



**USP <797>  
COMPLIANCE  
INAKIT**



HARDY DIAGNOSTICS

## **HardyVAL™ CSP Kits**

### **Microbial Contamination Testing for CSPs**

Hardy Diagnostics offers all the products you need to easily assess the risk of microbial contamination of your CSPs (Compounded Sterile Preparations) according to the USP, Chapter <797> requirements for media-fill challenge testing.

# Compliance was never so easy!

- ➔ One kit supplies what is needed to test the proficiency of one technician or pharmacist.
- ➔ Kits are available for low, medium, and high risk procedures.
- ➔ Components are in a self-contained ready-to-use kit.
- ➔ A results log sheet is included in each kit.
- ➔ Detailed instructions and diagrams are included with each kit.
- ➔ Expert Technical Support is available from our staff of microbiologists.

**USP<797>**  
**COMPLIANCE**  
**IN A KIT**



# HardyVAL™ CSP low-risk level

**Kit Contents** Cat. no. HVL1 (\$29.87)

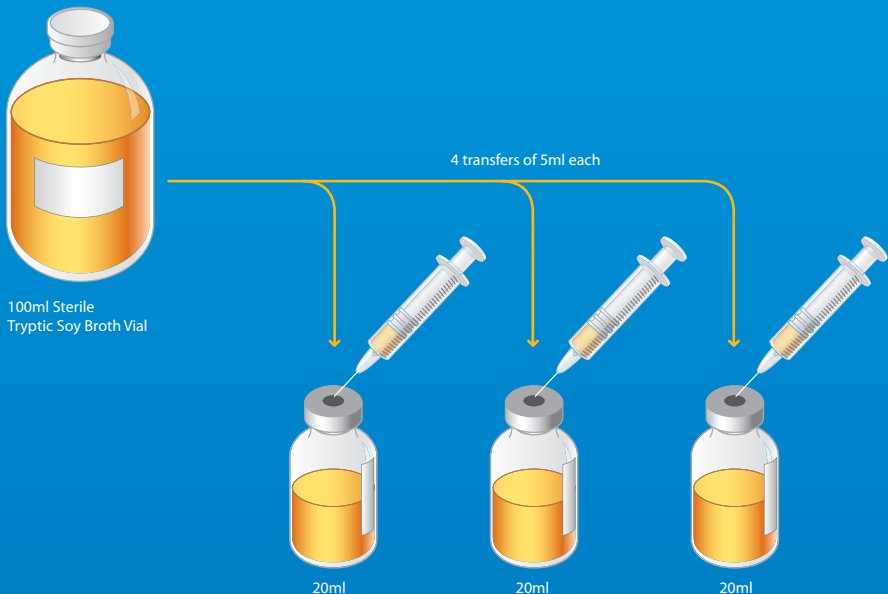
- 1 x 100ml Sterile Tryptic Soy Broth Vial
- 3 x 20ml Empty Sterile Vials
- 1 x Write-on Whirl-Pak® Bag
- 1 x Results Log Sheet



Prices are subject to change without notification.

## Procedure Summary (from USP <797>)

- 1 Aseptically transfer Tryptic Soy Broth to empty sterile vials using a sterile 10ml syringe.
- 2 Attach sterile adhesive seals.
- 3 Incubate at 25°C to 35°C.
- 4 Examine for turbidity at end of 14 days.



\*Syringe(s), needle(s), and adhesive seals not included.  
Whirl-Pak is a registered trademark of Nasco Industries, Inc.

