



HardyVAL™
MEDIA FILL TEST KITS

USP
<797>
COMPLIANCE

USP

<797> COMPLIANCE

HardyVAL™
MEDIA FILL TEST KITS

CONTENT

HardyVAL™ Introduction	1
HardyVAL™ Introduction Cont.	2
HardyVAL™ Test Kits	3
Hazardous Drug Manipulation Kit	8
Media Bags™	9
HardyVAL™ à la carte	10
Environmental Monitoring Media	12
Media for Surface Sampling	14
Air Sampling - TRIO.BAS™	15
Sterility Testing - Sterisart®	16
Sterility Testing - Direct Inoculation	18
HardyVAL™ Random Test	19
Growth Promotion Testing	20
Biological Indicators	20
Equipment	21

HardyValKits.com



FM 572526



Hardy Diagnostics adheres to cGMP, is licensed by the FDA as a medical device manufacturer, and its quality management system is ISO 13485 certified.

Headquarters

1430 West McCoy Lane
Santa Maria, CA 93455
800.266.2222
Sales@HardyDiagnostics.com
HardyDiagnostics.com

Distribution Centers

Santa Maria, California
Olympia, Washington
Salt Lake City, Utah
Phoenix, Arizona
Dallas, Texas
Springboro, Ohio
Lake City, Florida
Albany, New York
Raleigh, North Carolina

Compliance was never so easy!

Verify The Efficacy Of Your Aseptic Technique

Hardy Diagnostics offers all the products you need to easily assess the risk of microbial contamination of your CSPs (Compounded Sterile Preparations) according to USP Chapter <797>.

- ✓ Quality culture media tested for performance, pH and sterility
- ✓ Kits are designed to help you follow USP <797> guidelines
- ✓ Kits supply what is needed to test the proficiency and aseptic technique of technicians or pharmacists in a self-contained ready-to-use format
- ✓ Kits are available for low, medium, and high complexity procedures
- ✓ Results log sheet is included in each kit
- ✓ À la carte components enhance kits or allow for customized tests based on your compounding processes
- ✓ Expert technical support is available from our staff of microbiologists, call 800.266.2222 ext. 5755
- ✓ Surface Sampling
- ✓ Air Sampling
- ✓ Sterility Tests



HardyVAL™

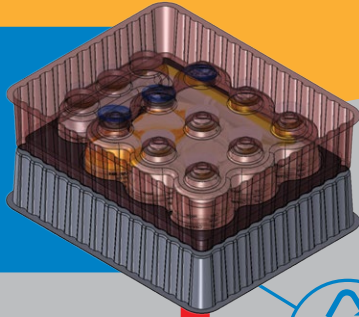
MEDIA FILL TEST KITS

ASEPTIC TECHNIQUE VALIDATION

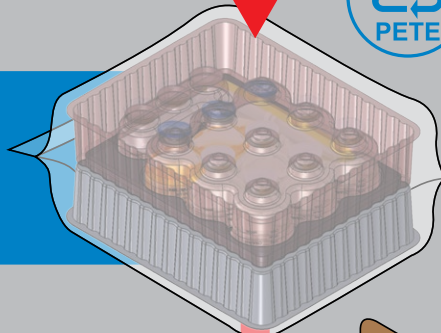
5
KITS

Choose from five pre-assembled kits for ease-of-use
OR create your own aseptic technique challenge with
our **à la carte line** of HardyVAL™ media and containers.

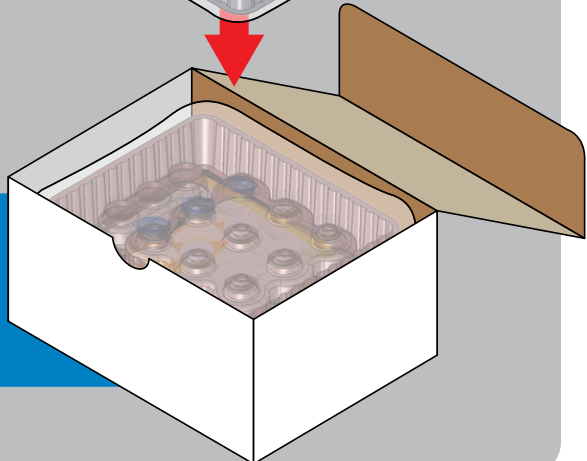
NEW fully
recyclable
thermoform
packaging



Clean
barrier
zip-bag



Sturdy
protective
box



How do I determine which kit or products are right for me?

