



**CTG Certification  
Network**

**Technical Support**

Phone: 317-713-8200

After-hours emergency: 317-752-3065

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## **Surface Area Monitoring Protocol**

### **Protocol Approvals**

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## **CTG Surface Area Monitoring Protocol—Version 1.0**



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## Surface Area 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

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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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## Surface Area Monitoring Protocol

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# Surface Area Monitoring Protocol

## **1.0 PURPOSE**

### **1.1 Purpose of the protocol**

The purpose of this test is the evaluation of surface areas within the ISO class 5 environment for the presence of microorganisms. Monitoring should occur during normal operations to allow for collection of meaningful data. This protocol is intended to provide for monitoring of surface micro contamination and should be supplemented with airborne as well as fingertip monitoring programs that will be covered in different protocols.

### **1.2 Description of Process**

Per USP<797> viable surface sampling is to occur on a periodic basis (at least twice per year) for all risk categories within ISO class 5 compounding environments. The surface sampling is accomplished by touching the agar surface of the contact plate. Two samples are to be taken in the critical compounding zone. The location is to be approximately twelve inches directly in front of each hand when inserted into the MIC. A third sample is to be taken on the inter door handle on the flat surface facing the interior of the chamber. After the samples are collected the cover is to be placed on the agar plate.



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## Surface Area 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: \_\_\_\_\_



## **Surface Area Monitoring Protocol**

### **2.0 Materials Required for Testing**

1. Three contact agar plates with growth media

Lot Number: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

2. Sterile alcohol or hydrogen peroxide for decontamination of the sampled area.
3. Labels for identification of samples by location
  - a. One sample each of the right hand and left hand floor surface area
  - b. One sample of the door handle area (note: in a MIC with dual airlocks sample each door.)
  - c. Two control samples (one positive and one negative)
5. Return shipper with ice packs if using an outside testing facility
6. Return shipping labels



## **Surface Area Monitoring Protocol**

### **3.0 Testing Instructions**

1. Remove the outside wrap of the ten contact plates in the airlock of the MIC and spray down the inter wrap. Close the outer door.
2. Open the inner door and remove sampling plates from the airlock. Open the package by removing the remaining wrap.
3. Sample as follows:
  - a. Sample location one—Remove the cover of the contact plate and slowly roll the exposed surface of the agar over the floor surface directly in front of the right glove port and twelve inches from the front of the chamber. After the surface contact replace the cover on the contact plate.
  - b. Sample location two—Remove the cover of the contact plate and slowly roll the exposed surface of the agar over the floor surface directly in front of the left glove port and twelve inches from the front of the chamber. After the surface contact replace the cover on the contact plate.
  - c. Sample location three—Sample the inter door handle on the flat surface facing the interior of the chamber. After the surface contact replace the cover on the contact plate.
4. After sampling is complete, clean the contacted area and sanitize with either sterile alcohol or hydrogen peroxide. Open internal door and remove the sampling plate.
5. Place the three samples plus two unopened (control) sample plates in the cooler 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.

