ASEPTIC TECHNIQUE
Checklist
with
MICROBIAL AIR SAMPLERS

HARDY DIAGNOSTICS
A Culture of Service™

TRIO.BAS™
BIOLOGICAL AIR SAMPLER

Aseptic technique refers to a set of specific practices and procedures performed under carefully controlled conditions with the goal of minimizing microbial (bacteria, fungi, etc.) contamination. The vast majority of incidents of contamination in cleanroom settings can be attributed to lab personnel. Adherence to appropriate garbing, hygiene, and workflow procedures assists in greatly reducing the risk of contamination events.

Actual Examples of FDA Infractions:

- "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 class 7 cleanroom environment."
- "Operators repeatedly displayed multiple poor aseptic practices..."

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

MICROBIAL AIR SAMPLER

	Actions:	Yes/No
1	Is the air sampler within its calibration window?	
2	Is the air sampler cleaned and disinfected according to established SOP?	
3	Was the aspiration chamber cover sterilized, if applicable?	
4	Was the volume of aspirated air correctly programmed?	
5	Was the aspirating 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

	Actions:	Yes/No
1	Were the culture plates stored correctly and at the right temperature prior to sampling?	
2	Have you confirmed the culture plates have not expired?	
3	Was the proper media selected for the sample type being collected?	
4	Were the culture plates stored correctly and at the right temperature after sampling?	
5	Were the culture plates refrigerated or forwarded to the lab immediately after monitoring/sampling?	

WORKING SURFACES

	Actions:	Yes/No
1	Is the working surface uncluttered, containing only items required for your specific activity?	
2	Was the work surfaced wiped with 70% sterile isopropyl alcohol before work?	
3	Are incubators, refrigerators, freezers, and other materials routinely cleaned and sterilized?	

CLEANROOM HANDLING AND WORKING ACTIVITY

	Actions:	Yes/No
1	Did you work slowly and deliberately, being mindful of aseptic technique?	
2	Did you re-use 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:	Yes/No
1	Was BSC used for placement of paper, pens, calculators, and labels?	
2	Are all sterile products within the hood placed at least 15cm inside the hood?	
3	Are all items in the hood placed away from 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 PERSONAL HYGIENE AND CORRECT GOWNING

	HANDWASHING	
	Actions:	Yes/No
1	Were hands and forearms washed with soap and water to the elbows for at least 30 seconds prior to compounding activities?	
2	Were hands and forearms to the elbows completely dried using either lint-free disposable towels or wipers?	
3	Was antiseptic hand cleansing performed using a waterless alcohol based surgical sanitizer following manufacturer's recommendations?	
4	Had all hand, wrist, and other exposed jewelry been removed?	

	HEAD COVERINGS	
	Actions:	Yes/No
5	Was the correct protective equipment worn?	
6	Were ears and all hair covered by the head and/or facial hair covering?	

	PERSONNEL PREPARATION	
	Actions:	Yes/No
7	Had all jewelry, bandanas, coats, jackets, scarves, sweats, vests, and all other outer garments been removed?	
8	Were artificial nails, cosmetics, visible piercings, or other items that may interfere with garbing removed?	

	GOWNS	
	Actions:	Yes/No
9	Did the non-shedding gown with sleeves fit correctly around the wrist and neck?	
10	Were disposable gowns properly discarded as recommended or reused inappropriately?	
11	Was all skin, including wrists and arms, covered? **Note: Long sleeves are not considered proper coverage.*	

	GLOVES	
	Actions:	Yes/No
12	Were the hands cleaned again enetering 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.*	
13	Were the sterile gloves the last item donned?	
14	Were the gloves in contact with non-sterile surfaces or components during the activites?	

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.

Operator

The Operator must:

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

Once all items are completed, the operator may start the cleaning and sterilization protocols to avoid possibility of contamination.

Remember:

- **Wash hands with approved disinfectant**
- **Don gloves**
- **Disinfect gloves**
- **Wear mask**
- **If working in a space with others, be mindful of distance**

Note: Never use a corrosive substance to clean your instrument or instruments parts

Disinfection of Aspirating Head(s)

Please check periodically: stainless steel aspirating heads should be periodically checked to ensure the perforations are not obstructed. Compressed air can be used to remove debris from the perforations.

• The stainless steel aspirating head can be used for subsequent cycles during the same day and same environment by disinfecting the outside and inside with a cleanroom-approved wiper 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. Stainless steel cover(s) are included with aspirating heads and should be used to avoid microbial contamination prior to use.

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

Disinfection of Sampler

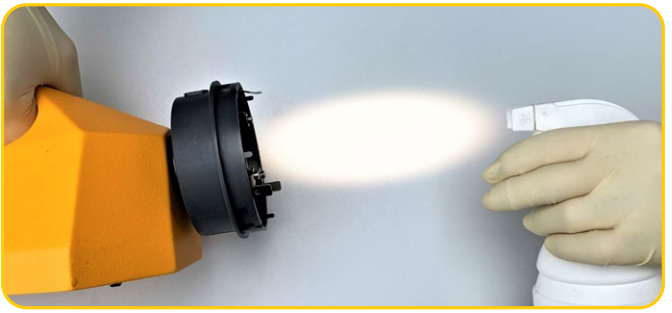
Prepare an appropriate surface on which to operate. The surface must be clean, flat and should be sanitized by a lint-free wipe/ towel saturated with 70% sterile isopropyl alcohol. Never use a corrosive cleanser.

• The body of the air sampler and base stations should be cleaned with a lint free wipe saturated with 70% isopropyl alcohol. Do not spray alcohol directly on to surface of sampler or base.

• All other components (cables, spare parts, etc.) should be disinfected in the same manner.

Disinfection of Screen, Aspirating Chamber, and Base Surface Bottom:
• Use a sterile swab saturated with 70% isopropyl alcohol.

Disinfection of Sample Head Interior:
• While the sample head is running, and from a distance of 5-6 inches away, spray 70% isopropyl alcohol into sample head for 5 seconds.



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

• The inside of the aspirating chamber should also be disinfected with a swab saturated with 70% isopropyl alcohol.

The TRIO.BAS™ Family of Samplers

HARDY DIAGNOSTICS
A Culture of Service™

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Headquarters

1430 West McCoy Lane
Santa Maria, CA 93455
800.266.2222
Sales@HardyDiagnostics.com
HardyDiagnostics.com

Distribution Centers

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Olympia, Washington
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