



# HD Check-In

## An interview with HD safety expert Fred Massoomi, RPh, PharmD, FASHP

*Fred Massoomi, RPh, PharmD, FASHP, is a researcher, educator and crusader for proper hazardous drug (HD) management and safe disposal of pharmaceutical waste. A renowned expert in HD safety, he has presented research and findings at professional meetings around the world, written numerous publications and developed continuing education programs. In a candid interview, Dr. Massoomi reviews the BD® HD Check System, the new rapid, handheld real-time device for the detection of environmental contamination.*

### Introduction

Occupational exposure to HDs poses serious risk to healthcare workers and patients.<sup>1-3</sup> To limit exposure, U.S. Pharmacopeia (USP) General Chapter <800> recommends routine surface sampling for HD residue as part of a multi-element process for ensuring safe handling of HDs.<sup>4</sup>

**How can a facility confirm that its substantial investment in USP <800> precautions is effective?**

### **Q: Have you had a chance to use the BD® HD Check System? If so, what is your opinion?**

I have been using HD Check in the field to monitor HD residue at several facilities. I find it fast, easy and reliable to use. It takes about 10 minutes to set up the device initially. After that, it takes less than 10 minutes to process a sample. This is a significant improvement over traditional wipe sampling kits that may take up to two weeks or longer to give a result, during which time HD residue may be spread to other locations.



**FIGURE 1**

In less than 10 minutes, the BD® HD Check System indicates whether HD contamination is present so that an Immediate Action Plan may be implemented, if needed.\*

\*Tests for select hazardous drugs

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HD Check provides a new way to validate USP <800> monitoring standards and safety for healthcare workers and patients in real time (Fig. 1).

**Q: Which drugs can HD Check be used to test for? Is this a limiting factor?**

HD Check can be used to test for methotrexate and doxorubicin, drugs frequently used in most facilities. Additional drug assays are under development. Testing for such frequently used drugs may not only confirm that their residue is present but also validate your cleaning processes and safe handling procedures for all HDs. If drug residue is present, an error has occurred in the HD safety process; this gap might allow contamination from other HDs to evade the process.

**Q: How would a facility develop a plan and/or protocol to use the HD Check device?**

First, I recommend conducting the USP <800>-required HD risk assessment as you would for any quality improvement process, starting with HD receipt and including storage, preparation, transportation, administration and disposal.<sup>4</sup> Second, review and compare the literature on traditional wipe sampling vs. the HD Check processes. Note the number of necessary steps and

processes and the timing of results. HD Check is a real-time approach to validating USP <800> monitoring standards, with the ultimate goal of protecting staff and patients.

Education for all healthcare workers who handle HDs is essential, especially nursing personnel, who often operate in an environment with limited protection, as well as pharmacists. HD Check may help protect everyone's safety. A positive result is feedback that indicates a need for additional cleaning and reevaluation of your cleaning processes and safe handling procedures. A negative result confirms that your processes are working effectively to prevent HD contamination.

Create an environmental sampling map that defines the frequency and sites of sampling.

**Q: Does facility size matter?**

While USP <800> does not provide guidance on compliance based on facility size or the number of HD doses given, HDs always pose risks, especially when sites have no controls in place. Per USP <800>, sites that handle HDs should perform wipe sampling by starting with a baseline measurement and continuing on a routine basis.<sup>4</sup> Real-time wipe sampling with HD Check provides data on the safety—

and helps validate the effectiveness—of a well-coordinated USP <800> monitoring program.

**Q: How is HD Check used in clinical practice?**

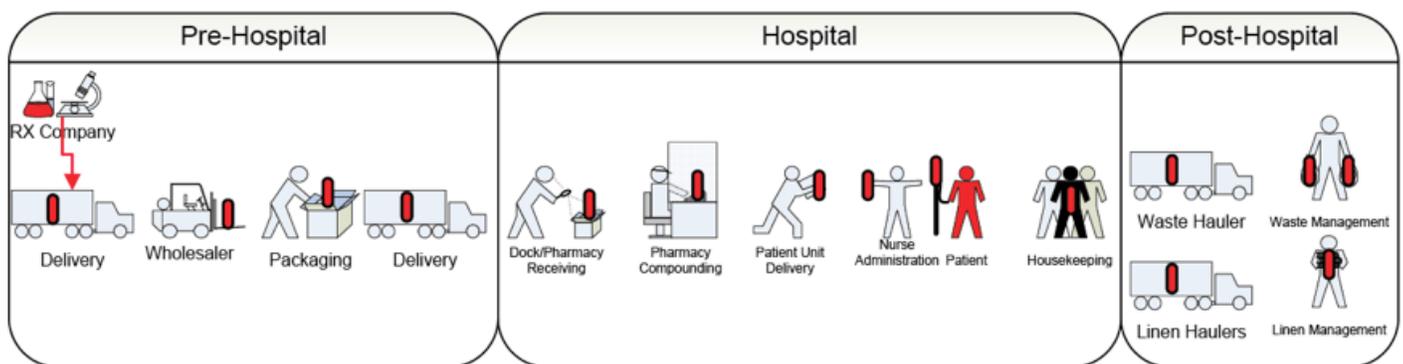
**Environmental sampling map sites**

An environmental sampling map defines sampling sites and frequency to ensure that institutional investment in USP <800> safety measures is working to limit HD exposure. Drug vials, package inserts and packaging often arrive at hospitals already contaminated. HD residue travels through the system, from the box to the patient to disposal (Fig. 2). In a perfect world, wipe testing to confirm that a surface is clean and ready for use would be performed after the cleaning of every HD compounding area. HD Check allows frequent testing at many sites of potential contamination and may provide evidence of compliance with HD standards throughout the process, from the loading dock to waste disposal.

