Aseptic Technique with TRIO.BAS™ Microbial Air Samplers

Checklist

TRIO.BAS®
BIOLOGICAL AIR SAMPLER

HARDY DIAGNOSTICS
A Culture of Service™

Aseptic Technique refers to a set of specific practices and procedures performed under carefully controlled conditions with the goal of minimizing microorganisms (bacteria, fungi, etc.) and contamination. The majority of contamination within aseptic processing clean rooms involves personnel. Appropriate gowning practices, correct personnel hygiene, and proper workflow can often eliminate the majority of contamination threats.

Actual Examples of FDA Form 483 Observations:

- "The cleanroom operator was observed re-using coveralls that were hanging on a hook in the anteroom."
- "Your cleanroom is maintained in a manner that could lead to product contamination. We observed the following clutter within the ISO Class 7 environment including a dispenser of clear adhesive tape, supply bins with various articles, and equipment that was not utilized during filling operations."
- "We observed the gowning practices of the pharmacist prior to the production. X entered the sterile production area wearing a single pair of non-sterile gloves. Within the cleanroom, X donned a second pair of gloves, sterile latex, powder free. When X's arms extended to ensure that the fingers filled the appropriate position, the pharmacist's bare wrist and forearm were exposed to the ISO 7 cleanroom environment."
- "Operators repeatedly displayed multiple poor aseptic practices..."

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The following checklist and accompanying TRIO.BAS™ instrument cleaning protocol guidelines are designed to assist in reinforcing aseptic technique practices when working with a TRIO.BAS™ air sampler.

MICROBIAL AIR SAMPLER: PREPARATIONS FOR SAMPLING

	Action	
	MICROBIAL AIR SAMPLER	Completed
1	Is the air sampler calibration date current?	
2	Is the air sampler cleaned and disinfected according to the established SOP?	
3	Was the aspiration chamber cover sterilized?	
4	Was the volume of aspirated air correctly programmed?	
5	Was the aspiration head opened and the culture media plate inserted inside the aspirating chamber with the correct technique?	
6	Was the culture plate lid placed on a sterile surface during sampling time?	
7	Was the culture plate from the aspirating chamber recovered in such a way as to avoid possible contamination?	
	CULTURE PLATES	Completed
1	Was the media brought to the correct temperature in preparation for sample collection?	
2	Were the culture plates labeled with the correct expiration date?	
3	Were the culture plates the correct media?	
4	Were the culture plates identified before sampling?	
5	Were the culture plates stored correctly and at the right temperature prior to incubation?	
6	Were the culture plates correctly packed after monitoring?	

WORKING AREA

	Actions	Completed
1	Is the working surface uncluttered, containing only items required for the specific activity?	
2	Was the work surfaced wiped with 70% sterile ethanol before work?	
3	Are incubators, refrigerators, freezers, and other materials routinely cleaned and sterilized?	

CLEANROOM HANDLING AND WORKING ACTIVITY

	Actions	Completed
1	Is work being performed slowly and deliberately, being mindful of aseptic techniques?	
2	Did you use new coveralls versus coveralls that may have been hanging on a hook in the anteroom?	
3	Were shoe covers, hair and facial hair covers, face mask/eye shields, and gloves replaced before re-entering the critical area?	

WORKFLOW MANIPULATION WITHIN ASEPTIC WORKSTATION

	Actions	Completed
1	Was the hood cleared of items such as paper, pens, calculators, and labels?	
2	Are all sterile products within the hood placed at least 15cm inside the hood?	
3	Are all items inside the hood outside of running air grate areas to avoid the outward flow of air?	
4	When the hood is turned on, is the air flow running for at least 30 minutes before use?	

CLEANROOM PERSONNEL CORRECT HYGIENE AND GOWNING

	Actions	
	HANDWASHING	Completed
1	Were hands and forearms washed with soap and water to the elbows for at least 30 seconds while in the ante-area?	
2	Were hands and forearms to the elbows completely dried using either lint-free disposable towels or an electric hand dryer?	
3	Was antiseptic hand cleansing performed using a waterless alcohol based surgical sanitizer following manufacturer's recommendations?	

	HEAD COVERINGS	Completed
4	Is the correct protective equipment worn?	
5	Is hair covered by the cap?	
6	Is the hair tied in the back?	

	GARBING ORDER	Completed
7	Has all jewelry, bandanas, coats, jackets, scarves, sweaters, vests been removed?	
8	Have you removed long sleeve shirts, artificial nails, cosmetics, visible piercings?	