# HardyVAL™ CSP medium-risk level

**Kit Contents** Cat. no. HVM1 (\$100.94)

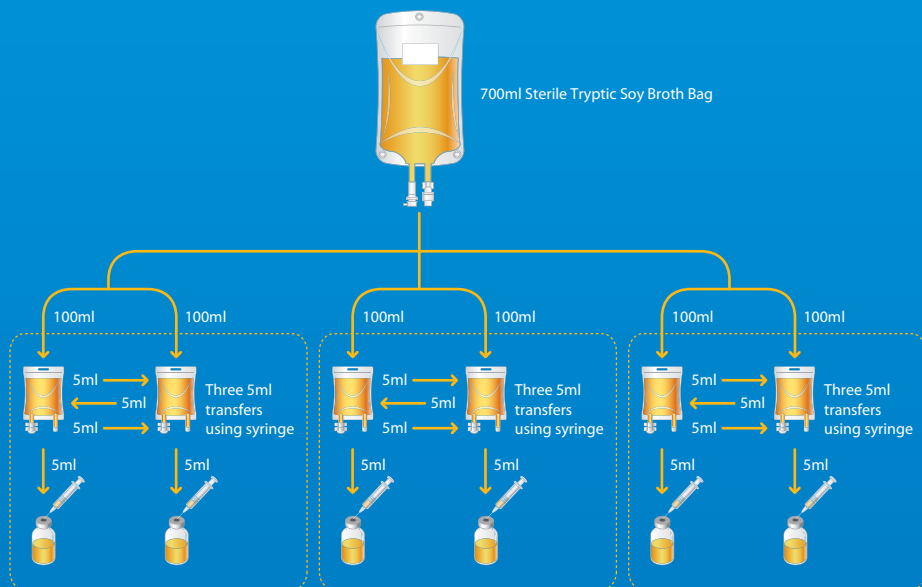
- 1 x 700ml Sterile Tryptic Soy Broth Bag
- 6 x 125ml Empty Sterile Bags
- 6 x 20ml Empty Sterile Vials
- 1 x Write-on Whirl-Pak® Bag
- 1 x Results Log Sheet



Prices are subject to change without notification.

## Procedure Summary (from USP <797>)

- 1 Aseptically transfer 100ml Sterile Tryptic Soy Broth to empty sterile bags using gravity tubing.
- 2 Transfer Tryptic Soy Broth between bags, using a sterile 10ml syringe.
- 3 Aseptically transfer 5ml Tryptic Soy Broth to small empty sterile vials.
- 4 Attach sterile adhesive seals.
- 5 Incubate at 25°C to 35°C.
- 6 Examine for turbidity at end of 14 days.



\*Syringe(s), needle(s), and adhesive seals not included.

Whirl-Pak is a registered trademark of Nasco Industries, Inc.

# HardyVAL™ CSP high-risk level

**Kit Contents** Cat. no. HVH1 (\$40.17)

- 1 x 3gm Tryptic Soy Broth Powder (non-sterile)
- 9 x 20ml Empty Sterile Vials
- 1 x Write-on Whirl-Pak® Bag
- 1 x Results Log Sheet



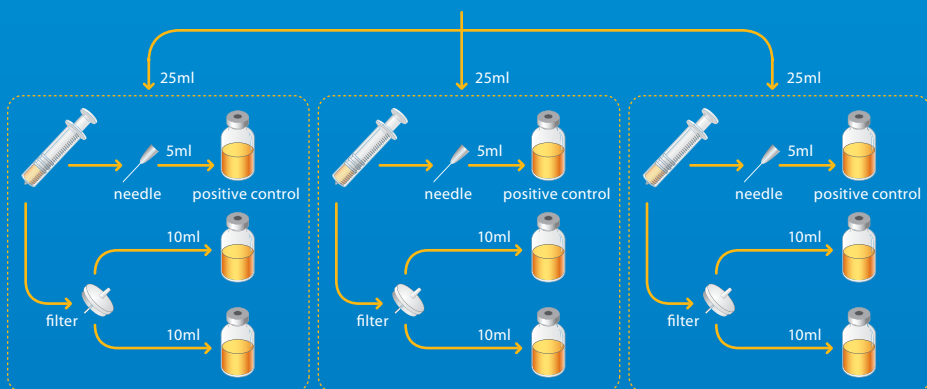
Prices are subject to change without notification.

## Procedure Summary (from USP <797>)

- 1 Unscrew cap and add 100ml of water (non-bacteriostatic) to Tryptic Soy Broth powder.
- 2 Screw on cap and mix.
- 3 Transfer the appropriate amounts of Tryptic Soy Broth to empty sterile vials using a sterile 30ml syringe with and without a 0.2 micron filter.
- 4 Attach sterile adhesive seals.
- 5 Incubate at 25°C to 35°C.
- 6 Examine for turbidity at end of 14 days.



Add 100ml non-bacteriostatic water\* to 3 grams Tryptic Soy Broth Powder



\*Syringe(s), needle(s), adhesive seals, non-bacteriostatic water, and filters not included.

Whirl-Pak is a registered trademark of Nasco Industries, Inc.

# HardyVAL™ CSP random testing

**Kit Contents** Cat. no. HVR1 (\$19.57)

5 x 5ml Double Strength Tryptic Soy  
Broth Syringes

5 x Write-on Whirl-Pak® Bags

1 x Results Log Sheet

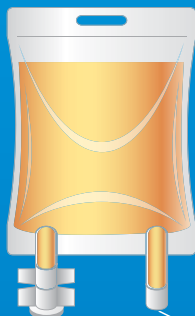
Test to be performed on  
returned I.V. solutions



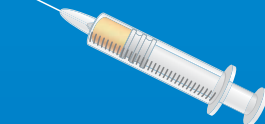
Prices are subject to change without notification.

