IFU

Instructions for Use

HAZ DETECT™ HARDYVAL™ HAZDETECT KIT

Cat. no. HVHAZ	HardyVal™ HazDetect Kit	1 kit
Each kit contains:		
Cat. no. HVFL50	Fluorescein Sodium Salt, 50mg	5ea
Cat. no. HVFL3	Fluorescein Solution, 0.05%, 3ml	5ea

INTENDED USE

Hardy Diagnostics HardyVal™ HazDetect Kit is recommended for simulating procedures where antineoplastic or other hazardous drugs are compounded or processed in order to imitate techniques used by health care professionals who manipulate hazardous drugs. 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, but is not intended to validate aseptic technique.[1,3] The kit contains materials for up to five individual tests to simulate the most common manipulations performed in oncology pharmacies.

This product is not intended to be used for the diagnosis of human disease. Contents of vials are non-sterile and should not be used for aseptic technique.

SUMMARY

The proper handling of hazardous drugs in healthcare settings promotes patient and worker safety, as well as reduces contamination to the environment. Healthcare personnel who handle hazardous drug preparations, and individuals who store, prepare, transport, or administer hazardous drugs, may be at risk for exposure. The CDC reports over 8 million health care workers are exposed to hazardous drugs each year.[2] Occupational exposure has been linked to infertility, birth defects, and certain cancers, and there are numerous studies confirming the incidence of occupational exposure to hazardous drugs. Consequently, USP <800>, in conjunction with information from the American Society of Health System Pharmacists (ASHP) and National Institute of Occupational Safety and Health (NIOSH), was created to outline the scope, responsibilities, controls, training, processing, and compounding requirements for hazardous drugs.[1-3]

NIOSH maintains a list of hazardous drugs used for patient administration, along with criteria used to identify hazardous drugs.[2] Each organization must maintain a list of hazardous drugs included on the NIOSH list, along with information on the risks associated with direct occupational exposure through skin or inhalation. All hazardous drugs must be handled appropriately according to their risk, or a risk assessment must be performed, and entities must follow specific containment strategies or document alternative strategies or work practices to minimize the risk of exposure.[2] Similarily, the ASHP maintains a technical bulletin on the handling of cytotoxic and hazardous drugs that require competency verification.[3] More recently, USP <800> introduced a requirement for risk assessment to determine

containment procedures for hazardous drugs that pose a significant risk for direct occupational exposure.[1]

HardyVal™ HazDetect includes materials for five independent tests. The kit contains five vials filled with 50mg of Fluorescein Sodium Salt that must be reconstituted when used and five tubes containing 3ml of a 0.05% Fluorescein Solution. HardyVal™ HazDetect can be used for training and competency verification to simulate procedures commonly used in the manipulation and handling of hazardous drugs. The kit complies with the U.S. Pharmacopoeia <800> requirements for training verification when used in conjunction with a UV light to verify test results. In addition, the fluorescein waste solution captured through the test can be used to verify the efficacy of hazmat cleaning procedures to simulate cleanup of a hazardous material spill.

FORMULA

Ingredients per liter of deionized water:*

Cat. no. HVFL3	
Fluorescein Sodium Salt	0.5g

Final pH 7.4 +/- 0.3 at 25ºC.

In addition, Cat. no. HVFL50 contains 50mg of Fluorescein Sodium Salt powder.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Storage: Upon receipt, store at 2-25ºC away from direct light. Product should not be used if there are any signs of deterioration, discoloration, contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product is for laboratory use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved precautions and techniques.

Check local, regional, and state regulations for appropriate waste disposal.

Refer to the document SDS Search instructions on the Hardy Diagnostics' website for more information.

PROCEDURE

The below method of use should be modified to reflect the training, written procedure, equipment, supplies, risk assessment, and containment procedures unique to each facility.

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 (e.g. Cat. no. UVL56, EA160, or LSS3) 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 Sodium Salt powder (Cat. no. HVFL50) 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. HVFL3) 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.

INTERPRETATION OF 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.

LIMITATIONS

Failure to adequately sanitize or disinfect surfaces in the work area or the outside of containers prior to use may result in an observation of fluorescent dye spots and a failed test. Clean surfaces and containers thoroughly and check for fluorescence prior to use.

Ultraviolet light may be harmful to eyes and exposed skin. Do not shine UV light directly into eyes or for prolonged periods on exposed skin.

Failure to turn off ambient lights or darken the work area prior to reading the test may result in a failure to fully detect fluorescent dye spots on surfaces and personnel.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard laboratory or compounding supplies and equipment such as a UV light (Cat. no. UVL56), empty flexible containers (e.g. minibag, 50-250ml capacity), diluents, disposable luer lock syringes, appropriate gauge needles, closed-system drug transfer devices, IV administration sets, personal protective equipment (e.g. gowns and gloves), waste containers, protective supplies, hazardous spill kits, as well as sanitizers and disinfectants are not provided.

QUALITY CONTROL

End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

PHYSICAL APPEARANCE

The HardyVal™ HazDetect Kit contains the following components*:
Fluorescein Sodium Salt should contain 50mg of a brown-red powder.
Fluorescein Solution, 0.05%, 3ml should appear clear and yellow-green in color.

*Components inside the kit may have different lot numbers and expiration dates. The expiration date of the completed kit is based on the component with the shortest shelf life. Quality Control testing was performed on the kit lot components, as stated above.

REFERENCES

1. The Official Compendia of Standards. USP General Chapter <800> Hazardous Drugs - Handling in Healthcare Settings. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

2. The National Institute for Occupational Safety and Health (NIOSH). Hazardous Drug Exposure in Healthcare. *The Centers for Disease Control and Prevention (CDC).* Atlanta, CA.

3. ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs, *American Journal of Hospital Pharmacy*, Volume 47, Issue 5, May 1990, pp 1033-149.

IFU-000780[A]

RESULTS LOG

Name: _____ Date Test Performed: _____

Signature: _____ Kit lot#: _____ Kit Expiration Date: _____

Test Date	Sample#	Prepared by	Hood/ Bench#	Kit lot	Supervisor	Initials	Number Dye Spots Counted Under UV Light		
							Gloves # Spots	Gown # Spots	Surface

1430 West McCoy Lane, Santa Maria, CA 93455, USA
Phone: (805) 346-2766 ext. 5658
Fax: (805) 346-2760
Website: HardyDiagnostics.com
Email: TechnicalServices@HardyDiagnostics.com
Ordering Information

Distribution Centers:
California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.