According to USP <797>:

"All compounding personnel must perform media-fill testing to assess their sterile technique and related practices initially and every 6 months after. When performing a media-fill test, simulate the most difficult and challenging compounding procedures and processing conditions encountered by the person, replacing all the components used in the CSPs with soybean-casein digest media."

Certificates of Analysis available 24-7 from
HardyDiagnostics.com



Recommended for verification of personal aseptic technique for low and medium complexity levels within a sterile compounding facility or other cleanroom application. Each kit contains enough media to perform aseptic technique verification for **up to five technicians**. Culture media is quality control tested for growth promotion, pH, and sterility.

Each kit contains:

- ▶ Tryptic Soy Broth (TSB), USP, Media Bags, 100ml, 5/kit
- ▶ Tryptic Soy Broth (TSB), USP, 20ml serum vial with needle-port septum, 15ml fill, 5/kit
- ▶ Tryptic Soy Broth (TSB), 3 ml Ampoules, (non-toxic red dye is added to the TSB to easily visualize the sample being transferred), 5/kit

5 tests per kit

HVMTK

Hardy **VAL**™ MTK
MULTIPLE TECHNICIAN VERIFICATION KIT

Cat. no. HVMTK



LOW-COMPLEXITY

MEDIA FILL TEST KIT

Cat. no. HVL1



100ml Sterile
Tryptic Soy Broth Vial

4 transfers of 5ml each



20ml vial



20ml vial



20ml vial

Kit Contents

- ▶ 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

Culture Media is quality control
tested for growth promotion,
pH and sterility

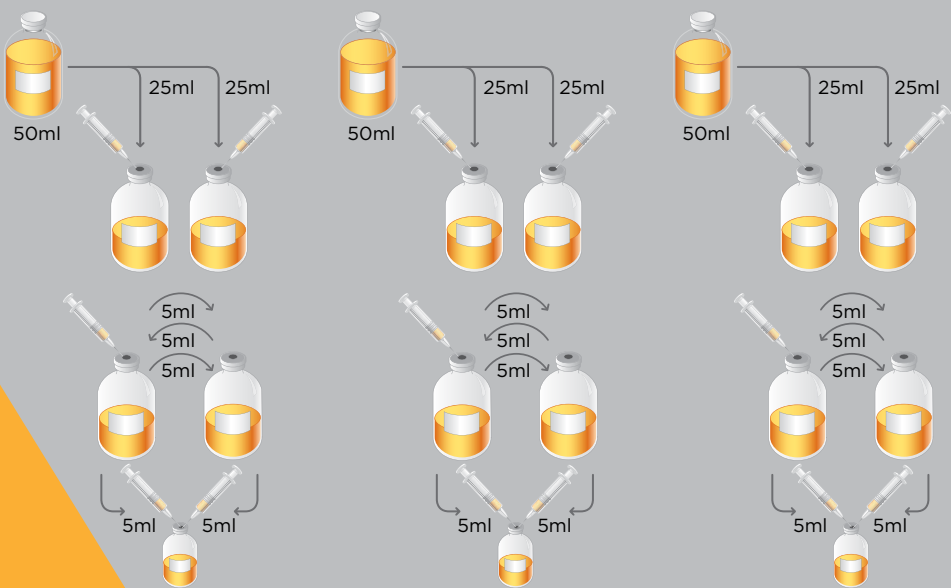
*Syringe(s), needle(s), and adhesive seals not included.

