Cultivate
A PARASOL MEDICAL PRODUCT

HazardTest™ Hazardous Drug Containment Evaluation Directions for Use

HazardTest™
Cat. # LV53

2023 USP <800> Hazardous Drug Containment Evaluation
For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate/cultivate-resources

Hazardous Drug Containment Testing Frequency

The effectiveness of training for HD handling competencies must be demonstrated by each employee. Personnel competency must be conducted initially and reassessed at least every 12 months.

Storage, Stability, and Destruction

Cultivate™ HazardTest™ kits should be kept unopened at room temperature and protected from light. The media should not be used if the expiration date has passed.

Intended Use

Cultivate™ HazardTest™ kit is recommended for simulating procedures where antineoplastic or other hazardous drugs are compounded by health care professionals who manipulate hazardous drugs in order to test proper technigue. The product is intended to fulfill the USP <800> criteria for personnel training and the American Society of Health System Pharmacists (ASHP) technical assistance bulletin for cytotoxic and hazardous drug handling competency verification. The HazardTest™ (Cat. No. LV53) kit does not contain a growth media and is not intended to test aseptic media-fill technique. The kit contains materials for up 5 technicians. This product is not intended to be used for the diagnosis of human disease.

Materials Supplied in HazardTest™ Kit

- 5 x 50mL vial with powdered fluorescein dye, non-sterile
- 5 x 3mL vial with fluorescein dye solution, non-sterile

Materials Supplied by User

- UV Light
- Empty flexible container (Minibag), 50-250mL capacity Diluent (NS, D5W, OR SWI)
- Luer lock syringes
- Appropriately sized needles
- Gloves, mates, gowns, disinfectants, waste containers, other protective supplies
- Closed-system drug transfer device Needle-less system
- IV Administration set

Procedures

You should modify the test instructions below to replicate your facilities training, written procedures, equipment, supplies and housekeeping policies.

Method of Use to Simulate Hazardous Drug Manipulation: Perform procedures in accordance with risk assessment or training.

The complexity of the procedure consists of:

A. Reconstituting a powder in a 50mL vial and transferring the liquid contents to a small flexible container (e.g. minibag, 50-250ml capacity)
B. Transferring the contents of a 3mL vial to a flexible container, and
C. Priming a typical IV administration set

1. Prepare and arrange all supplies in the area used for manipulating hazardous drugs such as a Biological Safety Cabinet (BSC) or similar containment area.
2. Disinfect the work area using standard procedures. Wipe or swab the benchtop and the outside of containers, vials, bag, and ports according to standard operating procedures.
3. Prior to performing the procedure, the supervisor should carefully shine a UV light (Cat. No. BL01) on all work surfaces, supplies, personal protective gear such as gloves, gown, etc. to ensure materials do not exhibit dye spots of fluorescence. Any materials that exhibit fluorescence should be re-cleaned, removed, or noted in the test log prior to initiating the procedure. Failure to note, remove, or clean any existing fluorescent dye spots could result in a failed test if the results are counted after the procedure is performed.
4. Using standard procedures and supplies, reconstitute the fluorescein powder (Cat. No. PL-V050) to mimic a standard drug reconstitution procedure.
5. Transfer the reconstituted solution to a flexible container, such as a minibag, and retain the flexible container for later use.
6. Transfer the contents of the fluorescein solution (Cat. No. L-V003) to the same flexible container.
7. ***Optional:*** spike the flexible container using the IV administration set following standard operating procedures. Prime the set to simulate standard administration procedures.

Method to Simulate Hazmat Cleanup Testing:

1. Retain the flexible container of fluorescein dye waste solution for hazardous cleanup testing.
2. Create a hole in the container and "spill" the contents in the work area to simulate a hazardous material accident.
3. After the appropriate remediation procedures are completed, shine a UV light on the spill area to evaluate the efficacy of cleaning procedures.

Interpreting Results

Turn off ambient lights in the work area prior to reading results. Count the number and size of dye spots from personal protective wear such as gloves and gowns, containers, the sides of the BSC, and the work area and record these in the results log. Fluorescent dye spots observed after testing indicate a breach in manipulation competency procedures. The lack of detectable dye spots after testing indicate a passing result.

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