



**CTG Certification
Network**

Viable Air Monitoring Protocol

Technical Support

Phone: 317-713-8200

After-hours emergency: 317-752-3065

Fax: 317-713-8201

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CTG Viable Air Monitoring Protocol—Version 1.0



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Viabale Air Monitoring Protocol

Signature below verifies that you have read and understand the protocols set forth by Containment Technologies Group, Inc. for the certification of CTG, Inc. products. These protocols are CTG, Inc. recommended guidelines.

Certification Company Name

Address

Phone

Printed Name of Professional Executing Today's Work

Signature

Date

A copy of this acknowledgement page needs to be sent back to CTG via fax (317-713-8201) along with Appendix A for every certification.



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ViabLe Air Monitoring Protocol

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ViabLe Air Monitoring Protocol

1.0 PURPOSE

1.1 Purpose of the protocol

The purpose of this test is the evaluation of airborne microorganisms both in the ISO class 5 environment and the room area surrounding the ISO class 5 environment. Monitoring should occur during normal operations to allow for collection of meaningful data. This protocol is intended to provide for monitoring of airborne particulate and should be supplemented with surface and fingertip monitoring programs that will be covered in different protocols.

1.2 Description of Process

Per USP<797> viable airborne sampling is to occur on a semiannual basis for all risk categories within ISO class 5 compounding environments. The airborne sampling is to include two samples of fifteen-minute duration at a flow rate of one CFM or 28.3 liters per minute. The fifteen-minute sample time represents 424.5 liters of air with two samples resulting in 849 liters consistent with the volume of 400 to 1000 described in USP<797>. A calibrated Andersen viable sampler is used for collection of the samples.

1.3 Detail description of Activities

A total of three samples are to be taken. The first two inside the MIC chamber and a third above the airlock. In dual chamber units three samples per chamber are required.

The location of the two inside samples are (1) the center of the compounding zone approximately 20 inches from the side wall and 12 inches from the back wall and (2) center of the airlock door approximately 12 inches from the side wall. The outside location is on top of the airlock.



ViabLe Air Monitoring Protocol

Facility Information:

Date of test: _____

Re-test date: _____

Test Report Number: _____

Tested by: _____

Unit Description: _____

Model: _____

Serial Number: _____

Location: _____

Client Information:

Facility Name: _____

Contact: _____

Address: _____

Phone: _____

City, State, Zip : _____

E-mail: _____



Viabie Air Monitoring Protocol

2.0 Materials Required for Testing

1. Andersen Model Number 10-709 sampler with an L-911 vacuum pump

Calibration date: _____

2. Five Media Growth 100 mm plates with growth media

Lot Number: _____ Expiration Date: _____

3. Sterile alcohol for decontamination of sampling head and outer wrap of plates

4. Labels for identification of samples

- a. Two samples inside
- b. One external sample
- c. Two control samples (one positive and one negative)

5. Return shipping container with ice packs when using an outside testing facility

6. Return shipping labels



Viabie Air Monitoring Protocol

3.0 Testing Instructions

1. Remove a trash container and install the trash port connector.
2. Remove the outside wrap of the five 100 mm sampling plates in the airlock of the MIC and spray down the inner wrap. Close the outer door.
3. Open inner door, move the package of plates into the main chamber and remove the remaining wrap.
4. Place the sampling head of the Anderson sampler in the airlock and spray down with alcohol. Close the outer door.
5. Open inner door and move the sampling head into the main chamber.
6. Attach the vacuum line from the vacuum pump to sampling head.
7. Remove one of the sampling plate lids and place the plate into the sampling head being careful not to touch any of the collection surface.
8. Locate the sampling head as follows:
 - a. Sample location one—center of compounding area (20” from sides and 12” from back. After fifteen minute sample period, remove sampling plate. (see #8)
 - b. Sample location two—center airlock door and twelve inches from sidewall. After fifteen minute sample period, remove sampling plate (see #8)
 - c. Place third sampling plate in sampling head for use outside of MIC on top of the airlock.
9. After sampling, the sampling plate is covered and turned upside down. After removal from the MIC, the top should be taped to secure it. Mark location the sample was taken from on the outside surface of the sampling plate with a permanent marker.
10. Disconnect the vacuum hose from the sampling head. Load another plate into the sampling head. Remove the sampling head through the airlock and place it on top (outside) of the airlock. Disconnect the vacuum hose from the trash port connector and connect it to the sampling head.
11. Sample location on top of the airlock for fifteen minutes.
12. Open the sampling head and remove the sampling plate. It is not necessary to return the sampling head or plate back into the isolator.
13. Place the three samples plus two unopened sample plates in the shipping container for shipment to testing laboratory. The ice packs in the cooler are to be frozen before shipment. A shipping label is included in the package received.