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

MEDIUM-COMPLEXITY

MEDIA FILL TEST KIT BASIC

Cat. no. HVM2



Kit Contents

- ▶ 3 x 50ml Serum Vials Sterile Tryptic Soy Broth
- ▶ 6 x 50ml Serum Vials (empty), sterile
- ▶ 3 x 20ml Serum Vials (empty), sterile
- ▶ 1 x Write-on Whirl-Pak® Bag
- ▶ 1 x Results Log Sheet

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

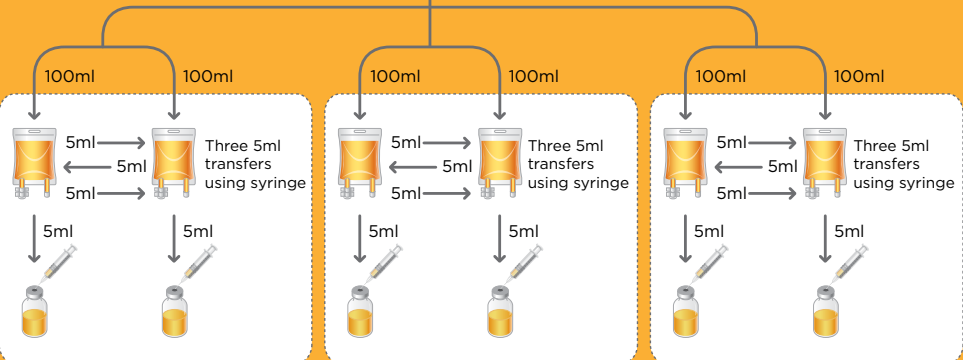
MEDIUM-COMPLEXITY

MEDIA FILL TEST KIT - COMPREHENSIVE

Cat. no. HVM1

Kit Contents

- ▶ 1 x 700ml Sterile Tryptic Soy Broth Bag
- ▶ 6 x 100ml Empty Sterile Bags
- ▶ 6 x 20ml Empty Sterile Vials
- ▶ 1 x Write-on Whirl-Pak® Bag
- ▶ 1 x Results Log Sheet



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

Culture Media is quality control tested
for growth promotion, pH and sterility

HIGH-COMPLEXITY

MEDIA FILL TEST KIT

Cat. no. HVH1

Hardy VAL™



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

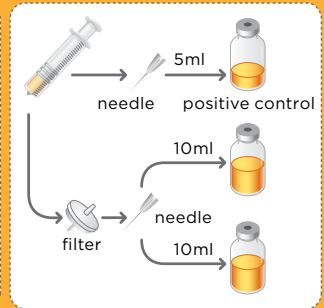
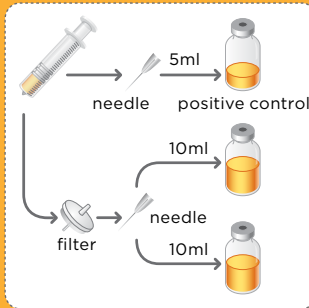
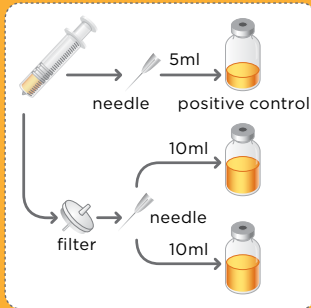


Screw on cap and mix

25ml

25ml

25ml



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

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

Kit Contents

- ▶ 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

NEW **HAZ**TM **HAZARDOUS DRUG** **DETECT** **MANIPULATION** **TECHNIQUE** TRAINING KIT

"The OSHA HCS and USP chapter <800> require employee training for the tasks that will be performed as part of the (hazardous drug compounding) safety program."

ASHP Guidelines on Handling Hazardous Drugs

Assists in training for drug handling competency and verification. Can be used to simulate spills and subsequent clean-up protocol processes.

Design a training method to reflect your most risk-associated process.

After performing the determined manipulation with the HAZ DETECT components, a black light shined on the working surface will reveal any spills and the need for technician retraining.

Cat. no. HVHAZ

Kit Contents

- ▶ 5 x 50mg fluorescein powder septum vials
- ▶ 5 x 3ml reconstituted fluorescein septum tubes
- ▶ 5 tests per kit



*Needles, syringes, mini bag (see HVB10), and
UV Lamp (see UVL56) not included.*



Hang Notch



TRYPTIC SOY BROTH MEDIA BAGS

Available in:

Media Bag TSB 100ml fill, 10pk	U100
Media Bag TSB 700ml fill, 10pk	HVB5

Needle Port

Spike Port

Ideal for verifying aseptic technique of pharmacists, nurses, or pharmaceutical manufacturing technicians.

