ChemoGLO™

A tool to monitor your environmental exposure to common antineoplastic agents used in preparation and administration areas.

User Manual

1. Introduction

ChemoGLO™ is a kit with a simple procedure to accurately quantify the amount of surface contamination from the use of *antineoplastic agents 5-fluorouracil, ifosfamide, cyclophosphamide**,** docetaxel, paclitaxel*, *methotrexate, platinum analogues, cytarabine, etoposide, vincristine, doxorubicin, daunorubicin, and busulphan* in the work environment.

The very nature of antineoplastic agents makes them harmful to healthy cells and tissues as well as to cancerous cells. For cancer patients with a life-threatening disease, there is certainly a great benefit to treatment with these agents. However, for the health care workers who are exposed to antineoplastic agents as part of their work practice, precautions should be taken to eliminate or reduce exposure as much as possible. Pharmacists who prepare these drugs or nurses who may prepare and / or administer them are the two occupational groups who have the highest potential exposure to antineoplastic agents. Evaluating environmental exposure to chemotherapy in the work place is an important occupational health preventative.

USP <797> states the following:

- Occupational exposure to hazardous drugs can result in (1) acute effects (such as skin rashes); (2) chronic effects (including adverse reproductive events); and (3) possibly cancer.
- Hazardous drugs shall only be prepared for administration under conditions that protect the healthcare workers and other personnel in the preparation and administration area; hazardous drugs shall be handled with caution using appropriate chemotherapy gloves during distribution, receiving, stocking, inventorying, preparing for administration, and disposal.
- Ongoing quality assurance shall be an integral part of hazardous drug preparation. In order to assure containment, especially in operations preparing large volumes of hazardous drugs, environmental sampling to detect uncontained hazardous drugs needs to be performed routinely (e.g., initially as a benchmark and at least every 6 months). This sampling shall include surface wipe sampling of the **working area of Biological Safety Cabinet** (BSC) and **Compounding Aseptic Containment Isolator** (CACI), **counter tops** where finished preparations are placed, areas adjacent to BSC and CAI, including **the floor directly under the working area**, and **patient administration areas**.
- Common marker hazardous drugs that can be assayed include *5-*

fluorouracil, ifosfamide, cyclophosphamide, paclitaxel, *docetaxel, methotrexate, platinum analogues, cytarabine, etoposide, vincristine, doxorubicin, daunorubicin, and busulphan*. If any measurable contamination (e.g., cyclophosphamide level greater than 1.00 ng/cm^2 has been found to cause human uptake) is found by any of these quality assurance procedures, practitioners shall make the decision to identify, document, and contain the cause of contamination. Such action may include retraining, thorough cleaning, and improving engineering controls.[1]

1. USP <797> Guidebook to Pharmaceutical Compounding—Sterile Preparations. United States Pharmacopeial Convention; 2008: 13-15

2. What to do after receiving the kit?

Please open the kit and immediately check all items. If any items are missing, please use the following contacts to request additional items.

Cara Zamboni
cara@chemoglo.com
(919) 428-6759

Please carefully read and follow all procedures outlined in this manual.

3. What is in the ChemoGLO™ kit?

- ✓ Plastic pouch: Site Map Form, User Manual and Brochure
- ✓ 24 removable colored dots (to mark corners of1ft^2 area)
- ✓ 12 labeled screw top vials with pre-filled solution* in sealed bag
- ✓ 12 swabs in a plastic bag
- ✓ 6 pairs of gloves
- ✓ 1 pen
- ✓ 1 paper tape measure
- ✓ 1 silver padded bag
- ✓ 1 return FedEx or UPS package label/envelope

Please retain the original shipping box and use for the return shipment.

***The ChemoGLO™ wiping solution is a proprietary mixture containing isopropyl alcohol. It is safe for use on the following surfaces: chemical resistant laminate, phenolic resin, epoxy resin, high-density polyethylene, 316 stainless steel, 304 stainless steel, 201 stainless steel. **Use with caution on other surfaces**.

4. What areas should I sample?

There are many areas that can be potentially contaminated with the antineoplastic agents. It is important to check contamination levels in these frequently used areas. These areas include, but are not limited to:

- Vertical laminar flow hood
- Tabletop and/or cart
- Countertop and/or Work bench
- Floor around chair and patient bed
- Floor in or outside preparation room

5. How do I complete the ChemoGLO™ Site Map Form?

The ChemoGLO™ Site Map Form is an important document for recording the wipe areas at your site. The Site Map Form provides sections to record the specific location of all 6 of your wipe samples. To meet regulatory compliance of USP <797>, future wipes should be conducted at the identical location of your previous wipes. Other important information including sponsor, site, contact information for reporting purposes and estimated drug doses at your site are also recorded here.