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**FIGURE 2**  
**HD process**

Occupational exposure to HDs remains a serious risk to healthcare personnel, with potential exposure occurring at numerous points of HD handling, from receiving the manufacturer's vials at the loading dock through disposal of the corresponding waste.



**Hazardous drug.** Note: Red indicates external contamination potential. Courtesy of Firouzan "Fred" Massoomi



HD Check may validate that cleaning processes and safe handling procedures are effective and help minimize the risk of HD residue transfer to other sites.

## Frequency

USP <800> requires sampling at baseline and “routinely” on the basis of the site’s needs.<sup>4</sup> Routine sampling is based on the assumption that all other USP <800> safety standards are being implemented. All safety measures must be in place every time an HD dose is handled. HD Check may validate that the whole process is working and identify what part of the process may need improvement and where contamination may be introduced. Cleaning and testing should be repeated until HD Check results are negative.

### When to use HD Check: best practice

- At least **daily** to validate that cleaning processes are effective
- Whenever **cabinets and surfaces where HDs are used are cleaned**
- Whenever a **spill occurs**. HD residue is hard to clean; HD Check may confirm that the spill has been effectively remediated or that further cleaning is required

### Q: What should be done if HD Check indicates that residue is present (a positive result)?

#### Take action

If HD Check results are positive, HD residue is present, and immediate action may be taken to ensure safety by following the USP <800> 4-Step Action Plan<sup>4</sup>:

1. Deactivate
2. Decontaminate
3. Clean
4. Disinfect

### How do you know if your cleaning worked? HD Check is an immediate point-of-use validation device.

This is the same plan that sites would execute after the traditional wipe test; however, weeks would have passed since testing, with workers exposed to a contaminated environment.

How do you know if your cleaning was effective? HD Check is an immediate point-of-use validation device. With HD Check, you may confirm whether your HD cleaning processes are effective. If you retest and still get a positive result, reclean and retest until the result is negative. If a site continuously receives positive results, current cleaning processes and products may be inadequate to eliminate the drugs being tested.

It is important to note that HD Check, when applied in a robust program to identify where HD residue is located throughout the HD handling continuum, supports process improvement. Continual testing may assist with identifying gaps in safety standard operating procedures to make them more successful in an institution’s overall safety plan. For example, we found HD residue on a shelf where commercial HDs are stored. Now, at HD receipt, receiving personnel don personal protective equipment (PPE) to handle the boxes, which are immediately placed and kept in a resealable bag until placement in the proper engineering control for everyone’s protection.

### Negative results today do not mean that tomorrow will be safe.

### Q: What if a facility’s results are negative—should they continue to test at the same frequency and locations?

Negative results today do not mean that tomorrow will be safe. HD safety includes

many steps to ensure safety and minimize risk; thus, USP <800> requires routine checks.<sup>4</sup> Negative results positively reinforce to staff that they are compliant with safety measures; these results should be shared with them to support continuous implementation of all safety processes.

### Q: How can facilities justify the cost of and/or demonstrate ROI for HD Check?

HD Check may help you validate the effectiveness of your investment in USP <800> safety measures. HDs have persistent residue; it is thus imperative to monitor that cleaning and safety processes are working to eliminate it. In sites without an environmental sampling program or with long delays between samplings, there may be continual occupational exposure of healthcare workers, as well as exposure of patients and families. HD Check is an evolutionary change in wipe sampling that provides a quick and economic way to measure safety.

### Q: Are there risks or liabilities associated with testing for environmental contamination?

It is important to educate staff about the reasons for implementing HD Check, by explaining that a positive result indicates a need for a corrective action plan, similar to corrective actions for any hazard in any job.

Monitoring with HD Check provides feedback. Positive results must activate an action plan to reclean and recheck until the site is clean. This demonstrates that the employer has done everything possible to protect workers. This process is very similar to how radiology departments monitor for radiation exposure and minimize the overall risk of exposure to healthcare workers.

Remember that the sampling process itself is a hazard. Staff must be trained to don PPE and dispose of testing items appropriately as if they are hazardous. Always assume that samples are hazardous.

**Q: If a facility does not test for environmental contamination, are they putting themselves at increased risk or liability?**

USP <800> has identified these hazards to healthcare workers; therefore, lack of sampling poses risk.<sup>4</sup> Sites must be able to defend why they are not complying with USP <800> recommendations. If a site decides not to sample, an employee has the right to file a complaint about nonadherence to standards with the U.S. Department of Labor; this may result in review by the Occupational Safety and Health Administration.<sup>5</sup>

**Q: Why are people reluctant to perform this type of testing?**

The people responsible for HD sites need to inform themselves about the differences between traditional wipe sampling, with its minimum two-week delay, vs. HD Check's real-time surveillance and validation program. HD Check's ease of use, real-time results and competitive pricing, plus a simple action plan for positive results, should make HD Check an essential part of any site's USP <800> compliance program.

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**Conclusion**

Given the serious consequences of occupational exposure to HDs, establishing a formal wipe analysis program for HD residue that uses HD Check may give pharmacy leadership the opportunity to identify specific risks throughout their facilities and respond by developing practices to continuously avert them.

**Disclosure**

Dr. Massoomi is employed by Visante, Inc. and serves in the Speaker Bureau and as a consultant to BD, ICU Medical, Baxter, Equashield and ProCE.

**References**

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**Simple steps**

I found that using HD Check is an intuitive and easy process. After assembling supplies, donning PPE and identifying the area to be tested with HD Check, follow these simple steps:



**1** Swab the test surface



**2** Transfer swab to the sampling tube and invert five times



**3** Squeeze four drops from tube onto assay cartridge and allow to develop for 5 minutes



**4** Insert the cartridge into HD Check and run the test



**5** Read the positive or negative result

**Get results in less than 10 minutes**

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