- ▶ Terminally autoclaved for high sterility assurance
- ▶ Quality tested to USP <71> Standards
- ▶ Tryptic Soy Broth (TSB) is manufactured in an ISO 13485 Facility
- ▶ Growth promotion testing performed on each lot of media
- ▶ Media Bags Cat. no. U100 are packaged in double 2ml zippered bags



Culture Media is quality control tested
for growth promotion, pH and sterility

DESIGN CUSTOM

MEDIA FILL MANIPULATIONS

to best simulate your most challenging
compounding processes with our

HardyTM VAL
a la carte
LINE OF MEDIA

Tryptic Soy Broth Ampoules

3ml glass ampoules of media
designed to complement
personal aseptic technique
proficiency tests as described
in USP procedures.

20/pk

R35



SCORE MARK

MEDIA IS TINTED
RED TO ASSIST
IN MEDIA
TRANSFER
VISUALIZATION

Media Bag

Terminally sterilized, empty,
100ml media bag,
10/pk

HVB10



Culture Media is quality control tested
for growth promotion, pH and sterility

Tryptic Soy Broth (Powder), USP

For High Complexity Compounding Simulations.

3gm of non-sterile TSB powder, 10/pk

U130



Tryptic Soy Broth, USP

100ml bottle with needle-port septum, 100ml fill, 10/pk

U101



Tryptic Soy Broth

Tryptic Soy Broth, 15ml, USP 10/pk

U382



Serum Vial

Empty vial, 20ml capacity, terminally autoclaved, 10/pk

SV20

Empty vial, 100ml capacity, terminally autoclaved, 10/pk

SV100

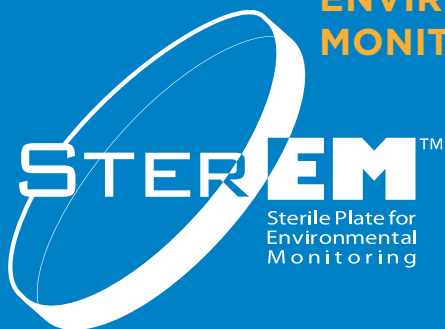


SV100



SV20

ENVIRONMENTAL MONITORING MEDIA



Manufactured in a licensed cGMP facility with a quality management system certified to ISO 13485. Irradiated, triple bagged media ensures safe and sterile transfer by removing one bag per pass-through material/air lock.

Sterile by Irradiation

Validated for a Sterility Assurance Level (SAL) of 10^{-5} .

Triple Bagged

Two nylon inner bags with an outer heat-sealed Mylar® bag.

Quality Manufacturing

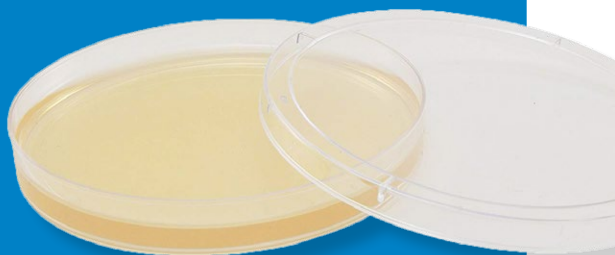
Manufactured in a licensed cGMP facility with a quality management system certified to ISO 13485.

Room Temperature

Convenient storage and ready-to-use.

Red-Tinted TSA dish option

Easy visual ID enables easy differentiation between TSA and SabDex.



84 Petri plate holder,
Cat. no. DURA84

Hardy Diagnostics


DuraRack™

Petri Plate Holder

For batching, safely transporting, and incubating 100mm culture plates. Helps streamline benchtop laboratory processing in your microbiology lab.

- Durable
- Autoclavable
- Coated steel wire rack
- Easy loading and unloading from the top
- Sturdy welded design

60 Petri plate holder, Each	DURA60
84 Petri plate holder, Each	DURA84



PREPARED MEDIA

Tryptic Soy Agar (TSA)

General growth medium for the isolation and cultivation of microorganisms. SterEM™, 15x100mm plate, triple bagged 10/pk

W570

Tryptic Soy Agar (TSA)

General growth medium for the isolation and cultivation of microorganisms. SterEM™, 15x100mm plate, triple bagged, 34ml fill 10/pk

W540

Tryptic Soy Agar (TSA)

