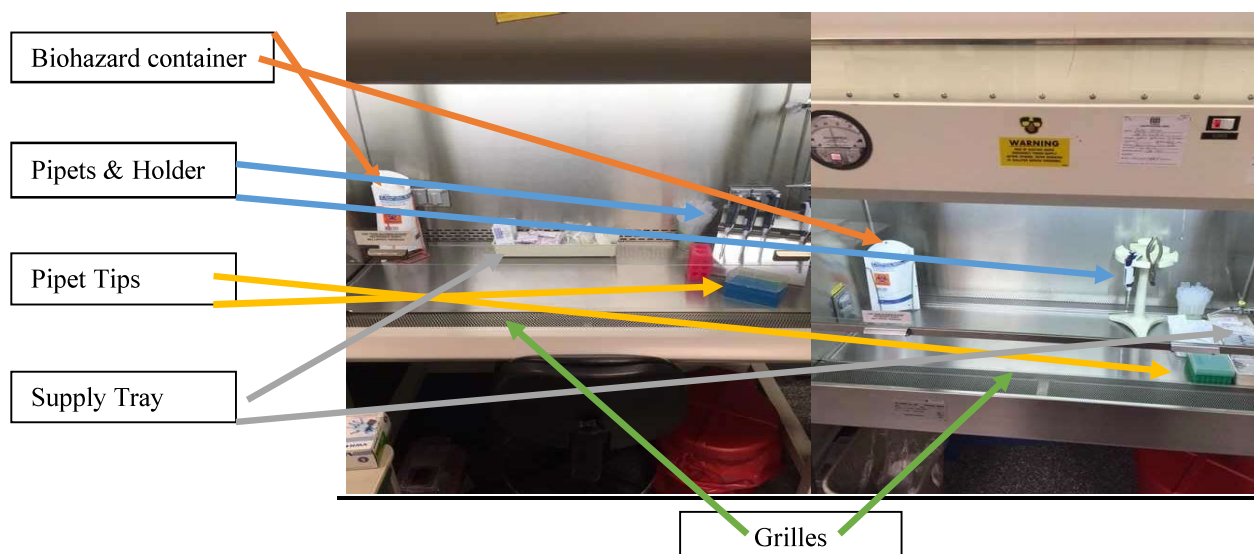
NOTE: *Never leave the ultraviolet (UV) light on while there are employees working in the immediate area.*

8.1.4 Check to determine that the drain valve is in the CLOSED position or the drain coupling is capped (*if applicable based on the cabinet that is being used*).

8.1.5 As with other laboratory workspaces, the interior area of the cabinet should be wiped down with a surface disinfectant BEFORE use. In the processing area when working with cellular products that will be directly infused into a patient, the cabinet should be cleaned **BEFORE** and **AFTER** each product has been processed.

NOTE: *Some disinfectants may corrode or stain the steel surfaces. If using a corrosive, rinse with deionized water after disinfecting to prevent corrosion.*

8.1.6 Clean the exterior of those items that remain inside the BSC (*such as the pipets and holder, supply tray, biohazard container, etc*). Whenever possible, all required materials should be placed in the cabinet before beginning your work to minimize the number of passes through the air barrier until the procedure is completed. **Materials should be arranged inside the cabinet so that clean and dirty materials are segregated, preferably on opposite sides of the work area.** Be sure germicidal wipes do not block airflow over the grilles.



NOTE: *Blocking the front and rear perforated grilles must be avoided as not to disrupt the airflow inside the cabinet.*

- 8.1.7 After your equipment is in place inside the cabinet, adjust the vertical sliding view screen so it is open approximately **eight to ten inches** (*depending on the type of BSC being used*). This approximate aperture opening is important to ensure proper airflow. If the aperture (sash) is not high enough, it will place additional stress on the motors of the biological safety cabinet. If the window is at the wrong height, an alarm may sound. There may be a metallic tape sensor noting the alarm position on the glass. Do NOT remove this sensor (*if applicable*).
- 8.1.8 After the cabinet has been running for at least **three minutes** with the view screen in proper position, you are ready to begin.
- 8.2 THE PROPER WAY TO WORK IN THE CABINET:
 - 8.2.1 Hands should be washed thoroughly with germicidal soap both BEFORE and AFTER working in the biological safety cabinet.
 - 8.2.2 Operators who work with cellular products that will go directly to a patient must wear PPE in an effort to maintain the sterility of the product being handled. This will help minimize the shedding of skin flora in the BSC while protecting hands and arms from contamination
 - long-sleeved disposable gown with tight-fitting cuffs with gloves pulled over the cuffs to ensure no skin is exposed
 - use sterile 70% Isopropyl Alcohol (IPA) or equivalent as needed on gloves to maintain sterility throughout procedure
 - 8.2.3 Perform all work on the depressed area of the solid work surface. Work with a limited number of slow movements. Since all of the equipment needed is already in the cabinet, moving arms in and out through the air barrier should be minimized and limited to the disposal of sharps and syringes
 - 8.2.4 Because opening and closing doors in the laboratory causes air disturbance which might interfere with cabinet airflow, this kind of activity should be kept to a minimum while the cabinet is in use
 - 8.2.5 Avoid using floor-type pipette discard containers. It is important that used pipettes be discarded into a suitable container within the cabinet; this will reduce the temptation to move in and out unnecessarily through the air barrier
 - 8.2.6 Always use good aseptic technique when working in the BSC
 - 8.2.7 **NEVER OPERATE YOUR CABINET WHILE A WARNING LIGHT OR ALARM IS ON.** These warning devices tell you when there has been some sort of compromise of cabinet integrity. Be sure to correct the problem before you continue your work, whether it is caused by insufficient suction in the exhaust system or improper positioning of the cabinet view screen. The operating position of the sash provides an approximate eight to ten inch high access opening. This restricted

opening permits optimum operating conditions for the cabinet. For operating comfort, it is recommended that the top of the operator's shoulder be at the same height as the bottom of the window. Because operator's will not all be the same height, it is suggested that an adjustable chair be provided.