The Site Map Form should be completed after each wipe area is complete. Wipe Area ID is specific to each test area. For example, “Hood 1” would correspond with an evaluation area in the hood. Please provide a thorough description of each wipe area, referencing stationary objects at the facility such as a sink or a cabinet, as a reference for reevaluation of the same area for future wipe testing.

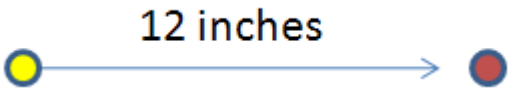
The completed ChemoGLO™ Site Map Form needs to be sent with the samples. Please write legibly.

6. ChemoGLO™ Wiping Procedure

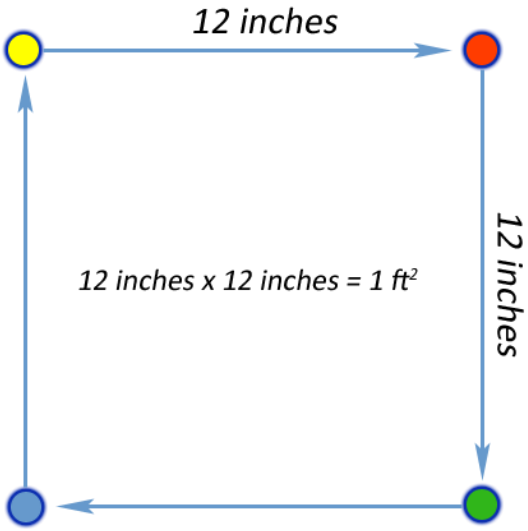
The materials in this kit are for 6 wipe areas at your site. The following instructions are for one wipe area. Please repeat for each of the 5 additional areas you decide to wipe at your site:

1. Put on gloves.

2. With the paper tape measure, measure out 12 inches of the area to be wiped.



3. Using four of the colored dots, place one at each corner so that the area measures 1 square foot (1 ft^2). **Please Note: the 1 square foot measurement area is for flat surface areas. However, you can wipe areas that are smaller than 1 square foot such as door knobs, keyboards, etc.

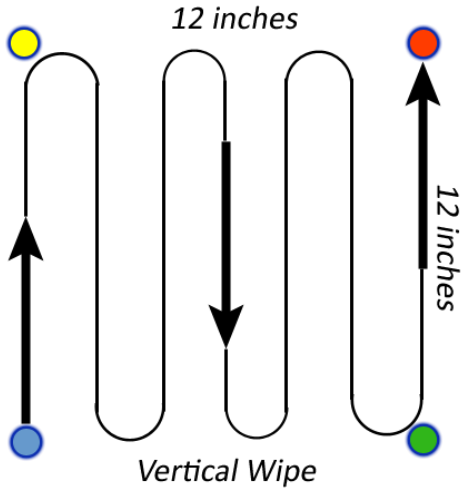


4. Select the two vials labeled “Wipe Area #1, V (Vertical)” and “Wipe Area #1, H (Horizontal).” Kits and kit contents are labeled with a Kit Identification Number. When using more than one kit, please match all vials and site map forms with the correct Kit Identification Number.

5. Take one swab out of the bag and place it in the vial labeled “Wipe Area #1, V.” Recap the vial and shake until the solution is absorbed in the swab.

6. Uncap the vial and spill the swab and contents of vial “Wipe Area #1, V” on to the area to be wiped.

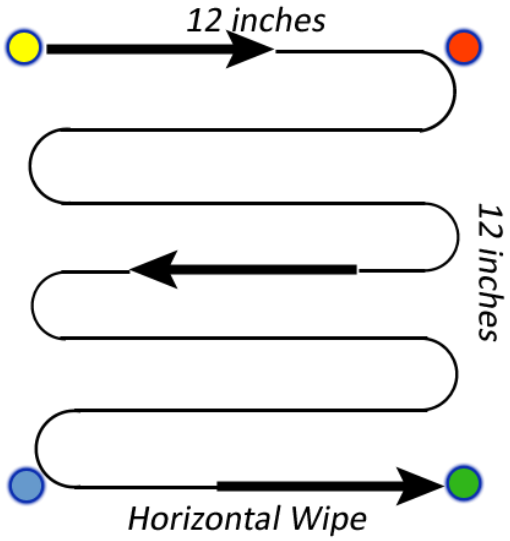
7. With a gloved hand, while being careful not to press too hard, use the swab, placed on its side lengthwise, to wipe the entire 1 square foot area with vertical strokes (up and down).