General growth medium for the isolation and cultivation of microorganisms. SterEM™, 15x100mm **Red Tinted** plate, triple bagged, 34ml fill 10/pk

W540R

Tryptic Soy Agar with Lecithin and Tween® 80

General growth medium for the isolation and cultivation of microorganisms. **Recommended for gloved fingertip sampling.** SterEM™, 15x100mm plate, triple bagged 10/pk

W520

SabDex Agar

For the detection and enumeration of yeasts and fungi. SterEM™, 15x100mm plate, triple bagged 10/pk

W565

SabDex Agar with Lecithin and Tween® 80

For the detection and enumeration of yeasts and fungi. SterEM™, 15x100mm plate, triple bagged, 34ml fill 10/pk

W595

R2A Agar

For enumeration of heterotrophic bacteria in water, especially potable water. SterEM™, 15x100mm plate, triple bagged 10/pk

W530

GLOVED FINGERTIP SAMPLING

Personnel monitoring (gloved fingertips) is required to be done at initial competency evaluation and no fewer than three times before being allowed to compound sterile preparations.



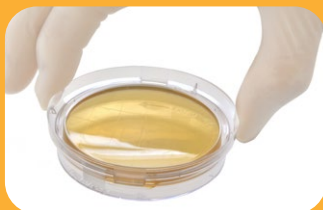
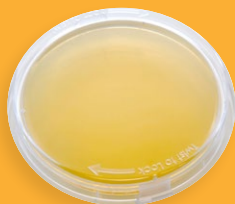
Gently press glove tips to plate surface.

Culture Media is quality control tested for growth promotion, pH and sterility

SURFACE SAMPLING

Surface sampling shall be performed in all ISO classified areas on a periodic basis per USP <797>

LOKTM TIGHT Contact Plate



Friction lid design keeps lids in place.
Locking feature assures lids stay secured.

TSA (Tryptic Soy Agar) with Lecithin and Tween® 80
For the cultivation and enumeration of microorganisms.
15x65mm contact plate,
10/pk **P34**



Tryptic
Soy
Agar

1. Twist and remove lid.



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



3. Twist clockwise until frosted bands line up and lock lids into place.

SabDex (Sabouraud Dextrose) Agar
For the cultivation of fungi.
15x65mm plate,
10/pk **P36**

MEA (Malt Extract Agar) with Lecithin and Tween
For the cultivation and enumeration of fungi.
15x65mm contact plate,
10/pk **P93**

IRRADIATED CONTACT PLATES

TSA (Tryptic Soy Agar) with Lecithin and Tween® 80, USP
For the cultivation and enumeration of microorganisms.
Recommended for surface sampling. Irradiated, triple bagged, 15x65mm,
10/pk **P520**

SabDex (Sabouraud Dextrose) Agar with Lecithin & Tween® 80, USP
For the cultivation of fungi.
Irradiated, triple bagged, 15x65mm,
10/pk **P595**

EnviroTransTM ENVIRONMENTAL SWAB RINSE KIT

PRE-MOISTENED, READY-TO-USE

This ready-to-use swab and tube is pre-filled with 5mls of terminally sterilized neutralizing saline. Simply remove the cap, which is attached to the Dacron® swab. Collect your sample by swabbing the surface, recap, and send to the lab. The solution can then be inoculated onto a Tryptic Soy Agar petri plate (Cat. no. G60). This kit is excellent for detection or enumeration of microorganisms from environmental surfaces and hard to reach areas.
5ml, 20/box **SRK55**





TRIO.BAS™
BIOLOGICAL AIR SAMPLER

The most complete
line of active impact
microbial air sampling
instruments available!



MONO



DUO

**BEST
SELLER**



TRIO

The **TRIO.BAS™** family of air samplers has a 40 year history and come from the engineers of the first portable air sampler. The instruments are lightweight, ergonomic, have data integrity with Bluetooth capability and use standard media. Choose a format to best fit your environmental monitoring needs. See our website and online **TRIO.BAS™** catalog for all available models.