## Does not fulfill requirements for USP <71> Sterility Testing.

- 1 Attach sterile needle to 5ml of Sterile Double Strength Tryptic Soy Broth syringe.
- 2 Draw 5ml of I.V. solution from the bag into the Double Strength Tryptic Soy Broth syringe.
- 3 Incubate at 25°C to 35°C.
- 4 Examine for turbidity at end of 14 days.



5ml Sterile Double Strength  
Tryptic Soy Broth Syringe



\*Sterile needles not included.

Whirl-Pak is a registered trademark of Nasco Industries, Inc.

# Environmental Monitoring

## air monitoring

USP <797> requires that the number of viable microorganisms in the air environment of the compounding area be evaluated. This test is to be performed at least monthly for low- and medium-risk preparations, and at least weekly for high-risk preparations. More frequent sampling will provide earlier detection of loss of environmental control. Hardy Diagnostics offers an easy way of accomplishing this using an impact air sampler.\*

### Impact Air Sampler - Active Sampling

- 1 Remove lid from plate and install plate in its holder.
- 2 Select settings on Spin Air sampler and press start.
- 3 Once the cycle is complete, replace lid and incubate at 33°C to 37°C. After 48 hours, count the number of colonies. Incubate MEA at 26°C to 30°C for 7 days.



### Spin Air Microbial Sampler

This innovative microbiological impact air sampler pulls air in a controlled fashion against the agar plate. The plate rotates during the process to

ensure maximum distribution of the microorganism throughout the plate surface. Holds 100mm petri dishes; the time, airflow, and rotation speed are variable. Carrying case and charger included. This unit is computer connectable and bar code compatible.

The unit comes fully calibrated. The current recommendation for periodic re-calibration is on a yearly basis or after 1 million liters of air has been sampled. Re-calibration of the unit can be obtained through the manufacturer. Cat. no. 5530 (\$3,884.00)

\*Recommended

**Tryptic Soy Agar\*** Cat. no. G60  
15x100mm plate (\$9.03/10 plates)

**Nutrient Agar** Cat. no. W51  
15x100mm plate (\$10.71/10 plates)

**MEA (Malt Extract Agar)** Cat. no. W28  
15x100mm plate (\$30.87/10 plates)

### Incubator

This compact incubator fits easily on most counter tops. The incubator holds a constant temperature to plus or minus one degree. It is made of powder coated steel and has an acrylic see-through door. It comes with two adjustable shelves. Capable of temperatures up to 60°C. Capacity is 0.8 cubic feet. The inside dimensions of the chamber are 13"W x 14"H x 16"D. Cat. no. 132000 (\$479.70)



### True-Tempe Thermometers

These environmentally safe thermometers contain no dangerous mercury; instead they are filled with red spirit alcohol. For additional safety, they are encased in a Teflon® coating to prevent breakage. Range is 18°C to 50°C, with 0.5°C divisions. 135mm in height. The thermometer is sealed within a fluid-filled unbreakable bottle to prevent temperature reading fluctuations, due to the opening and closing of the incubator door. Attached magnet allows for adherence to the inside wall of the incubator. Cat. no. 103015 (\$52.00)



# Environmental Monitoring

## surface sampling

Hardy Diagnostics offers a fast and convenient way to monitor the microbial bioburden of the work surface of your Laminar Air Flow Workbench. Contact agar plates are simply pressed onto the surface or glove fingertips, incubated, and colonies are counted.

### Surface Sampling (TSA with Lecithin & Tween®)

Surface sampling is recommended but not required. Samples should be collected at least monthly for low- and medium-risk operations and at least weekly for high-risk level compounding operations.



**1** Remove lid.



**2** Gently press plate to surface without twisting or sliding.



**3** Replace lid and incubate at 33°C to 37°C. After 48 hours, count the number of colonies.

### Fingertip Sampling (TSA with Lecithin & Tween®)

Personnel monitoring (glove fingertips) is required to be performed weekly for low- and medium-risk operations and daily for high-risk level compounding operations.



**1** Remove lid.



**2** Gently press glove tips to plate surface.



**3** Replace lid and incubate at 33°C to 37°C. After 48 hours, count the number of colonies.

#### Tryptic Soy Agar with Lecithin and Tween®

15x60mm contact plate - Cat. no. P34 (\$19.53/10 plates)

Prices are subject to change without notification.



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Tween is a registered trademark of ICI Americas, Inc.