



PRESS RELEASE

HardyVal Kits for USP <797> media-fill challenge testing for compounding-sterile preparations (CSPs)



Santa Maria, California, April 5, 2013

Hardy Diagnostics, an FDA licensed and ISO certified biomedical manufacturer, is pleased to announce the release of HardyVal Media-Fill Challenge Kits for USP <797> compliance testing for compounding-sterile preparations (CSPs).

HardyVal Kits are a unique line of ready-to-use media-fill challenge kits designed for use in validating pharmacy compounding personnel in accordance with USP <797> guidelines. Aseptic media-fill testing is part of an effective quality assurance program to ensure pharmaceutical processes and personnel produce sterile products, free from microbial contamination. Media-fill testing can be used to establish industry best practices and should be designed to mimic the most challenging or stressful conditions encountered during preparation of CSPs.

HardyVal CSP Kits are recommended as part of an industry quality assurance program used to identify potential areas for process improvement. Regular use can provide competitive customer quality confidence, as well as a standard of best practice to ensure regulatory compliance. Kits are available in several formats to satisfy varying degrees of compounding risk: Low-Risk (Cat. no. HVL1); Medium-Risk Comprehensive (Cat. no. HVM1); Medium-Risk Basic (Cat. no. HVM2);

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and High-Risk (Cat. no. HVH1). Each kit is ready-to-use and certifies one technician. A log sheet is included to record results for record retention.

Hardy Diagnostics offers instructions for use (IFU) with helpful diagrams to provide comprehensive technical information and assistance. In addition, Hardy offers a full line of Petri plates and products for environmental testing (surface and air) of sterile compounding areas in compliance with USP <797> guidelines, as well as a variety of prepared culture media for USP <71> Sterility Testing of compounded-sterile preparations. Look to Hardy Diagnostics to provide a competitive quality advantage.

ABOUT HARDY DIAGNOSTICS

Hardy Diagnostics, an FDA licensed manufacturer of medical devices for microbiological testing with an ISO 13485 certified Quality Management System, manufactures over 3,500 products for the culture and identification of bacteria and fungi from its California and Ohio manufacturing facilities. Headquartered in Santa Maria, CA, Hardy Diagnostics services over 8,000 laboratories throughout the nation.

The company, which is now employee owned, was founded in 1980 by Jay Hardy, a Clinical Laboratory Scientist from Santa Barbara, CA. Today, Hardy Diagnostics maintains eight distribution centers throughout the U.S. and exports products to over 30 foreign distributors.

The company's mission is to partner with its laboratory customers to prevent and diagnose disease. For more information on products and services and a complete profile on the company's history, visit www.HardyDiagnostics.com.

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