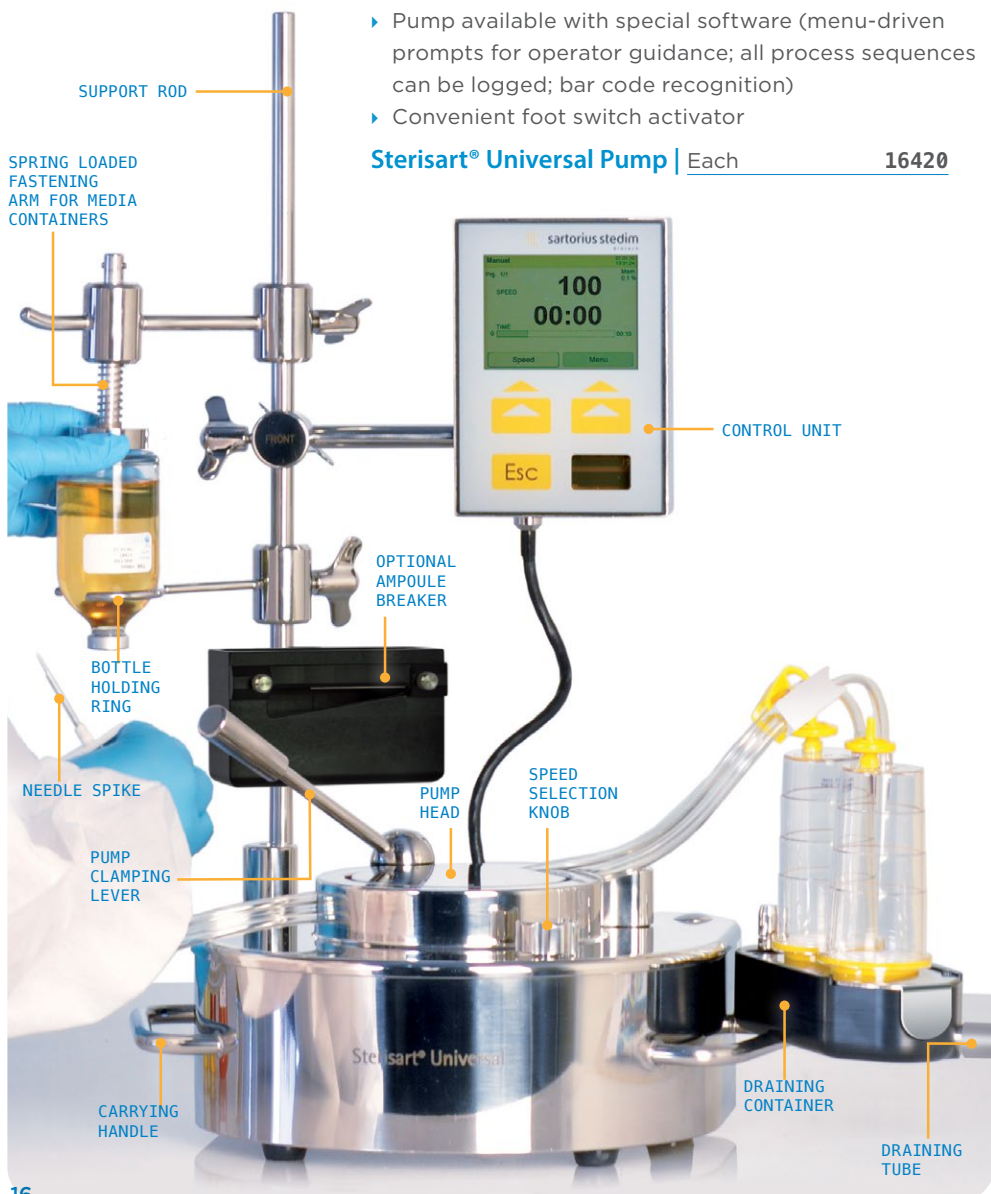
STERILITY TESTING OF YOUR FINISHED COMPOUNDED DRUG

Sterisart® UNIVERSAL PUMP STERILITY TESTING SYSTEM

FEATURES AND BENEFITS

- ▶ Gold standard for sterility testing of drugs
- ▶ Closed system – decrease the chance of technician contamination
- ▶ Rugged and maintenance-free
- ▶ Compact and ergonomic construction
- ▶ Pump available with special software (menu-driven prompts for operator guidance; all process sequences can be logged; bar code recognition)
- ▶ Convenient foot switch activator