8. Place the swab back in the vial marked “Wipe Area #1, V.” Screw on the cap. Place the vial in the silver padded bag.

9. In the second vial labeled “Wipe Area #1, H,” take another swab from the bag and place it into the vial. Cap the vial and shake until the solution is absorbed in the swab.

10. Uncap the vial and spill the swab and contents of vial “Wipe Area #1, H” on to the 1 ft^2 area you just wiped (each area is wiped both vertically and horizontally).

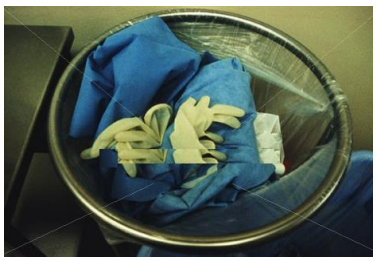


11. With a gloved hand, while being careful to not press too hard, wipe the entire area with horizontal strokes (side to side).

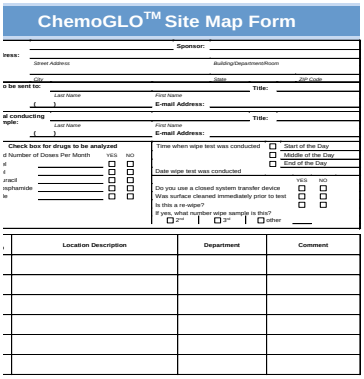
12. Place the swab back in the vial marked, “Wipe Area #1, H.” Screw on the cap.

13. Place the two vials in the silver padded bag.

14. Dispose of your gloves. Change gloves between different sites.



15. Mark on the **Site Map Form** information regarding the area wiped. If platinum analogues are selected for analysis, please indicate the type of area wiped (e.g. stainless steel, plastic, floor, etc.).



ChemoGLO™ Site Map Form

Sponsor:

Street Address | Building/Department/Room | City | State | ZIP Code

Last Name | First Name | Title: | E-mail Address:

Last Name | First Name | Title: | E-mail Address:

Check box for drugs to be analyzed

Number of Doses Per Month | YES | NO

Time when wipe test was conducted: Start of the Day | Middle of the Day | End of the Day

Date wipe test was conducted

Do you use a closed system transfer device | YES | NO

Was surface cleaned immediately prior to test

Is this a re-wipe?

If yes, what number wipe sample is this? 2nd | 3rd | other

Location Description	Department	Comment

16. Repeat steps 1-15 for each of the 5 additional areas to be wiped. Each site uses two swabs: one swab/vial for a horizontal (side to side) wipe and a second swab/vial for a vertical (up and down) wipe. Upon completion, you will have a total of 12 screw top vials containing swab.

17. If you elect to conduct a control, either wipe an area known not to be contaminated, or simply drop a swab in the vial without wiping an area. IF you conduct a control, please make a note in your records, and notify us AFTER you have received your report.

18. Please refrigerate any samples that will not be shipped the same day as the wipe sampling is completed.

7. How do I ship my samples back for analysis?

a. Place the silver bag, containing the 12 vials with the wiped swabs in the original shipping box.
b. Place the **Site Map Form** in the plastic folder in the shipping box.
c. Seal the shipping box.
d. Adhere the FedEx label and drop off with the carrier.

Shipments should be sent to:

ChemoGLO, LLC
C/O OpAns
4134 S. Alston Avenue
Suite 101
Durham, NC 27713
(919) 323-4300

8. How are the samples analyzed?

After the samples are shipped back to us, they will be analyzed within 2 weeks using our state-of-the-art technology. Concentrations of the contaminants agents' 5-fluorouracil, ifosfamide, cyclophosphamide, docetaxel, paclitaxel, methotrexate, cytarabine, doxorubicin, daunorubicin, etoposide, vincristine, busulphan, and platinum analogues are quantified down to 10 ng/ft^2 and 0.01 ng/cm^2.

9. When will I get my results?

Reports are issued via email within 3-4 weeks (4-6 weeks if requesting platinum analysis) of receiving the wipe sample package, provided all payment/contractual agreements have been met.

FOR SITE STUDY START UP / TECHNICAL INQUIRIES:

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