	GOWNS	Completed
9	Does the non-shedding gown with sleeves fit correctly around the wrist and neck?	
10	Are disposable gowns properly discarded as recommended?	

	GLOVES	Completed
11	Were the hands cleaned again upon entering the buffer area? Gloves are a leading source of contamination when donned too early. Contact with non-sterile sources is a primary concern and easily goes unnoticed.	
12	Were the sterile gloves the last item donned?	
13	Are you certain gloves were not in contact with non-sterile surfaces or components during the activities?	

	EXPOSED SKIN	Completed
14	Was all skin, including wrists and arms, covered?	

Disinfection of Work Surfaces

Before beginning a process, the Operator must:

- Prepare an appropriate surface on which to operate

- Check that the surface is clean, flat, and sterilized by a lint free towel or wipes saturated with 70% sterile isopropyl alcohol

Note: Never use a corrosive cleanser

Operator

The Operator must:

Complete the **Preparation for Sampling checklist** to confirm all items requested on the checklist are addressed before starting the cleaning procedure.

Once all needed items are present, the operator can start the cleaning and sterilization protocols.

- **Wash hands with approved antiseptic**
- **Wear gloves**
- **Disinfect gloves**
- **Wear mask**
- **If working in a space with others, respect the distance**

Note: Never use a corrosive substance, such as bleach, to clean your instrument or instrument's parts

Disinfection of Aspirating Head(s)

Please note: Stainless steel aspirating heads should be periodically checked to ensure the perforations are not obstructed with dirty material. Use compressed air to take out any debris from the perforations.

• Stainless steel aspirating heads can be used for subsequent cycles during the same day and same environment by disinfecting the outside and inside with a cleanroom approved wipe saturated with 70% isopropyl alcohol. Do not touch the external or internal parts.

• The stainless steel aspirating heads should be sterilized after daily activity by autoclaving at a minimum of 121°C for 20 minutes. Protect sterilized aspirating heads with stainless steel cover(s) or aluminum foil to avoid possible microbial contamination that could occur prior to use.

• The stainless steel aspirating head(s) must be disinfected externally with a lint-free towel or wipe saturated with 70% isopropyl alcohol.

• If using Daily Shift Heads, only the outer wrapping must be sterilized with a lint-free towel/ wipe saturated with 70% isopropyl alcohol as the Daily Shift Heads are already sterilized.

• If the air sampler is used in succession in different environments, remember to start in the cleanest area and finish in the dirtiest area.

Disinfection of Component Surfaces

Surfaces should be sanitized with a lint-free wipe/towel saturated with 70% sterile isopropyl alcohol. Do not use a corrosive cleanser.

• The body surfaces of air samplers and base stations must be cleaned with a wet cloth. Wipe the surface with a lint-free wipe saturated with 70% isopropyl alcohol.

• Do not spray the surface directly.

• For all other components (cables, spare parts, etc), use a towel/wiper saturated with 70% isopropyl alcohol.

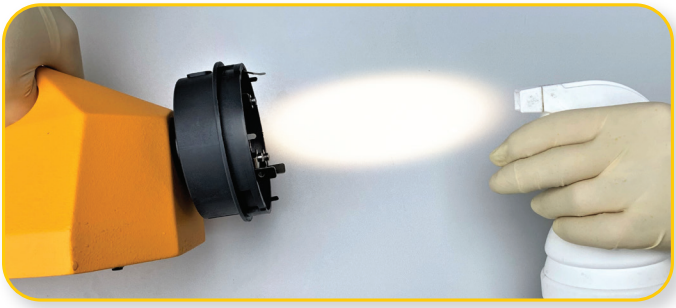
Disinfection of Screen:
• Use a sterile swab saturated with 70% isopropyl alcohol

Base Surface Bottom:
• Use a sterile swab saturated with 70% isopropyl alcohol

Disinfection of Aspirating Chamber:
• The inside part of the aspirating chamber should be disinfected with a sterile swab saturated with 70% isopropyl alcohol

Disinfection of Inner Chamber/Circuit:
• From a distance of about 15cm/5-6 inches, spray 70% isopropyl alcohol for five seconds while the instrument is on

• Wait about 5 minutes to dry the sampler. This operation should be ideally performed in a sterile laminar flow hood



The TRIO.BAS™ Family of Samplers

HARDY DIAGNOSTICS
A Culture of Service™

100% Employee Owned

bsi. ISO 13485 Medical Devices Quality Management
FM 572526

Hardy Diagnostics adheres to cGMP, is licensed by the FDA as a medical device manufacturer, and its quality management system is ISO 13485 certified.

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