Sterisart® Universal Pump | Each **16420**

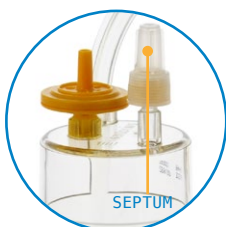


STERISART® NF CANISTERS FOR STERILITY TESTING

DISPOSABLE SAMPLE CANISTERS
AND ADAPTERS FOR USE WITH
STERISART® UNIVERSAL PUMP

FEATURES AND BENEFITS

- ▶ For sterility testing in isolators and clean benches
- ▶ Individually sterile
- ▶ Double-packaged
- ▶ Gamma irradiated
- ▶ Stainless steel needles



Sterisart® Canisters available with or without a needle port septum for sub-culturing



Pre-installed color-coded tube clamps



VHP resistant packaging



Stainless steel septum needle

Culture Media for Sterility Testing per USP <71>

- ▶ Tryptic Soy Broth (TSB), USP, 100ml fill, 100ml bottle with needle-port septum, 20/pk **U46**
- ▶ Fluid Thioglycollate, USP, 100ml fill, 100ml bottle with needle-port septum, 20/pk **U84**
- ▶ Fluid A, USP, 100ml fill, 100ml bottle with needle-port septum, 20/pk **U109**
- ▶ Fluid D, USP, 100ml fill, 100ml bottle with needle-port septum, 20/pk **U110**





STERILITY TESTING by Direct Inoculation

of Pharmaceuticals using
Hardy Diagnostics Media
<USP 71>

Drug solutions can be tested for sterility by direct inoculation into Tryptic Soy Broth (TSB) and Fluid Thioglycollate according to procedures found in <USP 71>. By incubating for 14 days, a lack of fungal, aerobic, and anaerobic bacterial contamination can be proven. Please consult <USP 71> (Table II) to verify proper inoculum size and media volume.

USP recommended media for direct inoculation



Tryptic Soy Broth, USP

Recommended for use as a general purpose medium for the isolation and cultivation of a wide variety of bacteria and fungi.

100ml glass bottle with needle port septum, 100ml fill,

20/pk U46

Tryptic Soy Broth, USP

Recommended for use as a general purpose medium for the isolation and cultivation of a wide variety of bacteria and fungi.

20ml glass bottle with needle port septum, 20ml fill,

50/pk U38

Fluid Thioglycollate Broth Medium with Indicator, USP

For the cultivation of anaerobic microorganisms.

100ml glass bottle with needle port septum, 100ml fill,

20/pk U84

20ml glass bottle with needle port septum, 20ml fill,

50/pk U68

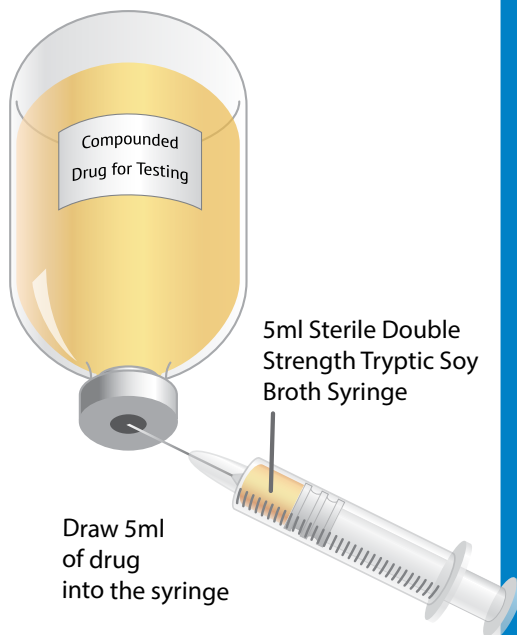
Culture Media is quality control tested for growth promotion, pH and sterility

Go to HardyDiagnostics.com for a complete listing of bottle and jar media.
Custom containers and fill volumes are available upon request.

HardyVAL™

RANDOM TESTING

Cat. no. HVR1



Use on expired or returned drugs to check sterility (for quality assurance purposes only).

Procedure Summary

1. Attach sterile needle to 5ml of sterile double strength Tryptic Soy Broth syringe.
2. Draw 5ml of compounded preparation into the Double Strength Tryptic Soy Broth Syringe.
3. Incubate syringe
4. Examine for turbidity at the end of 14 days.
5. Does not fulfill requirements for USP <71> Sterility Testing.

