

Evaluation of ICU Medical's ChemoLock™ System Using Methotrexate (MTX) as a Marker

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INTRODUCTION

The objective of the study was to perform simulated hazardous drug compounding activities with the ChemoLock system in a controlled laboratory setting and test surfaces in the direct compounding areas for surface contamination using MTX as a marker.

METHODS

Decontamination procedures were used to minimize MTX contamination on vials and surfaces prior to the study. Based on published studies, four common surface sampling zones within and around the biological safety cabinet workbench that were suspected to be the most likely contaminated surfaces were selected and demarcated using colored tape.

The ChemoLock closed system transfer device (CSTD) system consists of a vial access device, syringe adaptor, and intravenous bag spike. All simulated compounding duties were performed by a certified pharmacy technician trained in the use of the ChemoLock system. Prior to evaluation, the demarcated work-area surfaces within the BSC were decontaminated and wipe samples were collected from the four sampling zones. Each assessment consisted of three trials, which included three individual transfers of 12 mL of MTX from each of four vials followed by disconnecting and reconnecting from vial to IV bag. A total of 36 individual compounding transfers were completed for the study.

Wipe samples were taken by an independent Certified Industrial Hygienist (CIH) from the four sampling zones and from the compounder's gloves after each trial was complete. Samples were prepared and analyzed by a credentialed laboratory specializing in chemical analysis using a liquid chromatograph that was equipped with dual mass spectrometers (LC-MSMS) with a limit of quantitation (LOQ) of 10.00 nanograms (ng) per sample.

TABLE 1. SUMMARY OF ICU MEDICAL CHEMOLOCK TRIALS

Sample ID	Surface	Area, cm ²	MTX, ng	MTX conc., ng/cm ²	Comments
5297658	Field blank	na	nd	na	
5297659	Workbench left	400	nd	<0.025	Decontamination, Pre-Trial Sampling
5297660	Workbench right	400	nd	<0.025	
5298284	Grill	400	nd	<0.025	
5298285	Airfoil	400	nd	<0.025	
5298286	Gloves	na	nd	na	
5298287	Workbench left	400	nd	<0.025	ChemoLock, Trial 1
5298288	Workbench right	400	nd	<0.025	
5298289	Grill	400	nd	<0.025	
5298290	Airfoil	400	nd	<0.025	
5298291	Gloves	na	nd	na	
5298292	Workbench left	400	nd	<0.025	ChemoLock, Trial 2
5298293	Workbench right	400	nd	<0.025	
5298294	Grill	400	nd	<0.025	
5298295	Airfoil	400	nd	<0.025	
5298490	Gloves	na	nd	na	
8298491	Workbench left	400	nd	<0.025	ChemoLock, Trial 3
8298492	Workbench right	400	nd	<0.025	
8298493	Grill	400	nd	<0.025	
8298494	Airfoil	400	nd	<0.025	

na – not applicable

nd – not detected (<10 ng/sample)

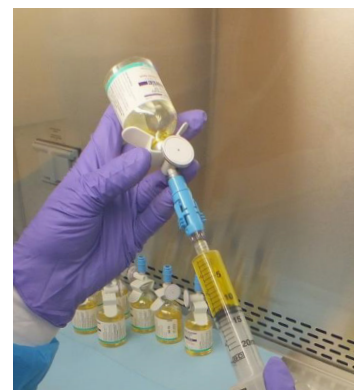


Photo 1. ICU Medical ChemoLock system, vial access.

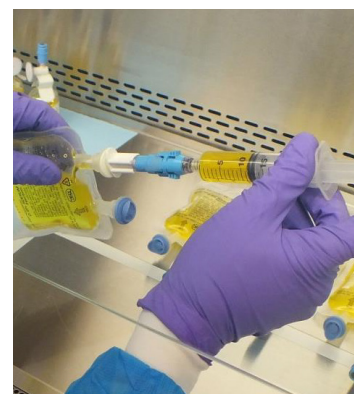


Photo 2. ICU Medical ChemoLock system, IV bag access.

RESULTS

Wipe samples collected from vials following the initial decontamination procedure and prior to use in the study were free of detectable MTX. MTX was not detected on any of the surface samples obtained prior to any of the work trials. Following trials with the ChemoLock system, no MTX was detected on working surfaces or the technician's gloves.

CONCLUSION

The results of this study demonstrate that, when used by a trained pharmacist, the ICU Medical ChemoLock system was effective in preventing detectable surface contamination during three separate trials of simulated compounding activities with known amounts of MTX.

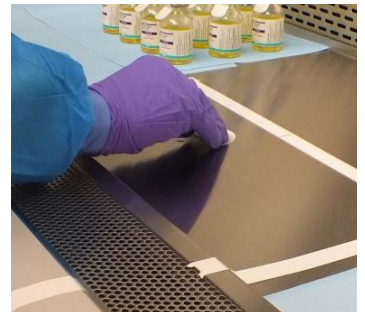


Photo 3. Wipe sample collected from BSC workbench (left).