- 8.2.8 After a procedure has been completed, the fan should be allowed to run for at least three minutes (*if not run continuously*) with no activity so that any airborne contaminants can be purged from the work area
- 8.2.9 The interior surfaces should be disinfected to include work surface, exterior surfaces of the items in the BSC (*as noted in pictures labeled in section 8.1.6*), walls of the BSC, and interior glass. Check the work area carefully for spills or splashes which might support bacterial growth. It is recommended that the cabinet be left running continuously to ensure containment and cleanliness. If the user needs to turn off the cabinet at the end of the shift, the window should be closed completely and the ultraviolet light turned on for 15 minutes. The sash alarm will be silenced when the window is in the closed position
- 8.2.10 Perform maintenance procedures as reflected on Biological Safety Cabinet – Maintenance Schedule (FRM1).
- 8.2.11 All bi-annual maintenance procedures and re-certification of the BSC as an ISO CLASS 5 environment (*as defined in accordance with EN/ISO 14644 methodology*) are performed by Precision Air Technologies for the laboratory. Bi-annual maintenance is performed on all seven (7) of the biological safety cabinets within the Stem Cell Laboratory.
 - BSC re-certification will be verified by reviewing and approving the certification reports
 - Viable active air sampling and contact plate sampling is also performed bi-annually on all seven (7) biological safety cabinets (*effective 12/18/2019*). Agar plates are used when testing air samples and touch plates in each BSC; air sample plates are placed as close to CENTER of the interior as possible. Touch plate is place off-center next to the air sampling plate. Agar plates are left in place in the BSC for ~ 30-60 minutes before plates are removed and packaged for testing.
 - UV light bulbs will be evaluated for intensity during preventative maintenance and/or replaced as deemed necessary (*based on the manufacturer's recommendations for the life of the bulbs*).
 - Magnehelic ranges will be calculated +/- 25% of the reading at the time of the PM. Ranges will be adjusted, if applicable, reviewed by QSU, and updated manually on the BSC worksheets if the PM was performed during the middle of the month
 - New labels will be prepared for the BSC worksheets reflecting the NEW ranges since the time of the last PM until the next PM procedure is performed

- If there is a failure noted during the PM, an **Out of Service** form will be placed on the BSC until an investigation has been initiated and completed to determine the risk associated with the failure identified

- 8.2.12 Documentation of all maintenance procedures is stored indefinitely. It is the responsibility of all laboratory personnel, who use the equipment, to document the maintenance procedures performed

NOTE: *Monthly maintenance requires that the entire hood be emptied (including the grill) so the entire cabinet can be disinfected. Pipets, pipet holder, supply tray, etc, (see pictures in Section 8.1.6) should also be wiped down/disinfected before those items are returned inside the BSC.*

Remember to also clean the glass (both inside and outside of the biological safety cabinet), the handles used to raise and lower the sash, and the panel with switches used to turn the cabinet on and off, UV light on and off, etc.

Run the UV light for at least 15 minutes post monthly maintenance procedure.

- 8.2.13 Refer to the Operator's Manual for Biological Safety Cabinets for details regarding maintenance and troubleshooting techniques.

8.3 COMMON ERRORS TO AVOID:

- 8.3.1 DON'T fail to turn ON the blowers.
- 8.3.2 DON'T have the view screen at the wrong height. EIGHT TO TEN INCHES is required to ensure proper airflow.
- 8.3.3 DON'T block air intake grilles.
- 8.3.4 DON'T overload the work area. Too many items in the hood can cause a disruption in the airflow.
- 8.3.5 NEVER use the cabinet to store supplies or laboratory equipment. (*See [pictures in Section 8.1.6]*)
- 8.3.6 DON'T leave an UV light on when people are in the room.
- 8.3.7 DON'T fail to disinfect surfaces both before and after working in the biological safety cabinet.
- 8.3.8 DON'T begin using the BSC until the cabinet has operated for three minutes with the view screen in the proper position.

9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-EQUIP-004 (FRM 1) Biological Safety Cabinet - Maintenance Schedule
- 9.2 STCL-FORM-036 Biological Safety Cabinet with Vacuum Trap and Paper Catch – Daily, Weekly, Monthly Maintenance Schedule.

10 REFERENCES

10.1 Operator's Manual for Biological Safety Cabinets, The Baker Company

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
08	B Waters-Pick	<ul style="list-style-type: none"> Section 8.2.2 removed reference to sterile and non-sterile gloves Section 8.2.3 removed "Operators working <u>with specimens that will not be infused directly to patients</u>, as is the case when plating CFU assays, do not have to wear sleeve covers over the arms of their disposable gowns" Section 8.2.12 added "Agar plates are used when testing air samples and touch plates in each BSC; air sample plates are placed as close to CENTER of the interior as possible. Touch plate is place off-center next to the air sampling plate. Agar plates are left in place in the BSC for ~ 30-60 minutes before plates are removed and packaged for testing". Section 8.2.12 added "UV light bulbs will be evaluated for intensity during preventative maintenance and/or replaced as deemed necessary (<i>based on the manufacturer's recommendations for the life of the bulbs</i>)".

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