Kit Contents

- ▶ 5 x 5ml Double Strength Tryptic Soy Broth Syringes
- ▶ 5 x Write-on Whirl-Pak® Bags
- ▶ 1 x Results Log Sheet



GROWTH PROMOTION TESTING USP <71>

QC MICROORGANISMS
FOR GROWTH
PROMOTION TESTING OF
YOUR CULTURE MEDIA



EZ-Accu Shot™ Select includes USP compendial QC microorganism strains for Growth Promotion Testing in one convenient package. EZ-Accu Shot™ Select lyophilized QC microorganism preparations are designed to deliver 10-100 CFU per 0.1 ml of hydrated suspension as recommended by the USP/JP/Ph. Eur. With little to no preparation time required and up to eight hours of stability, EZ-Accu Shot™ Select adds efficiency and flexibility to QC laboratories' busy schedules. Each 1.2 ml vial of hydrated suspension offers 10 inocula.



In addition to product Cat. no. 8172 shown above, this organism is also required for full compliance to USP <71>:

***Clostridium sporogenes*, ATCC® 19404**

- ▶ 5 vials with 1 pellet per vial,
- ▶ 5 vials of hydrating fluid
- ▶ Used for USP <62> and <71>
- ▶ ATCC Licensed Derivative®
- ▶ Cat. no. **0317A**

EZ-Accu Shot™ Select Licensed, traceable strains:

- ▶ *Bacillus spizizenii* ATCC® 6633™ *
- ▶ *Candida albicans* ATCC® 10231™ *
- ▶ *Pseudomonas aeruginosa* ATCC® 9027™ *
- ▶ *Staphylococcus aureus* ssp. *aureus* ATCC® 6538™ *

EZ-Accu Shot™ Select Kit includes:

- ▶ 1 vial of each microorganism (1 Lyophilized pellet per vial)
- ▶ 5 vials of hydrating fluid (1.2 mL in each vial)
- ▶ 5 peel-off labels, one for each strain

Kit

8172

BIOLOGICAL INDICATORS

SPORAMPULE®

SporAmpule® Liquid Biological Indicator, for Steam Sterilization

An error-free BI (Biological Indicator) system certified for use with steam sterilization processes. After processing in a normal load, the SporAmpule® is incubated at 56°C for 48 hours. A purple to yellow color change and visible turbidity of a processed SporAmpule® indicates sterilizer failure.

20/pk
100/pk

BST20
BST100



EQUIPMENT

IncuPRO™

DIGITAL INCUBATOR

The IncuPRO digital incubator is an economical and space-saving solution for incubating cultures, test kits, and many other research and medical sample work-ups. Perfect for benchtop use.

- ▶ Includes two shelves and accommodates up to four shelves
- ▶ Digital temperature readout with control dial
- ▶ Solid door style
- ▶ 0.8 cubic feet

Each

133000H



EXACT-TEMP REFRIGERATOR THERMOMETER

Thermometer probe stays inside, digital display stays outside. No need to open the door!

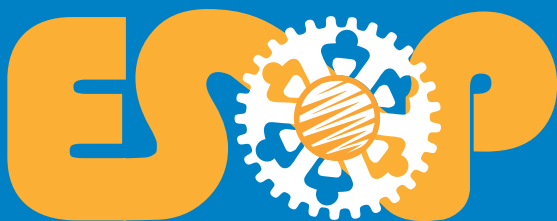
- ▶ Temperature probe remains in plastic bottle with insulating liquid.

- ▶ Min/Max alarm settings with nine foot sensor cable.
- ▶ Choose between Celsius and Fahrenheit ranging from -50°C to 70°C (-58 °F to 158 °F).
- ▶ Accurate up to ± 0.6 °C for precise measurements, Resolution: 0.1 °C.
- ▶ Display size is 1.75" x .75" for easy viewing, powered by one AAA battery (included).

Each

R80301





100% EMPLOYEE OWNED COMPANY



1430 West McCoy Lane
Santa Maria, CA 93455
800.266.2222
Sales@HardyDiagnostics.com
HardyDiagnostics.com

 **HARDY**
DIAGNOSTICS
A Culture of Service™